

TENDER REFERENCE NO.: KK/61/2026/LAB(TC)

**MINISTRY OF HEALTH
NEGARA BRUNEI DARUSSALAM**

**TO SUPPLY, DELIVER AND COMMISSION A LABORATORY
AUTOMATION SYSTEM ON EQUIPMENT RENTAL BASIS
FOR ROUTINE CHEMISTRY TESTING, INCLUDING
REAGENTS AND CONSUMABLES FOR NATIONAL
CLINICAL CHEMISTRY REFERENCE LABORATORY
(RIPAS HOSPITAL) AND CLINICAL CHEMISTRY
LABORATORY (PIHM HOSPITAL), DEPARTMENT OF
LABORATORY SERVICES, MINISTRY OF HEALTH FOR A
PERIOD OF SEVEN (7) YEARS**

TENDER FEES : \$2000.00

RECEIPT NO. :

CLOSING DATE : ON Tuesday, 05th May 2026

TIME : 2.00 PM

FOA :

**THE CHAIRMAN
MINI TENDER BOARD, TENDER BOX
GROUND FLOOR, MINISTRY OF HEALTH
COMMONWEALTH DRIVE
BANDAR SERI BEGAWAN BB3910
NEGARA BRUNEI DARUSSALAM**

(CLUSTERING)

SECTION 2

SPECIFICATIONS

TENDER REFERENCE NO.: KK/61/2026/LAB(TC)

INVITATION TO TENDER

TO SUPPLY, DELIVER AND COMMISSION A LABORATORY AUTOMATION SYSTEM ON EQUIPMENT RENTAL BASIS FOR ROUTINE CHEMISTRY TESTING, INCLUDING REAGENTS AND CONSUMABLES FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY (RIPAS HOSPITAL) AND CLINICAL CHEMISTRY LABORATORY (PIHM HOSPITAL), DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF SEVEN (7) YEARS

1. SUPPLY OF REAGENTS

- 1.1 To supply reagents and associated consumables (calibrators, controls, accessories and consumables) for the tests listed below.

APPENDIX A: SUMMARY OF UNIT PRICE OF REAGENT KIT (RIPAS HOSPITAL) (To be completed by Vendor for submission)

| NO. | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE / YEAR |
|-----|--|----------------|-----------------------------|
| | TOTAL LABORATORY AUTOMATION SYSTEM FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, RIPAS HOSPITAL | | |
| 1 | 25-OH Vitamin D | Per test | 8235 |
| 2 | Acetaminophen | Per test | 1649 |
| 3 | Alanine Transaminase (ALT) | Per test | 258339 |
| 4 | Albumin | Per test | 229127 |
| 5 | Alkaline Phosphatase (ALP) | Per test | 234182 |
| 6 | Alpha-1 Antitrypsin (A1AT) | Per test | 1552 |
| 7 | Alpha-fetoprotein (AFP) | Per test | 11733 |
| 8 | Amikacin | Per test | 4197 |
| 9 | Aminotransferase (AST) | Per test | 7670 |
| 10 | Ammonia | Per test | 6327 |
| 11 | Amylase | Per test | 17737 |
| 12 | Beta-2 Microglobulin (B2M) | Per test | 1403 |
| 13 | Beta-HCG | Per test | 14230 |
| 14 | Bicarbonate | Per test | 131417 |
| 15 | Bili Direct (DBIL) | Per test | 17442 |
| 16 | Bili Total (TBIL) | Per test | 250116 |
| 17 | CA-125 | Per test | 6728 |
| 18 | CA15-3 | Per test | 5245 |
| 19 | CA19-9 | Per test | 8898 |
| 20 | Calcium | Per test | 116752 |
| 21 | Calcium Urine | Per test | 1285 |
| 22 | Carbamazepine | Per test | 1457 |
| 23 | Carcinoembryonic antigen (CEA) | Per test | 8321 |
| 24 | Ceruloplasmin | Per test | 2342 |
| 25 | Chloride | Per test | 142362 |
| 26 | Chloride Urine | Per test | 2403 |
| 27 | Cholinesterase | Per test | 481 |
| 28 | Complement Component 3 (C3) | Per test | 4597 |
| 29 | Complement Component 4 (C4) | Per test | 4796 |
| 30 | Cortisol | Per test | 6590 |

| NO. | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE / YEAR |
|------------|---|-----------------------|------------------------------------|
| 31 | C-peptide | Per test | 2453 |
| 32 | C-Reactive Protein (CRP) | Per test | 142216 |
| 33 | Creatine Kinase | Per test | 21817 |
| 34 | Creatine Kinase-MB (CKMB) | Per test | 11024 |
| 35 | Creatinine | Per test | 421202 |
| 36 | Creatinine Urine | Per test | 72121 |
| 37 | Cyclosporine | Per test | 1305 |
| 38 | Digoxin | Per test | 1520 |
| 39 | Dehydroepiandrosterone sulfate (DHEAS) | Per test | 1699 |
| 40 | Estradiol (E2) | Per test | 3339 |
| 41 | Ferritin | Per test | 42811 |
| 42 | Folic Acid | Per test | 12716 |
| 43 | Follicle Stimulating Hormone | Per test | 5245 |
| 44 | Free Prostate Surface Antigen | Per test | 5122 |
| 45 | Free Thyroxine (FT4) | Per test | 74688 |
| 46 | Free Triiodothyronine (FT3) | Per test | 66936 |
| 47 | Gamma Glutamyl Transferase (GGT) | Per test | 251546 |
| 48 | Gentamicin | Per test | 8789 |
| 49 | Glucose | Per test | 227599 |
| 50 | Haptoglobin | Per test | 1798 |
| 51 | HDL Cholesterol | Per test | 171884 |
| 52 | Immunoglobulin A | Per test | 4175 |
| 53 | Immunoglobulin G | Per test | 3986 |
| 54 | Immunoglobulin M | Per test | 3661 |
| 55 | Insulin | Per test | 2227 |
| 56 | intact parathyroid hormone (iPTH) | Per test | 11418 |
| 57 | Iron | Per test | 42851 |
| 58 | Lactate | Per test | 8188 |
| 59 | Lactate Dehydrogenase (LDH) | Per test | 7096 |
| 60 | Lithium | Per test | 1297 |
| 61 | Luteinizing Hormone | Per test | 5749 |
| 62 | Magnesium | Per test | 48383 |
| 63 | Magnesium Urine | Per test | 1149 |
| 64 | Methotrexate | Per test | 1575 |
| 65 | Microalbumin | Per test | 52968 |
| 66 | NT-proBNP | Per test | 17348 |
| 67 | Phenobarbital | Per test | 922 |
| 68 | Phenytoin | Per test | 1884 |
| 69 | Phosphate | Per test | 107791 |
| 70 | Phosphate Urine | Per test | 1149 |
| 71 | Potassium (K) | Per test | 407368 |
| 72 | Potassium Urine | Per test | 2959 |
| 73 | Procalcitonin | Per test | 18196 |
| 74 | Progesterone | Per test | 5084 |
| 75 | Prolactin | Per test | 5420 |
| 76 | Protein Urine / CSF | Per test | 17216 |
| 77 | Rheumatoid Factor | Per test | 4287 |
| 78 | Salicylate | Per test | 1026 |
| 79 | Sex Hormone Binding Globulin (SHBG) | Per test | 1769 |
| 80 | Sodium (Na) | Per test | 404364 |
| 81 | Sodium Urine | Per test | 7144 |
| 82 | Tacrolimus | Per test | 1668 |
| 83 | Testosterone | Per test | 4344 |

| NO. | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE / YEAR |
|-----|--------------------------------------|----------------|-----------------------------|
| 84 | Theophylline | Per test | 1212 |
| 85 | Thyroid Stimulating Hormone (TSH) | Per test | 76417 |
| 86 | Total Cholesterol | Per test | 178510 |
| 87 | Total Prostate Surface Antigen | Per test | 8109 |
| 88 | Total Protein | Per test | 217999 |
| 89 | Transferrin | Per test | 41295 |
| 90 | Triglyceride | Per test | 175474 |
| 91 | Troponin I or Troponin T | Per test | 38204 |
| 92 | Urea | Per test | 415774 |
| 93 | Urea Urine | Per test | 1431 |
| 94 | Uric Acid | Per test | 148978 |
| 95 | Uric Acid Urine | Per test | 1161 |
| 96 | Valporic Acid | Per test | 2650 |
| 97 | Vancomycin | Per test | 6941 |
| 98 | Vitamin B12 | Per test | 14869 |

***Cost per test must INCLUDE and ACCOUNT FOR** the costs of the following:

- a. Rental of TLA system components and its accessory components such as PCs, printers & etc. (refer to the Specifications and Requirements below for details).
- b. Internal Quality Controls for each assay (third party IQC material). IQC shall be multi-level to be run daily (up to 4 times within 24 hours for select chemistry assays and once every 24 hours for immunoassays).
- c. Calibrator (as many as required by the system).
- d. Consumables required to perform the tests including but not limited to: analyzer bulk solutions (e.g. wash solutions), secondary sample cups (25,000pcs per year), secondary sample tubes for urine samples that are track-compatible (62,500pcs per year), bin liners for reaction vessels/tips & other wastes generated by the analyzers, sample tube sealers/cappers (quantity according to the estimated test usage).
- e. Other required accessories (quantity according to the estimated test usage).
- f. Two (2) technical staffs that shall work on-site from 7.45am – 12.30pm & 1.30pm – 4.30pm (refer to the Specifications and Requirements below for details).
- g. Services provided (refer to the Specifications and Requirements below for details)
- h. Expected test wastage due to limited/short reagent shelf life/onboard stability especially for slow usage reagents[^]

[^] Slow usage reagents for NCCRL are: *Aceta, A1AT, AST, B2M, Carbamazepine, Ceruloplasmin, Cholinesterase, C-Peptide, Digoxin, Dehydroepiandrosterone sulfate (DHEAS), LDH, Lithium, MTX, Phenytoin, Phenobarbital, Salicylate, Sex Hormone Binding Globulin (SHBG), Theophylline, Valproic Acid.*

APPENDIX B: SUMMARY OF UNIT PRICE OF REAGENT KIT (PIHM HOSPITAL)
(To be completed by Vendor for submission)

| NO | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE / YEAR |
|----|---|----------------|-----------------------------|
| | CHEMISTRY - IMMUNOASSAY ANALYZERS FOR CLINICAL CHEMISTRY LABORATORY, PIHM HOSPITAL | | |
| 1 | Alanine Transaminase (ALT) | Per test | 13200 |
| 2 | Albumin (ALB) | Per test | 13572 |
| 3 | Alkaline Phosphatase (ALP) | Per test | 12800 |
| 4 | Amylase | Per test | 4480 |
| 5 | BILI DIRECT | Per test | 4000 |
| 6 | BILI TOTAL | Per test | 13750 |
| 7 | CO2C Bicarbonate | Per test | 7500 |
| 8 | CRP16 | Per test | 9000 |
| 9 | Calcium | Per test | 6000 |
| 10 | Cholesterol | Per test | 12000 |
| 11 | CL-C (Chloride) | Per test | 20000 |
| 12 | CreaC (Creat) | Per test | 18000 |
| 13 | GGT | Per test | 13200 |
| 14 | Glucose | Per test | 12000 |
| 15 | K-C (Potassium) | Per test | 20000 |
| 16 | NA-C (Sodium) | Per test | 20000 |
| 17 | Phosphate | Per test | 5600 |
| 18 | Total Protein (TP) | Per test | 12800 |
| 19 | Triglyceride | Per test | 12000 |
| 20 | Uric Acid (UA) | Per test | 8960 |
| 21 | HDL Cholesterol | Per test | 11520 |
| 22 | Urea | Per test | 16800 |
| 23 | Troponin I or Troponin T | Per test | 4200 |

***Cost per test must INCLUDE and ACCOUNT FOR** the costs of the following (quantity required indicated):

- a. Rental of chemistry and immunoassay analyzers and accessory components such as printers & etc. (refer to the Specifications and Requirements below for details).
- b. Internal Quality Controls for each assay (third party IQC material). IQC shall be multi-level to be run daily.
- c. Calibrators (as many as required by the system).
- d. Consumables required to perform the tests including but not limited to: analyzer bulk solutions (e.g. wash solutions), secondary sample cups, bin liners for reaction vessels/tips & other wastes generated by the analyzers,
- e. Other accessories (quantity according to the estimated test usage).
- f. Services provided (refer to the Specifications and Requirements below for details).
- g. Expected test wastage due to limited/short reagent shelf life/onboard stability especially for slow usage reagents^^

^^Slow usage reagents for PIHM: *Amylase, Calcium, Direct Bili & Phosphate*

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|--|
| 1 | GENERAL TLA REQUIREMENTS (RIPASH) |
| 2 | <p>The provision of a Total Laboratory Automation (TLA) system on equipment rental basis for routine chemistry testing for National Clinical Chemistry Reference Laboratory, RIPAS Hospital which shall include but not limited to the following hardware components:</p> <ol style="list-style-type: none"> 1. Chemistry analyzer(s) 2. Immunoassay analyzer(s) 3. Sample track transport system 4. Sample Input module 5. Sample Output module 6. Pre-analytical assessment module for assessment of correct tube type, tube weight and other relevant parameters. 7. Centrifuge module(s) 8. Sample tube decapper module 9. Sample tube capper / sealer module 10. On-track Refrigerated Sample Storage Module 11. Sample buffer module to manage sample traffic (if required) <p>The quantity of each module above (which contributes to the system's throughput) shall be such that the test workload of the laboratory* is absorbed within the laboratory's turnaround time (TAT) requirement**. This target TAT must be achievable without relying on off-track centrifugation and front-loading to analyzers.</p> <p>*= Lab test workload (during a typical non-public holiday):</p> <ul style="list-style-type: none"> • About 25,000 chemistry tests per day • About 1,550 immunoassay tests per day • Peak sample receiving time: 1st peak at 11.00AM and 2nd (lower) peak at 2.00PM (About > 80% of samples received during these time) <p>**= Laboratory turnaround time (TAT) requirement:</p> <ul style="list-style-type: none"> • <u>2 hours</u> for A/E and inpatient samples, • Outpatient samples received at 11.00AM to be result by 4.30PM the same day. |
| 3 | Vendor must perform audit on the TLA system and perform the necessary settings optimization to improve TAT, reagents usage and to track health check-up / track operations review to ensure all components are working appropriately around 3 months, 1 year and 1.5 years post <i>Go-Live</i> date (Optimization phase). |
| 4 | All components of the TLA must be new and not refurbished model (Vendor to include a certified copy of instrument date of production). |
| 5 | The proposed TLA system configuration shall be optimized to fit the available designated lab floor space and ceiling height with enough space for staff to move about comfortable and safely. Vendor is required to conduct an onsite assessment of the current site. |
| 6 | Please provide the list of current users of the TLA system in its full configuration, including the list of current users of the analyzers. There must be a minimum of 20 current users (customers) of the offered analyzer model. |
| 7 | Please state the year the TLA entered international market. |
| 8 | The TLA system must be able to distribute the workload among the analyzers and modules to optimize work flow and reduce reagent, consumables and accessories wastage. |
| 9 | The TLA system must be able to fulfill all the requirements for test validation and QC management as to current ISO 15189 requirements. |
| 10 | The TLA system must be a closed system to minimize exposure of staff to potentially hazardous aerosols. |
| 11 | The analyzers must fully comply with the FDA or CE mark requirements and that a copy of the certificates must be submitted. |
| 12 | The analyzers shall be provided with a UPS to allow minimum operation of 1 hour without external power. Other components of the TLA should also be provided with UPS. |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| | UPS battery to be replaced free of charge periodically according to manufacturer's recommendation. UPS battery system to be maintained and tested as required according to manufacturer's recommendation. |
| 13 | Vendor shall maintain and replace any batteries that is required to power the TLA components according to manufacturer's requirement and recommendations. The cost to be included in the cost per test of the tender. |
| 14 | Period of delivery from vendor to end user of initial tests kits and components of the IAS must be ≤ 3 months from awarding of tender. |
| 15 | The TLA system must have the following capability: Prioritization of STAT samples <ul style="list-style-type: none"> • Please provide description of STAT prioritization during peak sample saturation on the system's track. • STAT prioritization <i>throughout</i> the majority of the components of the TLA system is preferred. |
| 16 | <ul style="list-style-type: none"> • Vendor shall submit simulation of TAT achievable by the proposed TLA using the laboratory's one-day LIS data. The simulation to include the estimated turnaround time (TAT) of samples put 'priority' samples (A/E cases and inpatient samples) from the time sample is introduced to the TLA track to time test results produced by the analyzers during peak hours. • Laboratory requirement: A/E and inpatient samples TAT within 2 hours with no samples being processed off-track/front-loading even during peak hours. <p>Note:</p> <ul style="list-style-type: none"> • TAT defined as the period from registration time and result generated by analysers • Priority of samples is by: <ol style="list-style-type: none"> 1. The source of the specimen (ordering locations) i.e., Emergency and Inpatient samples are considered high priority, or 2. According to priority category of each specimen ID sent from LIS, or 3. According to priority category of each specimen ID programmed on TLA middleware. |
| 17 | SAMPLE INPUT MODULE (RIPASH) |
| 18 | Must be flexible to allow both STAT and Routine automated continuous sample loading in a dedicated loading area. |
| 19 | Have an initial loading capacity of ≥ 300 sample tubes of varying conditions (variable sample loading bays) as follows or equivalent: - <ol style="list-style-type: none"> 1. Routine Capped uncentrifuged tubes 2. Routine Capped centrifuged tubes 3. Routine Uncapped tubes (Centrifuged) 4. Priority Capped uncentrifuged tubes 5. Priority Capped centrifuged tubes 6. Priority Uncapped tubes (Centrifuged) 7. Sealed input rack - for samples that has been sealed by the automation system and to be routed to on-track fridge. |
| 20 | Samples from the priority loading bay is introduced to the track first regardless of presence of samples in the routine bay |
| 21 | Components must be able to accept multiple tube sizes (e.g. 13 x 75 mm, 13 x 100 mm, 16 x 100mm). |
| 22 | Provide list of acceptable sample tube types (primary and secondary). |
| 23 | <ul style="list-style-type: none"> • BARCODES (RIPASH) |
| 24 | There must be positive sample identification with host query mode. |
| 25 | All TLA components/checkpoints must be able to read sample barcodes provided by Bru-HIMS (Laboratory Information System) |
| 26 | Vendor shall assist the laboratory in providing technical solutions should there be a significant no. of samples rejected by the TLA barcode reader. |
| 27 | TLA barcode scanner shall be able to read slightly slanted and / or inverted sample barcodes if the barcodes are within the scanner read zone. |

| NO. | SPECIFICATIONS AND REQUIREMENTS | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|---|-----|-----------|---|-----------------|---|---------------|---|----------------------------|---|---------|---|----------------------------|---|----------------------------|---|-------------------------|---|----------|---|------------------------|----|---------|----|---------|----|----------------------------|
| 28 | PRE-ANALYTICAL ASSESSMENT MODULE (RIPASH) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29 | The TLA system shall have the ability to do pre-analytical check on the sample tube for the following: - 1. Cap colour (tube type) correctly matches the test orders 2. Ensure each sample meets the minimum sample tube volume / weight (cut-off feature) to ensure enough serum is available for testing and to prevent analyzer's sample probe from being contaminated with serum separator gel should the liquid level sensing mechanism fail. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 30 | ON-TRACK CENTRIFUGE MODULE (RIPASH) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 31 | Programmable settings | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 32 | Minimum of 100 samples capacity (preferably spread across 3 or more centrifuge modules). Please state the sample capacity per centrifuge and how many centrifuge modules in your offer. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 33 | Intelligent setting to optimize sample turnaround time. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 34 | Programmable waiting time to load and start centrifuge. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 35 | Automated load balancing centrifuge with rapid ascend and descend features. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 36 | Low noise with user defined spin time and easy maintenance. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 37 | Vendor to also provide one (1) unit off-track refrigerated centrifuge with minimum capacity of 4 samples. This is for samples requiring refrigerated centrifugation such as samples for Ammonia and Lactate tests. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 38 | Vendor to perform centrifuge speed and timer check of all centrifuges provided annually according to protocol provided by the laboratory. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 39 | DECAPPER (RIPASH) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 40 | Able to de-cap rubber or plastic caps of different types and sizes without creating hazardous aerosols | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 41 | To de-cap samples prior to first analysis AND to de-cap samples from on-board storage for additional testing. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 42 | Vendor must provide a separate 'de-sealer' module if samples are not re-sealed using a cap but with other material. This is required to allow auto-resampling for test add-ons or other re-testing requests. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 43 | ANALYZERS (RIPASH) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 44 | <ul style="list-style-type: none"> Chemistry and immunoassay analyzers that covers the RIPASH test menu (see below) Quantity of each analyzer must be enough to support RIPASH workload within the required turnaround time (TAT). | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 45 | <ul style="list-style-type: none"> RIPASH TEST MENU The analyzers must have the following test menu within the TLA system: - <table border="1" data-bbox="306 1384 1388 2020"> <thead> <tr> <th>No.</th> <th>Test Name</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>25-OH Vitamin D</td> </tr> <tr> <td>2</td> <td>Acetaminophen</td> </tr> <tr> <td>3</td> <td>Alanine Transaminase (ALT)</td> </tr> <tr> <td>4</td> <td>Albumin</td> </tr> <tr> <td>5</td> <td>Alkaline Phosphatase (ALP)</td> </tr> <tr> <td>6</td> <td>Alpha-1 Antitrypsin (A1AT)</td> </tr> <tr> <td>7</td> <td>Alpha-fetoprotein (AFP)</td> </tr> <tr> <td>8</td> <td>Amikacin</td> </tr> <tr> <td>9</td> <td>Aminotransferase (AST)</td> </tr> <tr> <td>10</td> <td>Ammonia</td> </tr> <tr> <td>11</td> <td>Amylase</td> </tr> <tr> <td>12</td> <td>Beta-2 Microglobulin (B2M)</td> </tr> </tbody> </table> | No. | Test Name | 1 | 25-OH Vitamin D | 2 | Acetaminophen | 3 | Alanine Transaminase (ALT) | 4 | Albumin | 5 | Alkaline Phosphatase (ALP) | 6 | Alpha-1 Antitrypsin (A1AT) | 7 | Alpha-fetoprotein (AFP) | 8 | Amikacin | 9 | Aminotransferase (AST) | 10 | Ammonia | 11 | Amylase | 12 | Beta-2 Microglobulin (B2M) |
| No. | Test Name | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | 25-OH Vitamin D | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Acetaminophen | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | Alanine Transaminase (ALT) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | Albumin | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 | Alkaline Phosphatase (ALP) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | Alpha-1 Antitrypsin (A1AT) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7 | Alpha-fetoprotein (AFP) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8 | Amikacin | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 9 | Aminotransferase (AST) | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10 | Ammonia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 11 | Amylase | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12 | Beta-2 Microglobulin (B2M) | | | | | | | | | | | | | | | | | | | | | | | | | | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | |
|-----|---------------------------------|--|
| 13 | | Beta-HCG |
| 14 | | Bicarbonate |
| 15 | | Bili Direct (DBIL) |
| 16 | | Bili Total (TBIL) |
| 17 | | CA-125 |
| 18 | | CA15-3 |
| 19 | | CA19-9 |
| 20 | | Calcium |
| 21 | | Carbamazepine |
| 22 | | Carcinoembryonic antigen (CEA) |
| 23 | | Ceruloplasmin |
| 24 | | Chloride |
| 25 | | Cholinesterase |
| 26 | | Complement Component 3 (C3) |
| 27 | | Complement Component 4 (C4) |
| 28 | | Cortisol |
| 29 | | C-peptide |
| 30 | | C-Reactive Protein (CRP) |
| 31 | | Creatine Kinase |
| 32 | | Creatine Kinase-MB (CKMB) |
| 33 | | Creatinine |
| 34 | | Cyclosporine |
| 35 | | Digoxin |
| 36 | | Dehydroepiandrosterone sulfate (DHEAS) |
| 37 | | Estradiol (E2) |
| 38 | | Ferritin |
| 39 | | Folic Acid |
| 40 | | Follicle Stimulating Hormone |
| 41 | | Free Prostate Surface Antigen |
| 42 | | Free Thyroxine (FT4) |
| 43 | | Free Triiodothyronine (FT3) |
| 44 | | Gamma Glutamyl Transferase (GGT) |
| 45 | | Gentamicin |
| 46 | | Glucose |
| 47 | | Haptoglobin |
| 48 | | HDL Cholesterol |
| 49 | | Immunoglobulin A |

| NO. | SPECIFICATIONS AND REQUIREMENTS | |
|-----|---------------------------------|-------------------------------------|
| 50 | | Immunoglobulin G |
| 51 | | Immunoglobulin M |
| 52 | | Insulin |
| 53 | | intact parathyroid hormone (iPTH) |
| 54 | | Iron |
| 55 | | Lactate |
| 56 | | Lactate Dehydrogenase (LDH) |
| 57 | | Lithium |
| 58 | | Luteinizing Hormone |
| 59 | | Magnesium |
| 60 | | Methotrexate |
| 61 | | Microalbumin |
| 62 | | NT-proBNP |
| 63 | | Phenobarbital |
| 64 | | Phenytoin |
| 65 | | Phosphate |
| 66 | | Potassium (K) |
| 67 | | Procalcitonin |
| 68 | | Progesterone |
| 69 | | Prolactin |
| 70 | | Protein Urine & CSF |
| 71 | | Rheumatoid Factor |
| 72 | | Salicylate |
| 73 | | Sex Hormone Binding Globulin (SHBG) |
| 74 | | Sodium (Na) |
| 75 | | Tacrolimus |
| 76 | | Testosterone |
| 77 | | Theophylline |
| 78 | | Thyroid Stimulating Hormone (TSH) |
| 79 | | Total Cholesterol |
| 80 | | Total Prostate Surface Antigen |
| 81 | | Total Protein |
| 82 | | Transferrin |
| 83 | | Triglyceride |
| 84 | | Troponin I or Troponin T |
| 85 | | Urea |
| 86 | | Uric Acid |

| NO. | SPECIFICATIONS AND REQUIREMENTS | |
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| | 87 | Valproic Acid |
| | 88 | Vancomycin |
| | 89 | Vitamin B12 |
| 46 | All the assay kits must be CE & IVD - marked. | |
| 47 | Vendor shall declare any use of third-party reagents for any of the assays above. Third party reagents must have documented test validation report that was performed on the analyzer model used in this tender. | |
| 48 | Vendor shall describe any limitations to the possibility of using third party reagents. | |
| 49 | Reagents to require minimum or nil preparations. | |
| 50 | Vendor shall provide the test methods of the assays. The information shall be submitted in Appendix G. | |
| 51 | Minimal 'Hook Effect' in the immunoassays. Please declare any assay affected / potentially affected by 'Hook Effect'. Kindly include claims from the manufacturer with regard to the 'Hook Effect' and the manufacturer's protocol or recommendation for re-testing samples potentially affected by 'Hook Effect'. | |
| 52 | <ul style="list-style-type: none"> THROUGHPUT (RIPASH) | |
| 53 | <p>Vendor shall offer a suitable number of chemistry and immunoassay analyzers to achieve the following throughput:</p> <ul style="list-style-type: none"> Perform and complete 1,530 immunoassay tests and 25,000 chemistry tests in about 4.5 hours (include time from the sample first introduced on the track) High no. of testing capacity at a time (~>330 tests at a time for chemistry tests and ~>70 tests at a time for immunoassay tests). The main objective for requiring high throughput is to be able to load A/E and inpatient samples on the track even during peak hours while still achieving <2 hours TAT. | |
| 54 | <p>Short analysis time for critical tests (see below):</p> <ol style="list-style-type: none"> Na+, K+, Cl- Urea Troponin T/ Troponin I (<20 mins) Creatinine <p>(Please provide the analysis runtime of the tests above)</p> | |
| 55 | Analyzers able to do intra-cup replicates. | |
| 56 | Analyzers able to do auto-dilution and also user defined manual dilution factors that can be programmed into the system. | |
| 57 | Vendor shall perform dilution verification of all the programmable auto-dilution every two years. | |
| 58 | Analyzers must have minimum carryover between samples for all tests | |
| 59 | There must be random access with stat capability to the analyzers (off-track). | |
| 60 | The analysers must have user friendly touch colour monitor screens. | |
| 61 | Analyzers must be able provide result printout for individual patient sample with analyzer ID stated | |
| 62 | Analyzer able to perform serum haemolytic, icteric and lipemic (HIL) check by measurement of absorbance and auto-translatable into semi-quantitative HIL index. | |
| 63 | The analyser must be able to provide a countdown of tests remaining of reagent kit on board and their due calibration date. | |
| 64 | The analyser must have automated notification when a new lot require calibration | |
| 65 | The analyser must have automated notification of impending calibration expiry | |
| 66 | The analysers must have a minimal daily maintenance with short or no analyser downtime. | |
| 67 | Vendor shall perform initial verification of the HIL measurements/index | |
| 68 | <p>Vendor shall provide comprehensive HIL interference rules and guidelines from the Manufacturer to implement for sample rejection by tests for all tests (eg. H-index of +1: - to reject LDH result etc.).</p> <ul style="list-style-type: none"> Data to be provided in excel and word format in a comprehensive summary tabular format. | |
| 69 | Vendor shall provide the list of all interfering substances that may affect test results for each test | |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| | <ul style="list-style-type: none"> Data to be provided in excel format in a comprehensive summary tabular form). |
| 70 | <p>Analyzers or the TLA system must have sample volume sensing/detection and comparison with required volume.</p> <ol style="list-style-type: none"> Provide description of sample volume check especially for low volume samples (i.e. fail-safe system for low volume samples already inside the track). Describe how the sample probe will be prevented from contamination by serum separator gel for such cases. |
| 71 | <p>Analyzers or TLA system must be able to detect fibrin or solids in serums.</p> <ul style="list-style-type: none"> Describe the detection method and the fail-safe feature for samples with fibrin/solids already inside the track. |
| 72 | Analyzers able to analyse serum, plasma, urine, CSF, body fluid and supernatant. |
| 73 | Vendor shall provide the list the minimum sample volumes required to run each test (refer to test menu). -Data to be provided in excel format in a comprehensive summary tabular form. |
| 74 | Provide list of sample stability by tests in tabular form (excel) |
| 75 | Any IQC violation will automatically trigger deactivation of the offending test and disable the offending cartridge until user intervention allows reactivation. |
| 76 | RE-CAPPER OR RE-SEALER (RIPASH) |
| 77 | Tubes will be resealed or recapped prior to storage to prevent serum evaporation |
| 78 | Able to recap/reseal all primary tubes and any secondary tubes compatible to the analyzers provided by vendor. |
| 79 | SAMPLE OUTPUT MODULE (RIPASH) |
| 80 | <p>The system should be able to sort samples into variable output lane / tray categories as follows: -</p> <ol style="list-style-type: none"> Priority output lane: 1. For samples that failed to be aliquoted due to fibrin or low sample volume 2. Sample with unreadable barcode. Incomplete output lane: 1. When reagents are not onboard / disabled / samples not registered by Laboratory information system (LIS). Complete output lane: When on-track refrigerator is down (buffer lane). |
| 81 | Sorting area for ≥ 200 samples (Customizable quantity for each lane category). |
| 82 | ON-TRACK REFRIGERATED SAMPLE STORAGE MODULE (RIPASH) |
| 83 | Automated refrigerated stockyard capable of holding $\geq 10,000$ sample tubes. |
| 84 | Auto retrieval and reloading of sample to analyser for test add-on or batch testing (sample automatically routed to analyser). |
| 85 | Automated dispensing of expired samples with user-defined criteria for its disposal. |
| 86 | Auto-charting of temperature with alert |
| 87 | Annual temperature spatial distribution check of the fridge shall be performed by vendor. |
| 88 | SAMPLE TRACK TRANSPORT SYSTEM (RIPASH) |
| 89 | The transport system must be equipped with intelligent sample process management system to ensure optimum TAT. |
| 90 | The sample track shall have an efficient land system to avoid jams in sample transport |
| 91 | The sample track should Individual sample carriers with Radio Frequency Identification (RFID) or similar for efficient routing and sample trail log for traceability. |
| 92 | Ability to cross lanes for samples requiring destination re-routing / prioritization. |
| 93 | INFORMATION TECHNOLOGY (RIPASH) |
| 94 | There should be remote diagnostics facilities available |
| 95 | <ul style="list-style-type: none"> INTERFACING (RIPASH) |
| 96 | Analyzers must be interfaced bi-directionally to Bru-HIMS through a middleware provided by the vendor. Vendor shall obtain approval from MOH Bru-HIMS for interfacing and to ensure vendor comply to interfacing requirements. The cost of setting up the interface and other maintenance costs are to be borne by the vendor. |
| 97 | <ul style="list-style-type: none"> SOFTWARE COMPONENTS: MIDDLEWARE, TRACK MANAGEMENT, SERVER STORAGE AND CLIENT WORKSTATION PCs (RIPASH) |
| 98 | Vendors to provide four (4) client workstation PCs that are equipped with: - |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| | <ol style="list-style-type: none"> 1. Keyboard and mouse 2. Barcode scanner 3. Analyzer Middleware 4. Access to TLA track management. 5. Microsoft Office subscription for the period of the tender contract. 6. QC Management Software 7. Antivirus software for the period of the tender contract. |
| 99 | <p>All the PCs must have optimal storage, RAM, processor and updated operating system to handle heavy middleware, LIS and TLA track management software activity.</p> <p>Work activity that will be done on these PCs include but not limited to: -</p> <ol style="list-style-type: none"> 1. Result review on analyzer middleware for. 2. Tracking samples and managing TLA components on the TLA track management software. 3. Registering patient samples and reviewing laboratory results on the Laboratory Information System software. 4. QC management. <p>The above activities are heavy workload items as the TLA system is expected to process thousands of patient samples per day. Should the PCs start to lag and affect the laboratory work, vendor shall upgrade the PCs to ensure smooth operation.</p> |
| 100 | Vendor must maintain the internal server (if required by the TLA system) also having sufficient storage to cater the period of tender contract. |
| 101 | <p>Vendor to provide statistical analysis software for evaluating the analyzer performances such as precision, linearity, inter-instrument correlation, limit of blank, limit of detection, limit of quantitation, and reference range verification for two (2) users access (RIPASH and PIHMH).</p> <p>Alternatively, vendor may generate the statistical analysis reports using data provided by the laboratory.</p> |
| 102 | <ul style="list-style-type: none"> • IN-DEPTH MIDDLEWARE & QC MANAGEMENT SOFTWARE SPECIFICATIONS (RIPASH) |
| 103 | Able to auto-calculate estimated Glomerular Filtration Rate (eGFR) using the CKD-EPI equation. The eGFR result can be transmitted to LIS. |
| 104 | Able to generate measurement of uncertainty (MU). |
| 105 | Analyzer middleware must have the ability to perform test result auto-validation based on delta check, alert limit, reference range, instrument analytical range, HIL index and user defined rules. |
| 106 | Vendor to provide guideline and provide assistance to the lab for the implementation of test result auto-validation. |
| 107 | The middleware can flag and alert samples if they are haemolysed, lipemic and icteric using HIL index. Middleware must be able to hold tests that are affected by the haemolysed/icteric/lipemic samples depending on the HIL index. |
| 108 | <p>Middleware must be able to hold critical tests results, automatic repeat testing followed by user intervention before results can be released.</p> <p>Middleware also must be able to flag results that are only critical to certain locations only e.g. Troponin critical results only applicable for A/E locations.</p> |
| 109 | Middleware must be able to trigger auto-dilution and rerun samples with results higher than the analytical measuring range (AMR) where applicable. |
| 110 | Middleware must be able to auto rerun samples for subsequent test (reflex test) based on user defined rules such as FT4 and FT3 when TSH result is abnormal |
| 111 | Middleware must be able to flag samples whose delta check alerted. Subsequently requires user intervention prior to release of the results. |
| 112 | <p>Middleware contains an overview page for held/blocked results for: -</p> <ol style="list-style-type: none"> 1. Critical results 2. Auto-dilution 3. Haemolysed, Icteric, Lipemic samples |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| | 4. Tests with QC violation. |
| 113 | The middleware is able to do moving averages for patient results (preferable). |
| 114 | <p>During interruption of Bru-HIMS (LIS) service, the middleware must be able is to act a temporary laboratory information system (LIS) i.e. sample processing & result reporting resumes independently of actual LIS.</p> <p>Once Bru-HIMS (LIS) is back on live, the results from the pre-generated specimen IDs should be able to be transmitted back to the actual specimen ID on Bru-HIMS. Please describe and give details on how the middleware can perform this.</p> |
| 115 | Analyzer middleware must be able to produce result printout for individual patient sample with complete patient and sample identifiers, ordering location and reference range. This is required as a back-up should the LIS is down and cannot be used to generate patient sample result report. |
| 116 | Vendor to configure on the laboratory's reference ranges of lab test results into the middleware. |
| 117 | Able to and assist laboratory to generate monthly turnaround time (TAT) by test and by location. |
| 118 | Able to and assist laboratory to generate monthly statistics by tests and by specimen types. |
| 119 | <p>Vendor shall provide protocol for re-evaluation of results from a period of compromised analytical performance</p> <ul style="list-style-type: none"> • Middleware must be able to conveniently and quickly trigger mass re-testing of all affected samples in the situation of a compromised analytical performance from the time of last QC in-control. • Vendor must also provide a solution on how to extract the original test run result and the rerun result for comparative analysis. • The above must be able to be done in a systematic and convenient way in order to perform corrective actions and amend released lab results swiftly such as in cases of hundreds of results affected. <p>Please describe how your middleware will be able to do this.</p> |
| 120 | Vendor to cover the costs of installation, maintenance and upgrades of the middleware throughout the contract period |
| 121 | <ul style="list-style-type: none"> • QUALITY CONTROL MANAGEMENT (RIPASH) |
| 122 | Vendor must provide a QC Management Software that allows periodic IQC performance review. |
| 123 | QC management software must be linked to the Middleware to allow automated submission of QC results. Any QC violation will automatically trigger test result to be put on hold. Vendor to cover all connection and maintenance costs for the link. |
| 124 | QC Management software is able to generate Levy-Jennings Chart Plot for periodic review. |
| 125 | QC Management software is able to generate running QC CV% data for periodic review. Periodic QC performance data (Mean, SD and CV%) is exportable to excel format. |
| 126 | Vendor must assist in configuring new lot QC data on the QC management software. |
| 127 | Vendor must provide third party QC material and the laboratory shall be given online access to peer IQC performance database for comparison. Please provide details of IQC materials provided and the peer IQC database. |
| 128 | Must be barcoded QC materials |
| 129 | The IQC supplied shall have minimal lot to lot changes |
| 130 | QC materials requiring minimum preparation prior to use |
| 131 | QC materials preferred to have long shelf life (≥ 12 months). |
| 132 | Please list out QC materials stability for all tests. To provide in excel format. |
| 133 | The QC Management Software to be connected to middleware and includes auto upload of QC data to QC peer review module. |
| 134 | Vendor to cover the costs of installation, maintenance and upgrades of the QC software throughout the contract period |
| 135 | <ul style="list-style-type: none"> • MONITOR (RIPASH) |
| 136 | Vendor to provide high wall-mounted flat screen monitor for real time monitoring of TAT of STAT samples (A/E samples and inpatient samples, TAT < 2 hours). |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| 137 | <ul style="list-style-type: none"> • PRINTERS (RIPASH) |
| 138 | <p>Vendor to provide printers (inclusive of print cartridge costs) as follows: -</p> <ol style="list-style-type: none"> 1. Black ink printers connected to each analyzer or each single line of connected analyzer modules and middleware to print sample results and other data (E.g. IQC points, calibration results & etc.). 2. One (1) colour printer for printing monthly QC Levy-Jennings charts from analyzer's middleware or QC Management software. |
| 139 | <p>AFTER SALES SUPPORT (RIPASH)</p> |
| 140 | <p>Two (2) technical staffs (unless stated otherwise) that shall work on-site according to the working hours below:</p> <ol style="list-style-type: none"> 1. Monday – Thursday, from 7.45am – 12.15 pm & 1.30pm – 4.30pm. Ramadan month: 8.00am – 2.00pm. 2. Saturday, only one (1) staff is required to work at 7.45am – 12.15 pm & 1.30pm – 4.30pm. Ramadan month: 8.00am – 2.00pm. 3. Only one (1) staff is required to attend to work during public holidays (Fridays, Sundays and National holidays) from 7.45am – 12.15pm & 1.30pm – 4.30pm. Ramadan month: 8.00am – 2.00pm. <p>Vendor shall provide replacement staff if any of the two staff is unable to attend to work.</p> <p>The staffs must be:</p> <ol style="list-style-type: none"> 1. Local or PR 2. Have educational qualification minimum of Higher National Technical Education Certificate (HNTec) or equivalent in Laboratory Sciences or related fields. Higher qualification is an advantage. 3. Fully trained and competent to perform the job scope in Clause 141. 4. Working experience in related field is preferred. |
| 141 | <p>Technical staff job scope:</p> <ol style="list-style-type: none"> 1. Daily maintenance of the analyzers including topping-up reagents, supplies, disposing onboard wastes, running calibration, running IQC and troubleshooting IQC according to laboratory protocol. 2. Preparation of reagents for use on the analyzers if required. 3. Load patient samples onto the TLA system. 4. Any other daily maintenance of the TLA system as required. 5. Monthly QC data extraction (LJ Chart and CV%) according to Laboratory's template. 6. Stock check and monitoring including forecasting usage. 7. New reagent lot verification. 8. New QC lot comparison. 9. General quality monitoring of the TLA system such as fridge temperature, extract test statistics, test turnaround time, incident statistics e.g. hemolyzed samples and etc. 10. Assist laboratory during LIS downtime. 11. Assist laboratory to re-test samples that has compromised results and to extract results for re-evaluation. |
| 142 | <p>ENGINEER SUPPORT (RIPASH)</p> |
| 143 | <p>Vendor must provide ≥ 2 dedicated engineers based in Brunei Darussalam for hardware service support 24/7 throughout the contract period.</p> <p>Please submit list of engineers expected to work under this project and their period of working experience in related field.</p> |
| 144 | <p>Answering call and inquiries from laboratory staff inclusive of public holidays (less than 30 minutes)</p> |
| 145 | <p>Present themselves in the laboratory (≤ 2 hours of responding to the call)</p> |
| 146 | <p>Local engineers to maintain and have access to remote support from regional office.</p> |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| 147 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. |
| 148 | Vendor shall provide to end user, one (1) softcopy and one (1) hard copy of the maintenance log schedule listing out details of daily, weekly and other periodic scheduled preventive maintenance. |
| 149 | <u>All periodic maintenance</u> of all automation systems including analysers is to be carried out by vendor. |
| 150 | Engineer to perform scheduled preventive maintenance during off-peak hours (such as Fridays and Sundays) and the downtime for scheduled preventive maintenance should be < 8 hours, allowing the other mirror analyzers operational during this time. |
| 151 | Scheduled replacement of hardware (≤6 hours during off peak) |
| 152 | Vendor must keep buffer stock of necessary spare hardware parts in Brunei such as but not limited to sample probes and reagent probes to ensure downtime is kept to a minimum. |
| 153 | Vendor shall maintain complete records of service maintenance work done which must have countersignature by end user. A copy must be available to laboratory head when and if requested. |
| 154 | <ul style="list-style-type: none"> • CORRECTIVE MAINTENANCE RESPONSE TIME (NON-URGENT TEST E.G. IRON TEST) (RIPASH): - |
| 155 | To trouble shoot and replace locally available spare parts (≤6 hours) |
| 156 | Waiting for spare part from overseas affecting only partially of total service (< 72 hours) |
| 157 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. |
| 158 | <ul style="list-style-type: none"> • CORRECTIVE MAINTENANCE RESPONSE TIME (URGENT TESTS E.G. POTASSIUM, TROPONIN, B-HCG) (RIPASH) |
| 159 | To trouble shoot and resolve corrective issue (≤3 hours). |
| 160 | The end user reserves the right to broaden the urgent test menu as and when required. |
| 161 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. |
| 162 | APPLICATION SPECIALIST SUPPORT (RIPASH) |
| 163 | Vendor must provide ≥ 2 dedicated application specialists based in Brunei Darussalam for hardware service support 24/7 throughout the contract period |
| 164 | The application specialist must be fully trained and capable to handle all issues pertaining to the test's applications both chemistry and immunochemistry tests as well as having the knowledge, experience and skills to perform method verification as required by ISO15189. |
| 165 | The application specialist is responsible to perform method verification of all 89 tests to be done on analysers, including HIL index and auto-dilution verification during commissioning of the analyzer and preparation of the method verification report. Therefore, during the period of commissioning, the project may need more application specialists to perform the initial method verification (such as 3 or 4 personnel) than after the commissioning phase (≥ 2 personnel). |
| 166 | Answering call & queries from laboratory staff inclusive of public holidays (≤ 30 minutes). |
| 167 | Present themselves in the laboratory (≤ 2 hours of responding to the call). |
| 168 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. |
| 169 | The application specialist responsibility also includes assisting in monitoring results, re-establishing QC ranges, troubleshooting of Internal QC and External Quality Assurance Program Results, and assisting in preparation for ISO 15189 Assessments. |
| 170 | Continued support by Application specialist to update, customise, and validate auto verification rules, tests software, and middleware functions |
| 171 | All troubleshooting and corrective actions performed by the engineer and application team must address and resolve the root cause of the issue as much as possible. Monitoring and further testing must be done by the vendor should the root cause is not identified. |
| 172 | All service work by engineer and application team must be recorded in service reports in complete details and to be verified by laboratory personnel. Lab personnel may request for |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| | further corrective action / troubleshooting should the current action done deemed inadequate. |
| 173 | <ul style="list-style-type: none"> • CONTINUOUS SUPPORT (RIPASH) |
| 174 | Vendor must supply the following in a tabular format (excel): - <ol style="list-style-type: none"> 1. Analytical measuring range of each test 2. Linearity range of each test. 3. Reference range of each test. 4. Manufacturer's claim total within laboratory (total) precision of each test. 5. LOB, LOD & LOQ claim of each test. |
| 175 | Engineer to perform all periodic scheduled preventive maintenance of the TLA components including attending to breakdowns / issues. |
| 176 | Application specialists must perform reagent lot verification of all incoming new lot reagents according to laboratory's protocol. |
| 177 | Application specialists must perform annual linearity verification of all tests using linearity kits or patient samples provided by the lab |
| 178 | Application specialists must perform method verification should there be any change of method or formulation of the assays. The vendor shall cover the cost of the consumables, calibration material and reagents. |
| 179 | Annual temperature spatial distribution check of the on-track fridge to be performed by Application specialists/Engineer. |
| 180 | Application specialists/Engineer to perform centrifuge speed and timer check of all centrifuges provided annually according to protocol provided by the laboratory. |
| 181 | Application specialists to perform dilution verification of all the programmable auto-dilution every two years. |
| 182 | Application specialists to provide immediate remote and onsite assistance should there be any issues with the bidirectional connectivity between middleware and LIS throughout the period of the tender contract. |
| 183 | Engineer to perform periodic maintenance including parts replacement of water purification systems as required by the manufacturer's recommendations and to perform annual sterilization and as when needed. |
| 184 | Application specialists to perform back up of analyzer data (lab results, IQC data, calibration data) on a biweekly basis or as agreed by the user later on depending on how long the analyzer can operate optimally before it lags due to memory space. |
| 185 | To generate annual measurement of uncertainty report of all tests either from the middleware or QC management software. |
| 186 | Application specialist must assist senior lab personnel in any other periodical method verification as required by ISO 15189 |
| 187 | ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS (RIPASH) |
| 188 | Please summarize the data sheet of the proposed TLA system to include the following information: <ol style="list-style-type: none"> 1. Power requirements 2. Water requirements 3. Heat generation 4. Measurements and weight of the TLA components |
| 189 | Vendor to ensure all environmental requirements for optimal TLA system operations are fulfilled before installation, testing and commissioning. Should any renovation be required, Vendor shall comply with the Ministry's procedure for infection control risk assessment (ICRA), implementation and monitoring as set out in the document titled Construction and/or Renovation, Maintenance, Repair and Demolition in the Health Care Setting. Vendor is required to liaise with RIPAS Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation The system shall occupy space not more than the present system in the laboratory. If any renovation (electrical and/or environmental) is required, costs shall be borne by Vendor. |
| 190 | Prior to the proposed renovation work, vendor is required to conduct an onsite assessment of current site. |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|--|
| 191 | Onsite assessment can be arranged with prior notification and agreement of head of National Clinical Chemistry Reference Laboratory. |
| 192 | <p>The vendor shall ensure that the maximum structural loading limits of all floors where TLA system is to be installed are not exceeded.</p> <p>Vendor shall appoint a certified chartered engineer to assess the site's structural loading capacity against the proposed TLA system to be installed (Please state your appointed engineer and proof of qualification/certification).</p> <p>Should the maximum structural loading limits of the floors be exceeded, vendor must provide reinforcements to the floor to sustain the load of the TLA components. The vendor shall also ensure the floor site conforms to TLA system's manufacturer's specification.</p> <p>Any floor structural strengthening work to the TLA floor must not affect the area below the TLA floor (Breast Imaging Centre) including no interruption to their power supply, dust pollution and etc. Breast Imaging Centre area is designated as off-limits for any construction/renovation activities.</p> |
| 193 | Should the TLA system configuration requires moving the power outlets, work benches, desks, water pipes, waste pipes, lockers, biosafety cabinet and others, vendor shall be responsible to relocate these items and bear the costs . |
| 194 | <p>Water requirements: Low water consumption. If water is required, state how much and what purity, with provision of water purification system included. All costs for installing water requirements shall be borne by the Vendor.</p> <ul style="list-style-type: none"> • Vendor to provide two (2) water tank to ensure system is able to run at least 4 hours when external water supply is unavailable. • Vendor to supply the appropriate quantity of water purifier / de-ionizer systems according to TLA manufacturer's recommendations (including supply of contingency units if the first set of units failed) with appropriate filters to produce water that meets requirement for clinical lab diagnostic use. <ul style="list-style-type: none"> • Vendor must perform water sterilization periodically and to perform filter change as needed. Water resistivity and sterility must meet manufacturer's requirement and to perform the maintenance/servicing if fall below the standard. Any other required maintenance and repair work needed for the water systems shall be borne by vendor. • Vendor to install sediment filters prior to the purification systems. • Vendor to provide and install water pumps and piping as required to ensure water supply is directed from the water tanks to the site of testing sufficiently. <p>Vendor is required to liaise with RIPAS Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation</p> |
| 195 | <p>Please provide specification for power requirement. Vendor's TLA system must not exceed the laboratory's existing electric current capacity.</p> <p>All costs for installing electrical requirements shall be borne by the Vendor. Vendor shall install dedicated power sockets for the TLA system direct to the nearest Distribution Board (DB). A qualified electrician shall be appointed by the vendor to perform all the electrical works.</p> <p>All the electrical wires shall be covered with PVC trunk properly for safety precautions.</p> |
| 196 | Electrical Safety – Vendor shall test for and maintain the electrical safety of all equipment and accessory devices installed throughout their usage period. This include conducting electrical safety testing upon installation & during preventive maintenance (at least every six |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| | (6) months) using calibrated device. Electrical safety testing report shall be submitted to the laboratory for acceptance. |
| 197 | Vendor shall supply, install, test and commission additional Cat6A UTP cable with uPVC conduit/casing and faceplate to the hospital network point if the existing points are not enough and located far away from the TLA system. This is to establish connectivity between the supplied TLA system and its accessory devices/machines/PCs to the hospital's Laboratory Information System (LIS) network. |
| 198 | Before commencing any site preparation or installation, the Vendor is required to contact and consult the RIPAS Hospital Estate Department. This is mandatory to confirm that all work meets departmental regulations and receives Estate's approval. |
| 199 | Temperature and humidity requirement: preferably 22 – 28 °C and up to 80% relative humidity. |
| 200 | Floor area and drainage requirements: preferably adaptable to present facilities. |
| 201 | Heat and noise generation: preferably less than 7,000 BTU per unit and ≤ 65 dBA at the front of the unit while at full operation. |
| 202 | Vendor shall provide and install one (1) air conditioning (AC) unit – 4.0 horsepower inclusive of maintenance and repair as needed. This is to ensure sufficient cooling of the environment from the heat generated by the TLA system and as contingency if RIPAS Hospital's central air conditioning is down. |
| 203 | Low generation of hazardous chemical or biological waste. |
| 204 | If biological liquid waste is generated, the supplier shall provide the following for suitable waste containers; <ul style="list-style-type: none"> i. Two waste containers shall be capped, have an inlet and outlet, easy to handle and do not hold more than 15L of liquid waste ii. When the production of waste liquid is more than 15L/day, a direct waste pipe shall be installed. A pre-dilution container shall be provided with easy access to add disinfectant and dispose of waste liquid. A preventive pipe shall be installed to prevent overflowing liquid waste from the waste containers. Proper guidelines to disinfect the liquid waste that is acceptable to ISO 15189 shall be provided. |
| 205 | The successful vendor shall keep the area behind of the equipment tidy and clean at all times. All wires and cables shall be properly covered using PVC trunk, flexible wire and cable cover or equivalent that is acceptable to the laboratory. |
| 206 | Any steps to switch on or off any main electrical or plumbing supply must require prior consent from in charge of Estate Department, RIPAS Hospital |
| 207 | Any environmental impact of site preparation work (e.g. dust, sound, vibration and waste removal) must be minimal to both the public and the laboratory staff. |
| 208 | All necessary precautions must be taken by vendor to ensure minimal disruption to current laboratory services during site preparation, installation, testing and commissioning phase. |
| 209 | Workers are required to wear RIPAS Hospital issued temporary workers pass at all times when on work site |
| 210 | INSTALLATION, TESTING AND COMMISSIONING (RIPASH) |
| 211 | The vendor will be represented by suitable qualified and competent staff for all the necessary installation, testing and commissioning work. The following may be required: - <ol style="list-style-type: none"> 1. Project Supervisor / Manager 2. Application Specialists 3. Engineers 4. IT specialist |
| 212 | The vendor shall ensure any temporary modifications to door or windows to create passage of components of TLA system to site is subsequently restored to original condition. |
| 213 | The vendor shall ensure all work are carried out with minimal disruption to lab Services |
| 214 | The vendor shall ensure that the safety and security of the staff, patients, contents, and premises are not compromised in the installation process |

| NO. | SPECIFICATIONS AND REQUIREMENTS | | | | | | | | | | | | | | | | | | |
|-----|---|-----|-----------|---|----------------------------|---|---------------|---|----------------------------|---|---------|---|-------------|---|------------|---|------------------|---|-------|
| 215 | The vendor guarantees that on completion of the installation, the IAS is free from any defects and is completely safe for operations | | | | | | | | | | | | | | | | | | |
| 216 | <p>INITIAL METHOD VERIFICATION</p> <p>Vendor must perform a complete method verification of all the tests across all mirror analyzers, including, but not limited to: -</p> <ol style="list-style-type: none"> 1. Precision 2. Accuracy 3. Linearity 4. Limit of blank, limit of detection and limit of quantitation. 5. Carryover 6. Inter-instrument comparison between all new analyzers and existing analyzers. 7. Inter-instrument comparison between new analyzers. 8. Reference range verification 9. verification of the HIL measurements/index 10. Verification of auto-dilutions that are available on the analyzers. <p>Vendor must perform the method verification according to protocols that meets the requirement of ISO15189 and the laboratory's internal requirement depending on the nature of testing with the total cost borne by the vendor including the costs of reagents, calibrators, IQC, linearity kits and consumables.</p> <p>Report of the verification study shall be submitted to the Head of Section and then for final approval by the Director of Department of Laboratory Services.</p> | | | | | | | | | | | | | | | | | | |
| 217 | Vendor shall also present the verification study findings to senior laboratory representatives on submission of the verification study report. | | | | | | | | | | | | | | | | | | |
| 218 | Senior laboratory representative may request vendor to re-do any study that failed the set acceptable criteria or deemed inadequate and request changes to report template/format. | | | | | | | | | | | | | | | | | | |
| 219 | Final report to be submitted in both softcopy and two (2) hardcopy format. All raw results from the analyzers must be attached together with the report. | | | | | | | | | | | | | | | | | | |
| 220 | The scope of testing and commissioning shall also include visual inspection for damage and/or corrosion of TLA system, safety, and neatness. | | | | | | | | | | | | | | | | | | |
| 221 | Application specialists are required to run and obtain 20 IQC data points per level of all the tests using the QC lot that is expected to be used on the Go-Live date just prior to the Go-Live date. This is required for establishment of QC target means and CV goals. | | | | | | | | | | | | | | | | | | |
| 222 | Vendor to assist the lab to perform a mock/trial run of the TLA system before the Go-live date using dummy samples. The lab orders are to be replicated as close as possible. | | | | | | | | | | | | | | | | | | |
| 223 | ANALYZERS FOR CLINICAL CHEMISTRY LAB (PIHMH) | | | | | | | | | | | | | | | | | | |
| 224 | <ul style="list-style-type: none"> • Vendor must provide Chemistry and Immunoassay analyzers that covers the PIHMH test menu (see below). • One (1) Chemistry analyzer and one (1) immunoassay analyzer. • The same brand as the analyzers offered for the TLA system | | | | | | | | | | | | | | | | | | |
| 225 | <p><u>PIHM Hospital TEST MENU</u></p> <table border="1" data-bbox="309 1585 1002 2033"> <thead> <tr> <th data-bbox="309 1585 389 1637">No.</th> <th data-bbox="389 1585 1002 1637">Test Name</th> </tr> </thead> <tbody> <tr> <td data-bbox="309 1637 389 1688">1</td> <td data-bbox="389 1637 1002 1688">Alanine Transaminase (ALT)</td> </tr> <tr> <td data-bbox="309 1688 389 1740">2</td> <td data-bbox="389 1688 1002 1740">Albumin (ALB)</td> </tr> <tr> <td data-bbox="309 1740 389 1792">3</td> <td data-bbox="389 1740 1002 1792">Alkaline Phosphatase (ALP)</td> </tr> <tr> <td data-bbox="309 1792 389 1843">4</td> <td data-bbox="389 1792 1002 1843">Amylase</td> </tr> <tr> <td data-bbox="309 1843 389 1895">5</td> <td data-bbox="389 1843 1002 1895">BILI DIRECT</td> </tr> <tr> <td data-bbox="309 1895 389 1946">6</td> <td data-bbox="389 1895 1002 1946">BILI TOTAL</td> </tr> <tr> <td data-bbox="309 1946 389 1998">7</td> <td data-bbox="389 1946 1002 1998">CO2C Bicarbonate</td> </tr> <tr> <td data-bbox="309 1998 389 2033">8</td> <td data-bbox="389 1998 1002 2033">CRP16</td> </tr> </tbody> </table> | No. | Test Name | 1 | Alanine Transaminase (ALT) | 2 | Albumin (ALB) | 3 | Alkaline Phosphatase (ALP) | 4 | Amylase | 5 | BILI DIRECT | 6 | BILI TOTAL | 7 | CO2C Bicarbonate | 8 | CRP16 |
| No. | Test Name | | | | | | | | | | | | | | | | | | |
| 1 | Alanine Transaminase (ALT) | | | | | | | | | | | | | | | | | | |
| 2 | Albumin (ALB) | | | | | | | | | | | | | | | | | | |
| 3 | Alkaline Phosphatase (ALP) | | | | | | | | | | | | | | | | | | |
| 4 | Amylase | | | | | | | | | | | | | | | | | | |
| 5 | BILI DIRECT | | | | | | | | | | | | | | | | | | |
| 6 | BILI TOTAL | | | | | | | | | | | | | | | | | | |
| 7 | CO2C Bicarbonate | | | | | | | | | | | | | | | | | | |
| 8 | CRP16 | | | | | | | | | | | | | | | | | | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | |
|-----|---|--------------------------|
| | 9 | Calcium |
| | 10 | Cholesterol |
| | 11 | CL-C (Chloride) |
| | 12 | CreaC (Creat) |
| | 13 | GGT |
| | 14 | Glucose |
| | 15 | K-C (Potassium) |
| | 16 | NA-C (Sodium) |
| | 17 | Phosphate |
| | 18 | Total Protein (TP) |
| | 19 | Triglyceride |
| | 20 | Uric Acid (UA) |
| | 21 | HDL Cholesterol |
| | 22 | Urea |
| | 23 | Troponin I or Troponin T |
| 226 | All the assay kits must be CE & IVD - marked. | |
| 227 | Vendor to declare any use of third-party reagents for any of the assays above. Third party reagents must have documented test validation report that was performed on the analyzer model used in this tender. | |
| 228 | Vendor shall provide the test methods and technology of the analyzers and a list of current users in the region. | |
| 229 | <p>INITIAL METHOD VERIFICATION</p> <p>Vendor must perform a complete method verification of all the tests across all mirror analyzers, including, but not limited to: -</p> <ol style="list-style-type: none"> 1. Precision 2. Accuracy 3. Linearity 4. Limit of blank, limit of detection and limit of quantitation. 5. Carryover 6. Inter-instrument comparison between all new analyzers and existing analyzers. 7. Inter-instrument comparison between new analyzers. 8. Reference range verification 9. verification of the HIL measurements/index 10. Verification of auto-dilutions that are available on the analyzers. <p>Vendor must perform the method verification according to protocols that meets the requirement of ISO15189 and the laboratory's internal requirement depending on the nature of testing with the total cost borne by the vendor including the costs of reagents, calibrators, IQC, linearity kits and consumables.</p> <p>Report of the verification study shall be submitted to the Head of Section and then for final approval by the Director of Department of Laboratory Services.</p> | |
| 230 | Minimal 'Hook Effect' in the immunoassays. | |
| 231 | Please declare any assay affected / potentially affected by 'Hook Effect'. Kindly include claims from the manufacturer with regard to the 'Hook Effect' and the manufacturer's protocol or recommendation for re-testing samples potentially affected by 'Hook Effect'. | |
| 231 | Analyzers able to do intra-cup replicates. | |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| 232 | Analyzers able to do auto-dilution and also user defined manual dilution factors that can be programmed into the system. |
| 233 | Vendor to perform dilution verification of all the programmable auto-dilution every two years. |
| 234 | Analyzers must have minimum carryover between samples for all tests |
| 235 | There must be random access with stat capability to the analyzers. |
| 236 | The analysers must have user friendly touch colour monitor screens. |
| 237 | Analyzers must be able provide result printout for individual patient sample with analyzer ID stated |
| 238 | The analyser should provide a countdown of tests remaining of reagent kit on board and their due calibration date. |
| 239 | The analyser should have automated notification when a new lot reagent require calibration |
| 240 | The analyser should have automated notification of impending calibration expiry |
| 241 | The analyser should have option to override calibrator/reagent expiry |
| 242 | Analyzer able to perform serum haemolytic, icteric and lipemic (HIL) check by measurement of absorbance and auto-translatable into semi-quantitative HIL index. |
| 243 | Vendor to perform initial verification of the HIL measurements/index |
| 244 | Vendor to provide comprehensive HIL interference rules and guidelines from the Manufacturer to implement for sample rejection by tests for all tests (eg. H-index of +1: - to reject LDH result etc.). - Data to be provided in excel and word format in a comprehensive summary tabular format. |
| 245 | Vendor to provide the list of all interfering substances that may affect test results for each test -Data to be provided in excel format in a comprehensive summary tabular form). |
| 246 | Analyzers have sample volume sensing/detection and comparison with required volume. |
| 247 | Analyzers able to detect fibrin or solids in serums. |
| 248 | Analyzers able to analyse serum, plasma, urine, CSF, body fluid and supernatant. |
| 249 | List the minimum sample volumes required to run each test (refer to test menu). -Data to be provided in excel format in a comprehensive summary tabular form). |
| 250 | Provide list of sample stability by tests in tabular form (excel) |
| 251 | INTERFACING (PIHMH) |
| 252 | Analyzers must be interfaced bi-directionally to Bru-HIMS through a middleware provided by the vendor. Vendor shall obtain approval from MOH Bru-HIMS for interfacing and to ensure vendor comply to interfacing requirements. The cost of setting up the interface and other maintenance costs are to be borne by the vendor. |
| 253 | MIDDLEWARE & WORKSTATION (PIHMH) |
| 254 | Able to auto-calculate estimated Glomerular Filtration Rate (eGFR) using the CKD-EPI equation. The eGFR result can be transmitted to LIS. |
| 255 | Able to generate measurement of uncertainty (MU). |
| 256 | Analyzer middleware must have the ability to perform test result auto-validation based on delta check, alert limit, reference range, instrument analytical range, HIL index and user defined rules. |
| 257 | Vendor to provide guideline and provide assistance to the lab for the implementation of test result auto-validation. |
| 258 | The middleware can flag and alert samples if they are haemolysed, lipemic and icteric using HIL index. Middleware must be able to hold tests that are affected by the haemolysed/icteric/lipemic samples depending on the HIL index. |
| 259 | Middleware must be able to hold critical tests results, automatic repeat testing followed by user intervention before results can be released. |
| 260 | Middleware must be able to trigger auto-dilution and rerun samples with results higher than the analytical measuring range (AMR) where applicable. |
| 261 | Middleware must be able to flag samples whose delta check alerted. Subsequently requires user intervention prior to release of the results. |
| 262 | Middleware contains an overview page for held/blocked results for: - 1. Critical results 2. Auto-dilution 3. Haemolysed, Icteric, Lipemic samples Tests with QC violation. |
| 263 | The middleware is able to do moving averages for patient results (preferable). |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| 264 | During interruption of Bru-HIMS (LIS) service, the middleware must be able is to act a temporary laboratory information system (LIS) i.e. sample processing & result reporting resumes independently of actual LIS. |
| 265 | Analyzer middleware must be able to produce result printout for individual patient sample with complete patient and sample identifiers, ordering location and reference range. This is required as a back-up should the LIS is down and cannot be used to generate patient sample result report. |
| 266 | Vendor to configure on the laboratory's reference ranges of lab test results into the middleware. |
| 267 | Able to and assist laboratory to generate monthly turnaround time (TAT) by test and by location. |
| 268 | Able to and assist laboratory to generate monthly statistics by tests and by specimen types. |
| 269 | Vendor to cover the costs of installation, maintenance and upgrades of the middleware throughout the contract period |
| 270 | Vendors to provide one (1) client workstation PCs that are equipped with: - <ol style="list-style-type: none"> 1. Keyboard and mouse 2. Barcode scanner 3. Analyzer Middleware 4. Microsoft Office subscription for the period of the tender contract. 5. QC Management Software 6. Antivirus software for the period of the tender contract. |
| 271 | QUALITY CONTROL (PIHMH) |
| 272 | Vendor must provide a QC management software to allow periodic review of QC performance. |
| 273 | Must be bar coded QC materials |
| 274 | The IQC supplied should have minimal lot to lot changes |
| 275 | QC materials requiring minimum preparation prior to use |
| 276 | QC materials preferred to have long shelf life (≥12 months). |
| 277 | Please list out QC materials stability for all tests. To provide in excel format. |
| 278 | QC management software must be linked to the Middleware to allow automated submission of QC results. Any QC violation will automatically trigger test result to be put on hold. Vendor to cover all connection and maintenance costs for the link. |
| 279 | QC Management software is able to generate Levy-Jennings Chart Plot for periodic review. |
| 280 | QC Management software is able to generate running QC CV% data for periodic review. Periodic QC performance data (Mean, SD and CV%) is exportable to excel format. |
| 281 | Vendor must assist in configuring new lot QC data on the QC management software. |
| 282 | Vendor must provide third party QC material and the laboratory should be given online access to peer IQC performance database for comparison. Please provide details of IQC materials provided and the peer IQC database. |
| 283 | The QC Management Software to be connected to middleware and includes auto upload of QC data to QC peer review module. |
| 284 | Vendor to cover the costs of installation, maintenance and upgrades of the QC software throughout the contract period |
| 285 | PRINTERS (PIHMH) |
| 286 | Vendor to provide printers (inclusive of print cartridge costs) as follows: - Black ink printers connected to each analyzer or each single line of connected analyzer modules including middleware to print sample results and other data (E.g. IQC points, calibration results & etc.)). |
| 287 | AFTER SALES SUPPORT (PIHMH) |
| 288 | ENGINEER SUPPORT (PIHMH) |
| 289 | Vendor must provide ≥ 1 dedicated engineer based in Brunei Darussalam for hardware service support 24/7 throughout the contract period. |
| 290 | Answering call and inquiries from laboratory staff inclusive of public holidays (less than 30 minutes) |
| 291 | Present themselves in the laboratory (≤ 2 hours of responding to the call) |
| 292 | Local engineers to maintain and have access to remote support from regional office. |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| 293 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. |
| 294 | Vendor shall provide to end user, one (1) softcopy and one (1) hard copy of the maintenance log schedule listing out details of daily, weekly and other periodic scheduled preventive maintenance. |
| 295 | <u>Weekly maintenance</u> of all automation systems including analysers is to be carried out by vendor. |
| 296 | Engineer to perform scheduled preventive maintenance during off-peak hours and the downtime for scheduled preventive maintenance should be < 8 hours. |
| 297 | Scheduled replacement of hardware (≤6 hours during off peak) |
| 298 | Vendor must keep buffer stock of necessary spare hardware parts in Brunei such as but not limited to sample probes and reagent probes to ensure downtime is kept to a minimum. |
| 299 | Vendor shall maintain complete records of service maintenance work done which must have countersignature by end user. A copy must be available to laboratory head when and if requested. |
| 300 | CORRECTIVE MAINTENANCE RESPONSE TIME (NON-URGENT TEST E.G. IRON TEST) (PIHMH): - |
| 301 | To trouble shoot and replace locally available spare parts (≤6 hours) |
| 302 | Waiting for spare part from overseas affecting only partially of total service (< 72 hours) |
| 303 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. |
| 304 | CORRECTIVE MAINTENANCE RESPONSE TIME (URGENT TESTS E.G. POTASSIUM, TROPONIN) (PIHMH) |
| 305 | To trouble shoot and resolve corrective issue (≤3 hours) |
| 306 | The end user reserves the right to broaden the urgent test menu as and when required |
| 307 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. |
| 308 | APPLICATION SPECIALIST SUPPORT (PIHMH) |
| 309 | Vendor must provide ≥ 1 dedicated application specialists based in Brunei Darussalam for hardware service support 24/7 throughout the contract period |
| 310 | The application specialist must be fully trained and capable to handle all issues pertaining to the test's applications both chemistry and immunochemistry tests as well as having the knowledge, experience and skills to perform method verification as required by ISO15189. |
| 311 | The application specialist is responsible to perform method verification of all tests to be done on analysers, including HIL index and auto-dilution verification during commissioning of the analyzer and preparation of the method verification report. |
| 312 | Answering call & queries from laboratory staff inclusive of public holidays (≤ 30 minutes). |
| 313 | Present themselves in the laboratory (≤ 2 hours of responding to the call). |
| 314 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. |
| 315 | The application specialist responsibility also includes assisting in monitoring results, re-establishing QC ranges, troubleshooting of Internal QC and External Quality Assurance Program Results, and assisting in preparation for ISO 15189 Assessments. |
| 316 | All troubleshooting and corrective actions performed by the engineer and application team must address and resolve the root cause of the issue as much as possible. Monitoring and further testing must be done by the vendor should the root cause is not identified. |
| 317 | All service work by engineer and application team must be recorded in service reports in complete details and to be verified by laboratory personnel. Lab personnel may request for further corrective action / troubleshooting should the current action done deemed inadequate. |
| 318 | CONTINUOUS SUPPORT (PIHMH) |
| 319 | Vendor must supply the following in a tabular format (excel): - 1. Analytical measuring range of each test 2. Linearity range of each test. |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| | 3. Reference range of each test. 4. Manufacturer's claim total within laboratory (total) precision of each test. 5. LOB, LOD & LOQ claim of each test. |
| 320 | Engineer to perform all periodic scheduled preventive maintenance of the analyzers including attending to breakdowns / issues. |
| 321 | Application specialists must perform reagent lot verification of all incoming new lot reagents according to laboratory's protocol. |
| 322 | Application specialists must perform annual linearity verification of all tests using linearity kits or patient samples provided by the lab |
| 323 | Application specialists must perform method verification should there be any change of method or formulation of the assays. The vendor shall cover the cost of the consumables, calibration material and reagents. |
| 324 | Application specialists to perform dilution verification of all the programmable auto-dilution every two years. |
| 325 | To generate annual measurement of uncertainty report of all tests either from the middleware or QC management software. |
| 326 | Application specialists to provide immediate remote and onsite assistance should there be any issues with the bidirectional connectivity between middleware and LIS throughout the period of the tender contract. |
| 327 | Engineer to perform periodic maintenance including parts replacement of water purification systems as required by the manufacturer's recommendations and to perform annual sterilization and as when needed. |
| 328 | Application specialists to perform back up of analyzer data (lab results, IQC data, calibration data) on a monthly basis or as agreed by the user later on depending on how long the analyzer can operate optimally before it lags due to memory space. |
| 329 | Application specialist must assist senior lab personnel in any other periodical method verification as required by ISO 15189 |
| 330 | ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS (PIHMH) |
| 331 | <p>Vendor to ensure all environmental requirements for optimal operation of the analyzers are fulfilled before installation, testing and commissioning. Should any renovation be required, Vendor shall comply with the Ministry's procedure for infection control risk assessment (ICRA), implementation and monitoring as set out in the document titled Construction and/or Renovation, Maintenance, Repair and Demolition in the Health Care Setting. Vendor is required to liaise with PIHM Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation</p> <p>The system shall occupy space not more than the present system in the laboratory. If any renovation (electrical and/or environmental) is required, costs shall be borne by Vendor.</p> |
| 332 | Prior to the proposed renovation work, vendor is required to conduct an onsite assessment of current site. |
| 333 | Onsite assessment can be arranged with prior notification and agreement of head of PIHM Hospital Laboratory. |
| 334 | <p>Water requirements: Low water consumption. If water is required, state how much and what purity, with provision of water purification system included. All costs for installing water requirements shall be borne by the Vendor.</p> <ul style="list-style-type: none"> • Vendor to provide one (1) water tank to ensure system is able to run at least 4 hours when external water supply is unavailable. • Vendor to supply the appropriate quantity of water purifier / de-ionizer systems according to manufacturer's recommendations if with appropriate filters to produce water that meets requirement for clinical lab diagnostic use. • Vendor must perform water sterilization periodically and to perform filter change as needed. Water resistivity and sterility must meet manufacturer's requirement and to perform the maintenance/servicing if fall below the standard. Any other required maintenance and repair work needed for the water systems shall be borne by vendor. • Vendor to install sediment filters prior to the purification systems. • Vendor to provide and install water pumps and piping as required to ensure water supply is directed from the water tanks to the site of testing sufficiently. |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| | Vendor is required to liaise with PIHM Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation |
| 335 | Please provide specification for power requirement. All costs for installing electrical requirements shall be borne by the Vendor. All the electrical wires shall be covered with PVC trunk properly for safety precautions. Vendor is required to liaise with PIHM Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation. |
| 336 | Electrical Safety – Vendor shall test for and maintain the electrical safety of all equipment and accessory devices installed throughout their usage period. This include conducting electrical safety testing upon installation & during preventive maintenance (at least every six (6) months) using calibrated device. Electrical safety testing report shall be submitted to the laboratory for acceptance. |
| 337 | Temperature and humidity requirement: preferably 22 – 28 °C and up to 80% relative humidity. |
| 338 | Floor area and drainage requirements: preferably adaptable to present facilities. |
| 339 | Heat and noise generation: preferably less than 7,000 BTU per unit and ≤ 65 dBA at the front of the unit while at full operation. |
| 340 | Low generation of hazardous chemical or biological waste. |
| 341 | If biological liquid waste is generated, the supplier shall provide the following for suitable waste containers; i. Two waste containers shall be capped, have an inlet and outlet, easy to handle and do not hold more than 15L of liquid waste. ii. When the production of waste liquid is more than 15L/day, a direct waste pipe shall be installed. A pre-dilution container shall be provided with easy access to add disinfectant and dispose of waste liquid. A preventive pipe shall be installed to prevent overflowing liquid waste from the waste containers. Proper guidelines to disinfect the liquid waste that is acceptable to ISO 15189 shall be provided. |
| 342 | The successful vendor shall keep the area behind of the equipment tidy and clean at all times. All wires and cables shall be properly covered using PVC trunk, flexible wire and cable cover or equivalent that is acceptable to the laboratory. |
| 343 | Any environmental impact of site preparation work (e.g. dust, sound, vibration and waste removal) must be minimal to both the public and the laboratory staff. |
| 344 | All necessary precautions must be taken by vendor to ensure minimal disruption to current laboratory services during site preparation, installation, testing and commissioning phase. |
| 345 | Workers are required to wear PIHM Hospital issued temporary workers pass at all times when on work site |
| 346 | SUPPLY OF REAGENTS AND CONSUMABLES (RIPASH & PIHMH) |
| 347 | All reagents must remain stable throughout the shelf life when stored at their stated temperature. |
| 348 | All reagents must have a long shelf life from the date of acceptance. Any loss incurred from expired reagents and expired onboard stability of the reagents will be borne by vendor as the laboratory will only be charged based on tests performed statistics. |
| 349 | Staggered delivery of reagents and consumables shall be according to user's schedule. |
| 350 | Delivery shall be direct to National Clinical Chemistry Reference Laboratory (NCCRL), RIPAS Hospital for P.O. generated by NCCRL. |
| 351 | Delivery shall be direct to Clinical Chemistry Laboratory PIHM Hospital (Temburong) for P.O. generated by PIHMH Lab. |
| 352 | Should the reagents require inversion on their arrival at the laboratory, vendor to perform the inversion after the Delivery Order and the reagents are cross-checked and before arranging the reagents in the storage space. |
| 353 | On delivery, vendor is also required to arrange reagents in the store sites (cold room, freezer, fridge or dry store room) according to "First-In, First-Out" (FIFO) i.e. the older, nearing expiry date stocks to be arranged at the frontmost whereas the newer, longer expiry date stocks on the aftmost part of the shelves. |
| 354 | Reagent kit size for all tests must be fit for purpose to optimise cost savings. |
| 355 | The reagents supplied should have minimal lot to lot changes. |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
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| 356 | The IQC materials supplied should have minimal lot to lot changes i.e. enough stock to use until nearing IQC material expiry date. |
| 357 | Vendor shall provide documentation evidence that the transport and storage of the reagents and calibrators are in accordance to temperature requirements of manufacturers. |
| 358 | Vendor to assist the laboratory to manage reagent usage especially for reagents with short onboard stability to ensure low wastage. |
| 359 | Delivery and storage of reagents to the laboratory by vendor should be such that there is optimum use of the limited laboratory storage facilities (<1-2 months usage at the laboratory storage space) |
| 360 | Vendor shall keep their buffer stock (> 3 months usage) at the local representative for the laboratory's use as contingency to ensure minimal interruption of the laboratory services. However, the laboratory is not obliged to purchase any or the whole of the buffer stock. Please describe your storage space that can be allocated for this project. |
| 361 | Any defect and contaminations occurring along the line should be replaced by the next shipment or at the earliest shipment. |
| 362 | Should there be any discontinuity of reagents due to non-compliance in the manufacturing of reagents; the vendor must be able to provide an alternative so that the test requests are still available for the customers. |
| 363 | LITERATURE (RIPASH & PIHMH) |
| 364 | To supply one (1) softcopy and one (1) set of hard copy of the Operating Manual and Service Manual including circuit diagrams of the equipment shall be provided upon commissioning. |
| 365 | To supply the laboratory with one (1) set of Material Safety Data Sheet (MSDS) for all reagents, bulk solutions, calibrators and IQC materials. |
| 366 | To supply one (1) hardcopy and one (1) softcopy of maintenance log with list of details of daily, weekly and other periodic scheduled preventive maintenance. |
| 367 | TRAINING (RIPASH & PIHMH) |
| 368 | On-site training for ALL staff members expected to handle the machine. Please ensure that adequate time is allocated such that training will take place in small groups to minimize staff shortage in the laboratory. |
| 369 | Certificate of competence is to be issued to all trainees after completion of training. |
| 370 | The successful tenderer needs to ensure the key users are updated on any relevant information related to the laboratory testing. They shall provide ONE off-site training for two (2) key users per year of contract. All expenses for attending the training shall be borne by the vendor; full registration, air ticket, daily allowance, accommodation, transport to and from the airport and place of training. Training may be in the form of operator's training, workshop, congress, international conference including 3rd-party conference, or other forms of training that is deemed appropriate and relevant. |
| 371 | Inviting speakers from overseas to give talks or presentations to the users on topics related to the laboratory testing as part of users' continuous education. Certificate of attendance is to be issued to all trainees after completion of training. |
| 372 | FINANCIAL AGREEMENT (RIPASH & PIHMH) |
| 373 | The cost of testing must be charged based on the test count (test performed) accumulated at the end of each month. Vendor must extract a test count statistic from the TLA system (RIPASH) and the analyzer system (PIHMH) which will be used for invoicing. Test count definition: Includes tests performed for: - 1. Completed results from patient samples (including reruns), 2. Completed results from Internal Quality Control runs. 3. Completed results from Calibration runs. 4. Completed results from EQA sample runs. 5. and other periodic and <i>ad hoc</i> verification studies including reagent lot verification (except for initial method verification and method verification during assay method change / formula change). |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| | <p>Note: Cost per test should also account for expected test wastage due to limited/short reagent shelf life/onboard stability especially for slow usage reagents.</p> <ul style="list-style-type: none"> ▪ ^ Slow usage reagents for NCCRL are: <i>Aceta, A1AT, AST, B2M, Carbamazepine, Ceruloplasmin, Cholinesterase, C-Peptide, Digoxin, Dehydroepiandrosterone sulfate (DHEAS), LDH, Lithium, MTX, Phenytoin, Phenobarbital, Salicylate, Sex Hormone Binding Globulin (SHBG), Theophylline, Valproic Acid.</i> ▪ <i>Slow usage reagents for PIHM are Amylase, Calcium, Direct Bili & Phosphate</i> |
| 374 | Vendor to submit a <u>sample</u> of a generated monthly test count statistic report together with the tender contract offer document. The data can be extracted either from the TLA software / middleware / analyzer. |
| 375 | <p>A rental agreement of the TLA components and its accessories at RIPAS Hospital and the immunoassay and chemistry analyzers at PIHM Hospital is required over a period of seven (7) years including the provision of the reagent kits, internal quality controls, calibrators, consumables and other accessories, two (2) on-site technical staff including after sales services indicated in detail above for performing the estimated total no. of tests in this contract.</p> <p>The total costs are to be absorbed to the cost per test which will be charged based on the test count accumulated at the end of each month. However, contract agreement shall be terminated when estimated total no. of tests is exceeded.</p> |
| 376 | Supply of the test kit including reagent, internal quality controls, calibrators, consumables and other accessories is based on the number of tests required in the Purchase Order according to an agreed schedule period. |
| 377 | Should there be any discontinuity of reagents due to non-compliance in the manufacturing of reagents; the vendor must be able to provide an alternative so that the test requests are still available for the customers. |
| 378 | All costs incurred for the supply and delivery of test kit including reagents, consumables and accessories, equipment and other accessories & support services required by the tender will be borne by the successful vendor. |
| 379 | <p>User shall have the rights to refuse delivery of items that do not meet the acceptance criteria such as, but not limited to, the following:</p> <ol style="list-style-type: none"> 1. Tampered or damaged box 2. Leakage upon delivery 3. Items stored pre-delivery not in accordance to manufacturer's instructions 4. Expiry date not meeting requirement |
| 380 | <p>User shall have the rights to return any items, and to be replaced at no extra cost, if found not meeting the acceptance criteria upon opening a pack such as, but not limited to, the following:</p> <ol style="list-style-type: none"> 1. Tampered or damaged packaging 2. Evident of leakage or damaged products 3. Expired products that are evidently less than the requirement calculated from delivery date 4. Leakage upon delivery |
| 381 | <p>EXIT CLAUSE:</p> <p>The tender contract shall be automatically terminated even though tender has not yet expired and this shall be in effect due to, but not limited to, the following:</p> <ol style="list-style-type: none"> 1. When the testing is no longer required or relevant i.e. test is obsolete, to the laboratory or department. 2. When the item(s) set out in this tender is/are no longer required by the laboratory or the Department. 3. When the approved budget allocation for this tender contract has been used up before the tender contract expires whereby a renewal of tender shall be submitted by the user for an open advertisement subject to approval by the Mini Tender Board (<i>Lembaga Tawaran Kecil</i>). |
| 382 | OTHERS |
| 383 | Should the laboratory is being relocated, vendor must assist in the relocation of the TLA components and its accessories. This also applies to the analyzers in PIHM Lab if needed. |

| NO. | SPECIFICATIONS AND REQUIREMENTS |
|-----|---|
| 384 | <p>Should there be any discontinuity of testing due to non-compliance in the analytical system (analyzer breakdown, IQC failures & etc.); the vendor must be able to provide an alternative so that the test requests are still available for the customers.</p> <p>E.g. Providing logistics to transport samples to other laboratory (reference laboratory or district laboratory and vice versa or private laboratory for urgent tests). All cost incurred to be borne by vendor.</p> |
| 385 | <p>DELIVERY PERIOD: Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order</p> |
| 386 | <p>PRICE VALIDITY: The quotation shall remain valid for 12 MONTHS from the final date for the submission of the quotation and no supplier may withdraw his/her quotation within that period. The Government reserves the right to extend this period if deemed necessary provided that such extension to the quotation validity period shall have written consent of the supplier(s).</p> |

NOTE:

VENDOR'S OFFER - (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy)

Vendor shall submit simulation of TAT achievable by the proposed TLA using the laboratory's one-day LIS data. The simulation to include the estimated turnaround time (TAT) of 'priority' samples (A/E cases and inpatient samples) from the time sample is introduced to the TLA track to time results produced by the analyzers during peak hours.

Appendix C

(Data to be submitted in excel form in USB device)

| NO. | GENERAL SPECIFICATIONS* |
|------------|--|
| A | Model & Brand |
| B | Country of Origin |
| C | Total Price Per Test (CIF): B\$ |
| D | Price Ranking: |
| E | Where marketed |
| F | Year of Manufacture |
| G | Warranty: |
| H | Delivery Time: |
| I | Power Requirements: |
| J | Battery Back-up: |
| K | International Safety Standard: |
| L | Technical Support: |
| M | Equipment Whole Life Support |
| N | Dimensions (WxHxD) cm: |
| O | Weight (kg): |
| P | User Manuals |
| Q | Service Manuals |
| R | Spare-parts & Consumables Listing |
| S | Technical Training On-Site: |
| T | Site Requirements: |

*To all participating companies, please fill in the table above along with your other documents during submission of tender.

Appendix D

(Data to be submitted in excel form in USB device)

| NO. | GENERAL SPECIFICATIONS* |
|-----|-----------------------------------|
| A | Model & Brand |
| B | Country of Origin |
| C | Total Price Per Test (CIF): B\$ |
| D | Price Ranking: |
| E | Where marketed |
| F | Year of Manufacture |
| G | Warranty: |
| H | Delivery Time: |
| I | Power Requirements: |
| J | Battery Back-up: |
| K | International Safety Standard: |
| L | Technical Support: |
| M | Equipment Whole Life Support |
| N | Dimensions (WxHxD) cm: |
| O | Weight (kg): |
| P | User Manuals |
| Q | Service Manuals |
| R | Spare-parts & Consumables Listing |
| S | Technical Training On-Site: |
| T | Site Requirements: |

*To all participating companies, please fill in the table above along with your other documents during submission of tender.

Appendix E
(Data to be submitted in excel form in USB device)

| NO. | NAME OF QC, CALIBRATORS, CONSUMABLES AND ACCESSORIES** | PRODUCT CODE | PACKAGING SIZE | QUANTITY REQUIRED PER YEAR |
|---|---|---------------------|-----------------------|-----------------------------------|
| Total Laboratory Automation (TLA) system for routine clinical chemistry testing at National Clinical Chemistry Reference Laboratory, RIPAS Hospital | | | | |

** To all participating companies, please fill in the table above along with your other documents during submission of tender. List out all the QC, calibrator, consumables and accessories that are required to run the tests (costs of these items are all to be included in the cost per test).

Appendix F
(Data to be submitted in excel form in USB device)

| NO. | NAME OF QC, CALIBRATORS, CONSUMABLES AND ACCESSORIES** | PRODUCT CODE | PACKAGING SIZE | QUANTITY REQUIRED PER YEAR |
|---|---|---------------------|-----------------------|-----------------------------------|
| One (1) Chemistry analyzer and one (1) immunoassay analyzer for routine clinical chemistry testing at Clinical Chemistry Laboratory, PIHM Hospital. | | | | |

** To all participating companies, please fill in the table above along with your other documents during submission of tender. List out all the QC, calibrator, consumables and accessories that are required to run the tests (costs of these items are all to be included in the cost per test).

Appendix G
Summary of Test Characteristics for RIPAS Hospital Test Menu
(Data to be submitted in excel form in USB device)

| No | Assay Name | Reagent Packaging size | Reagent Preparation requirement | Reagent/Product Code | Test Method | Testing time | Specimen type | Specimen tube type | Sample volume required | Specimen stability | Reference ranges from IFU | Analytical Measuring Range | LOQ | LOD | LOB | Manufacturer's Claim Total Within Lab Precision. | Recommended sample dilution factors (Please state if they are manual / onboard auto dilutions) | Diluent for dilution | |
|----|------------|------------------------|---------------------------------|----------------------|-------------|--------------|---------------|--------------------|------------------------|--------------------|---------------------------|----------------------------|-----|-----|-----|--|--|----------------------|--|
| | | | | | | | | | | | | | | | | | | | |

Appendix H
Summary of Test Characteristics for PIHM Hospital Test Menu
(Data to be submitted in excel form in USB device)

| No | Assay Name | Reagent Packaging size | Reagent Preparation requirement | Reagent/Product Code | Test Method | Testing time | Specimen type | Specimen tube type | Sample volume required | Specimen stability | Reference ranges from IFU | Analytical Measuring Range | LOQ | LOD | LOB | Manufacturer's Claim Total Within Lab Precision. | Recommended sample dilution factors (Please state if they are manual / onboard auto dilutions) | Diluent for dilution | |
|----|------------|------------------------|---------------------------------|----------------------|-------------|--------------|---------------|--------------------|------------------------|--------------------|---------------------------|----------------------------|-----|-----|-----|--|--|----------------------|--|
| | | | | | | | | | | | | | | | | | | | |

SECTION 3
FORMS TO BE USED
CONTENTS

SCHEDULE 1 - TENDER FORM

SCHEDULE 2 - INFORMATION SUMMARY

SCHEDULE 3 - SUB-CONTRACTS

SCHEDULE 4 - COMPANY BACKGROUND

SCHEDULE 5 - REFERENCES

SCHEDULE 6 - SUBMISSION OF SAMPLE

SCHEDULE 7 - LETTER OF DECLARATION

SCHEDULE 1

TENDER FORM

To:

TENDER REFERENCE NO.: KK/61/2026/LAB(TC)

INVITATION TO TENDER

TO SUPPLY, DELIVER AND COMMISSION A LABORATORY AUTOMATION SYSTEM ON EQUIPMENT RENTAL BASIS FOR ROUTINE CHEMISTRY TESTING, INCLUDING REAGENTS AND CONSUMABLES FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY (RIPAS HOSPITAL) AND CLINICAL CHEMISTRY LABORATORY (PIHM HOSPITAL), DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF SEVEN (7) YEARS

TENDER OF (*name of tenderer*) _____

Company/Business Registration No _____

Tender Closing Date _____

1. SUPPLY OF REAGENTS

1.1 To supply reagents and associated consumables (calibrators, controls, accessories and consumables) for the tests listed below.

**APPENDIX A: SUMMARY OF UNIT PRICE OF REAGENT KIT (RIPAS HOSPITAL)
(To be completed by Vendor for submission)**

| USER'S REQUIREMENTS | | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|--|--------------------------------------|----------------|----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| NO. | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| TOTAL LABORATORY AUTOMATION SYSTEM FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, RIPAS HOSPITAL | | | | | | | | | |
| 1 | 25-OH Vitamin D | Per test | 8235 | | | | | | |

| NO. | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|-----|--------------------------------------|----------------|----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 2 | Acetaminophen | Per test | 1649 | | | | | | |
| 3 | Alanine Transaminase (ALT) | Per test | 258339 | | | | | | |
| 4 | Albumin | Per test | 229127 | | | | | | |
| 5 | Alkaline Phosphatase (ALP) | Per test | 234182 | | | | | | |
| 6 | Alpha-1 Antitrypsin (A1AT) | Per test | 1552 | | | | | | |
| 7 | Alpha-fetoprotein (AFP) | Per test | 11733 | | | | | | |
| 8 | Amikacin | Per test | 4197 | | | | | | |
| 9 | Aminotransferase (AST) | Per test | 7670 | | | | | | |
| 10 | Ammonia | Per test | 6327 | | | | | | |
| 11 | Amylase | Per test | 17737 | | | | | | |
| 12 | Beta-2 Microglobulin (B2M) | Per test | 1403 | | | | | | |
| 13 | Beta-HCG | Per test | 14230 | | | | | | |
| 14 | Bicarbonate | Per test | 131417 | | | | | | |
| 15 | Bili Direct (DBIL) | Per test | 17442 | | | | | | |
| 16 | Bili Total (TBIL) | Per test | 250116 | | | | | | |
| 17 | CA-125 | Per test | 6728 | | | | | | |

| NO. | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|-----|--------------------------------------|----------------|----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 18 | CA15-3 | Per test | 5245 | | | | | | |
| 19 | CA19-9 | Per test | 8898 | | | | | | |
| 20 | Calcium | Per test | 116752 | | | | | | |
| 21 | Calcium Urine | Per test | 1285 | | | | | | |
| 22 | Carbamazepine | Per test | 1457 | | | | | | |
| 23 | Carcinoembryonic antigen (CEA) | Per test | 8321 | | | | | | |
| 24 | Ceruloplasmin | Per test | 2342 | | | | | | |
| 25 | Chloride | Per test | 142362 | | | | | | |
| 26 | Chloride Urine | Per test | 2403 | | | | | | |
| 27 | Cholinesterase | Per test | 481 | | | | | | |
| 28 | Complement Component 3 (C3) | Per test | 4597 | | | | | | |
| 29 | Complement Component 4 (C4) | Per test | 4796 | | | | | | |
| 30 | Cortisol | Per test | 6590 | | | | | | |
| 31 | C-peptide | Per test | 2453 | | | | | | |
| 32 | C-Reactive Protein (CRP) | Per test | 142216 | | | | | | |
| 33 | Creatine Kinase | Per test | 21817 | | | | | | |

| NO. | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|-----|--|----------------|----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 34 | Creatine Kinase-MB (CKMB) | Per test | 11024 | | | | | | |
| 35 | Creatinine | Per test | 421202 | | | | | | |
| 36 | Creatinine Urine | Per test | 72121 | | | | | | |
| 37 | Cyclosporine | Per test | 1305 | | | | | | |
| 38 | Digoxin | Per test | 1520 | | | | | | |
| 39 | Dehydroepiandrosterone sulfate (DHEAS) | Per test | 1699 | | | | | | |
| 40 | Estradiol (E2) | Per test | 3339 | | | | | | |
| 41 | Ferritin | Per test | 42811 | | | | | | |
| 42 | Folic Acid | Per test | 12716 | | | | | | |
| 43 | Follicle Stimulating Hormone | Per test | 5245 | | | | | | |
| 44 | Free Prostate Surface Antigen | Per test | 5122 | | | | | | |
| 45 | Free Thyroxine (FT4) | Per test | 74688 | | | | | | |
| 46 | Free Triiodothyronine (FT3) | Per test | 66936 | | | | | | |
| 47 | Gamma Glutamyl Transferase (GGT) | Per test | 251546 | | | | | | |
| 48 | Gentamicin | Per test | 8789 | | | | | | |
| 49 | Glucose | Per test | 227599 | | | | | | |

| NO. | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|-----|--------------------------------------|----------------|----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 50 | Haptoglobin | Per test | 1798 | | | | | | |
| 51 | HDL Cholesterol | Per test | 171884 | | | | | | |
| 52 | Immunoglobulin A | Per test | 4175 | | | | | | |
| 53 | Immunoglobulin G | Per test | 3986 | | | | | | |
| 54 | Immunoglobulin M | Per test | 3661 | | | | | | |
| 55 | Insulin | Per test | 2227 | | | | | | |
| 56 | intact parathyroid hormone (iPTH) | Per test | 11418 | | | | | | |
| 57 | Iron | Per test | 42851 | | | | | | |
| 58 | Lactate | Per test | 8188 | | | | | | |
| 59 | Lactate Dehydrogenase (LDH) | Per test | 7096 | | | | | | |
| 60 | Lithium | Per test | 1297 | | | | | | |
| 61 | Luteinizing Hormone | Per test | 5749 | | | | | | |
| 62 | Magnesium | Per test | 48383 | | | | | | |
| 63 | Magnesium Urine | Per test | 1149 | | | | | | |
| 64 | Methotrexate | Per test | 1575 | | | | | | |
| 65 | Microalbumin | Per test | 52968 | | | | | | |

| NO. | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|-----|--------------------------------------|----------------|----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 66 | NT-proBNP | Per test | 17348 | | | | | | |
| 67 | Phenobarbital | Per test | 922 | | | | | | |
| 68 | Phenytoin | Per test | 1884 | | | | | | |
| 69 | Phosphate | Per test | 107791 | | | | | | |
| 70 | Phosphate Urine | Per test | 1149 | | | | | | |
| 71 | Potassium (K) | Per test | 407368 | | | | | | |
| 72 | Potassium Urine | Per test | 2959 | | | | | | |
| 73 | Procalcitonin | Per test | 18196 | | | | | | |
| 74 | Progesterone | Per test | 5084 | | | | | | |
| 75 | Prolactin | Per test | 5420 | | | | | | |
| 76 | Protein Urine / CSF | Per test | 17216 | | | | | | |
| 77 | Rheumatoid Factor | Per test | 4287 | | | | | | |
| 78 | Salicylate | Per test | 1026 | | | | | | |
| 79 | Sex Hormone Binding Globulin (SHBG) | Per test | 1769 | | | | | | |
| 80 | Sodium (Na) | Per test | 404364 | | | | | | |
| 81 | Sodium Urine | Per test | 7144 | | | | | | |

| NO. | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|-----|--------------------------------------|----------------|----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 82 | Tacrolimus | Per test | 1668 | | | | | | |
| 83 | Testosterone | Per test | 4344 | | | | | | |
| 84 | Theophylline | Per test | 1212 | | | | | | |
| 85 | Thyroid Stimulating Hormone (TSH) | Per test | 76417 | | | | | | |
| 86 | Total Cholesterol | Per test | 178510 | | | | | | |
| 87 | Total Prostate Surface Antigen | Per test | 8109 | | | | | | |
| 88 | Total Protein | Per test | 217999 | | | | | | |
| 89 | Transferrin | Per test | 41295 | | | | | | |
| 90 | Triglyceride | Per test | 175474 | | | | | | |
| 91 | Troponin I or Troponin T | Per test | 38204 | | | | | | |
| 92 | Urea | Per test | 415774 | | | | | | |
| 93 | Urea Urine | Per test | 1431 | | | | | | |
| 94 | Uric Acid | Per test | 148978 | | | | | | |
| 95 | Uric Acid Urine | Per test | 1161 | | | | | | |
| 96 | Valporic Acid | Per test | 2650 | | | | | | |
| 97 | Vancomycin | Per test | 6941 | | | | | | |

| USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | | |
|---------------------|--------------------------------------|----------------|--|--------------------------------------|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| NO. | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE/ YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 98 | Vitamin B12 | Per test | 14869 | | | | | | |

*Cost per test must INCLUDE and ACCOUNT FOR the costs of the following:

- a. Rental of TLA system components and its accessory components such as PCs, printers & etc. (refer to the Specifications and Requirements below for details).
- b. Internal Quality Controls for each assay (third party IQC material). IQC shall be multi-level to be run daily (up to 4 times within 24 hours for select chemistry assays and once every 24 hours for immunoassays).
- c. Calibrator (as many as required by the system).
- d. Consumables required to perform the tests including but not limited to: analyzer bulk solutions (e.g. wash solutions), secondary sample cups (25,000pcs per year), secondary sample tubes for urine samples that are track-compatible (62,500pcs per year), bin liners for reaction vessels/tips & other wastes generated by the analyzers, sample tube sealers/cappers (quantity according to the estimated test usage).
- e. Other required accessories (quantity according to the estimated test usage).
- f. Two (2) technical staffs that shall work on-site from 7.45am – 12.30pm & 1.30pm – 4.30pm (refer to the Specifications and Requirements below for details).
- g. Services provided (refer to the Specifications and Requirements below for details)
- h. Expected test wastage due to limited/short reagent shelf life/onboard stability especially for slow usage reagents^

^ Slow usage reagents for NCCRL are: *Aceta, A1AT, AST, B2M, Carbamazepine, Ceruloplasmin, Cholinesterase, C-Peptide, Digoxin, Dehydroepiandrosterone sulfate (DHEAS), LDH, Lithium, MTX, Phenytoin, Phenobarbital, Salicylate, Sex Hormone Binding Globulin (SHBG), Theophylline, Valproic Acid.*

APPENDIX B: SUMMARY OF UNIT PRICE OF REAGENT KIT (PIHM HOSPITAL)

(To be completed by Vendor for submission)

| NO | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|---|--------------------------------------|----------------|-----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE / YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| CHEMISTRY - IMMUNOASSAY ANALYZERS FOR CLINICAL CHEMISTRY LABORATORY, PIHM HOSPITAL | | | | | | | | | |
| 1 | Alanine Transaminase (ALT) | Per test | 13200 | | | | | | |
| 2 | Albumin (ALB) | Per test | 13572 | | | | | | |
| 3 | Alkaline Phosphatase (ALP) | Per test | 12800 | | | | | | |
| 4 | Amylase | Per test | 4480 | | | | | | |
| 5 | BILI DIRECT | Per test | 4000 | | | | | | |
| 6 | BILI TOTAL | Per test | 13750 | | | | | | |
| 7 | CO2C Bicarbonate | Per test | 7500 | | | | | | |
| 8 | CRP16 | Per test | 9000 | | | | | | |
| 9 | Calcium | Per test | 6000 | | | | | | |
| 10 | Cholesterol | Per test | 12000 | | | | | | |
| 11 | CL-C (Chloride) | Per test | 20000 | | | | | | |
| 12 | CreaC (Creat) | Per test | 18000 | | | | | | |
| 13 | GGT | Per test | 13200 | | | | | | |

| NO | USER'S REQUIREMENTS | | | VENDOR'S OFFER (vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | |
|----|--------------------------------------|----------------|-----------------------------|--|----------------------------------|----------------|-------------------------------|----------------------|-------------------|
| | ITEM DESCRIPTIONS AND SPECIFICATIONS | PACKAGING SIZE | TOTAL ESTIMATE USAGE / YEAR | ITEM DESCRIPTIONS AND SPECIFICATIONS | PART/ CATALOGUE NUMBER AND BRAND | PACKAGING SIZE | TOTAL QUANTITY OFFERED / YEAR | *COST PER TEST (B\$) | TOTAL COSTS (B\$) |
| 14 | Glucose | Per test | 12000 | | | | | | |
| 15 | K-C (Potassium) | Per test | 20000 | | | | | | |
| 16 | NA-C (Sodium) | Per test | 20000 | | | | | | |
| 17 | Phosphate | Per test | 5600 | | | | | | |
| 18 | Total Protein (TP) | Per test | 12800 | | | | | | |
| 19 | Triglyceride | Per test | 12000 | | | | | | |
| 20 | Uric Acid (UA) | Per test | 8960 | | | | | | |
| 21 | HDL Cholesterol | Per test | 11520 | | | | | | |
| 22 | Urea | Per test | 16800 | | | | | | |
| 23 | Troponin I or Troponin T | Per test | 4200 | | | | | | |

***Cost per test must INCLUDE and ACCOUNT FOR** the costs of the following (quantity required indicated):

- a. Rental of chemistry and immunoassay analyzers and accessory components such as printers & etc. (refer to the Specifications and Requirements below for details).
- b. Internal Quality Controls for each assay (third party IQC material). IQC shall be multi-level to be run daily.
- c. Calibrators (as many as required by the system).
- d. Consumables required to perform the tests including but not limited to: analyzer bulk solutions (e.g. wash solutions), secondary sample cups, bin liners for reaction vessels/tips & other wastes generated by the analyzers,
- e. Other accessories (quantity according to the estimated test usage).
- f. Services provided (refer to the Specifications and Requirements below for details).
- g. Expected test wastage due to limited/short reagent shelf life/onboard stability especially for slow usage reagents^^

^^Slow usage reagents for PIHM: *Amylase, Calcium, Direct Bili & Phosphate*

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|-----|--|---|
| 1 | GENERAL TLA REQUIREMENTS (RIPASH) | |
| 2 | <p>The provision of a Total Laboratory Automation (TLA) system on equipment rental basis for routine chemistry testing for National Clinical Chemistry Reference Laboratory, RIPAS Hospital which shall include but not limited to the following hardware components:</p> <ol style="list-style-type: none"> 1. Chemistry analyzer(s) 2. Immunoassay analyzer(s) 3. Sample track transport system 4. Sample Input module 5. Sample Output module 6. Pre-analytical assessment module for assessment of correct tube type, tube weight and other relevant parameters. 7. Centrifuge module(s) 8. Sample tube decapper module 9. Sample tube capper / sealer module 10. On-track Refrigerated Sample Storage Module 11. Sample buffer module to manage sample traffic (if required) <p>The quantity of each module above (which contributes to the system's throughput) shall be such that the test workload of the laboratory* is absorbed within the laboratory's turnaround time (TAT) requirement**. This target TAT must be achievable without relying on off-track centrifugation and front-loading to analyzers.</p> <p>*= Lab test workload (during a typical non-public holiday):</p> <ul style="list-style-type: none"> ▪ About 25,000 chemistry tests per day ▪ About 1,550 immunoassay tests per day ▪ Peak sample receiving time: 1st peak at 11.00AM and 2nd (lower) peak at 2.00PM (About > 80% of samples received during these time) <p>**= Laboratory turnaround time (TAT) requirement:</p> <ul style="list-style-type: none"> ▪ <u>2 hours</u> for A/E and inpatient samples, ▪ Outpatient samples received at 11.00AM to be resulted by 4.30PM the same day. | <p>Vendor shall submit simulation of TAT achievable by the proposed TLA using the laboratory's one-day LIS data. The simulation to include the estimated turnaround time (TAT) of 'priority' samples (A/E cases and inpatient samples) from the time sample is introduced to the TLA track to time results produced by the analyzers <u>during peak hours</u>.</p> |

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|-----|--|---|
| 3 | Vendor must perform audit on the TLA system and perform the necessary settings optimization to improve TAT, reagents usage and to track health check-up / track operations review to ensure all components are working appropriately around 3 months, 1 year and 1.5 years post <i>Go-Live</i> date (Optimization phase). | |
| 4 | All components of the TLA must be new and not refurbished model (Vendor to include a certified copy of instrument date of production). | |
| 5 | <p>The proposed TLA system configuration shall be optimized to fit the available designated lab floor space and ceiling height with enough space for staff to move about comfortable and safely.</p> <p>Vendor is required to conduct an onsite assessment of the current site.</p> | |
| 6 | Please provide the list of current users of the TLA system in its full configuration, including the list of current users of the analyzers. There must be a minimum of 20 current users (customers) of the offered analyzer model. | |
| 7 | Please state the year the TLA entered international market. | |
| 8 | The TLA system must be able to distribute the workload among the analyzers and modules to optimize work flow and reduce reagent, consumables and accessories wastage. | |
| 9 | The TLA system must be able to fulfill all the requirements for test validation and QC management as to current ISO 15189 requirements. | |
| 10 | The TLA system must be a closed system to minimize exposure of staff to potentially hazardous aerosols. | |
| 11 | The analyzers must fully comply with the FDA or CE mark requirements and that a copy of the certificates must be submitted. | |
| 12 | <p>The analyzers shall be provided with a UPS to allow minimum operation of 1 hour without external power. Other components of the TLA should also be provided with UPS.</p> <p>UPS battery to be replaced free of charge periodically according to manufacturer's recommendation.</p> <p>UPS battery system to be maintained and tested as required according to manufacturer's recommendation.</p> | |

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| 13 | Vendor shall maintain and replace any batteries that is required to power the TLA components according to manufacturer's requirement and recommendations. The cost to be included in the cost per test of the tender. | |
| 14 | Period of delivery from vendor to end user of initial tests kits and components of the IAS must be ≤ 3 months from awarding of tender. | |
| 15 | The TLA system must have the following capability: Prioritization of STAT samples <ul style="list-style-type: none"> ▪ Please provide description of STAT prioritization during peak sample saturation on the system's track. ▪ STAT prioritization <i>throughout</i> the majority of the components of the TLA system is preferred. | |
| 16 | <ul style="list-style-type: none"> ▪ Vendor shall submit simulation of TAT achievable by the proposed TLA using the laboratory's one-day LIS data. The simulation to include the estimated turnaround time (TAT) of samples put 'priority' samples (A/E cases and inpatient samples) from the time sample is introduced to the TLA track to time test results produced by the analyzers <u>during peak hours</u>. ▪ Laboratory requirement: A/E and inpatient samples TAT within 2 hours with no samples being processed off-track/front-loading even during peak hours. Note: <ul style="list-style-type: none"> ▪ TAT defined as the period from registration time and result generated by analysers ▪ Priority of samples is by: <ol style="list-style-type: none"> 1. The source of the specimen (ordering locations) i.e., Emergency and Inpatient samples are considered high priority, or 2. According to priority category of each specimen ID sent from LIS, or 3. According to priority category of each specimen ID programmed on TLA middleware. | |
| 17 | SAMPLE INPUT MODULE (RIPASH) | |
| 18 | Must be flexible to allow both STAT and Routine automated continuous sample loading in a dedicated loading area. | |

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| 19 | Have an initial loading capacity of ≥ 300 sample tubes of varying conditions (variable sample loading bays) as follows or equivalent: - <ol style="list-style-type: none"> 1. Routine Capped uncentrifuged tubes 2. Routine Capped centrifuged tubes 3. Routine Uncapped tubes (Centrifuged) 4. Priority Capped uncentrifuged tubes 5. Priority Capped centrifuged tubes 6. Priority Uncapped tubes (Centrifuged) 7. Sealed input rack - for samples that has been sealed by the automation system and to be routed to on-track fridge. | |
| 20 | Samples from the priority loading bay is introduced to the track first regardless of presence of samples in the routine bay | |
| 21 | Components must be able to accept multiple tube sizes (e.g. 13 x 75 mm, 13 x 100 mm, 16 x 100mm). | |
| 22 | Provide list of acceptable sample tube types (primary and secondary). | |
| 23 | BARCODES (RIPASH) | |
| 24 | There must be positive sample identification with host query mode. | |
| 25 | All TLA components/checkpoints must be able to read sample barcodes provided by Bru-HIMS (Laboratory Information System) | |
| 26 | Vendor shall assist the laboratory in providing technical solutions should there be a significant no. of samples rejected by the TLA barcode reader. | |
| 27 | TLA barcode scanner shall be able to read slightly slanted and / or inverted sample barcodes if the barcodes are within the scanner read zone. | |
| 28 | PRE-ANALYTICAL ASSESSMENT MODULE (RIPASH) | |
| 29 | The TLA system shall have the ability to do pre-analytical check on the sample tube for the following: - <ol style="list-style-type: none"> 1. Cap colour (tube type) correctly matches the test orders 2. Ensure each sample meets the minimum sample tube volume / weight (cut-off feature) to ensure enough serum is available for testing and to prevent analyzer's sample probe from being contaminated with serum separator gel | |

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| | should the liquid level sensing mechanism fail. | |
| 30 | ON-TRACK CENTRIFUGE MODULE (RIPASH) | |
| 31 | Programmable settings | |
| 32 | Minimum of 100 samples capacity (preferably spread across 3 or more centrifuge modules). Please state the sample capacity per centrifuge and how many centrifuge modules in your offer. | |
| 33 | Intelligent setting to optimize sample turnaround time. | |
| 34 | Programmable waiting time to load and start centrifuge. | |
| 35 | Automated load balancing centrifuge with rapid ascend and descend features. | |
| 36 | Low noise with user defined spin time and easy maintenance. | |
| 37 | Vendor to also provide one (1) unit off-track refrigerated centrifuge with minimum capacity of 4 samples. This is for samples requiring refrigerated centrifugation such as samples for Ammonia and Lactate tests. | |
| 38 | Vendor to perform centrifuge speed and timer check of all centrifuges provided annually according to protocol provided by the laboratory. | |
| 39 | DECAPPER (RIPASH) | |
| 40 | Able to de-cap rubber or plastic caps of different types and sizes without creating hazardous aerosols | |
| 41 | To de-cap samples prior to first analysis AND to de-cap samples from on-board storage for additional testing. | |
| 42 | Vendor must provide a separate 'de-sealer' module if samples are not re-sealed using a cap but with other material. This is required to allow auto-resampling for test add-ons or other re-testing requests. | |

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|-----|--|---|-----------|---|-----------------|---|---------------|---|----------------------------|---|---------|---|----------------------------|---|----------------------------|---|-------------------------|---|----------|---|------------------------|----|---------|----|---------|----|----------------------------|----|----------|----|-------------|----|--------------------|--|
| 43 | ANALYZERS (RIPASH) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 44 | <ul style="list-style-type: none"> ▪ Chemistry and immunoassay analyzers that covers the RIPASH test menu (see below) ▪ Quantity of each analyzer must be enough to support RIPASH workload within the required turnaround time (TAT). | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 45 | <p>- <u>RIPASH TEST MENU</u> The analyzers must have the following test menu within the TLA system: -</p> <table border="1" data-bbox="277 596 1270 1390"> <thead> <tr> <th data-bbox="277 596 389 647">No.</th> <th data-bbox="389 596 1270 647">Test Name</th> </tr> </thead> <tbody> <tr><td data-bbox="277 647 389 699">1</td><td data-bbox="389 647 1270 699">25-OH Vitamin D</td></tr> <tr><td data-bbox="277 699 389 750">2</td><td data-bbox="389 699 1270 750">Acetaminophen</td></tr> <tr><td data-bbox="277 750 389 801">3</td><td data-bbox="389 750 1270 801">Alanine Transaminase (ALT)</td></tr> <tr><td data-bbox="277 801 389 852">4</td><td data-bbox="389 801 1270 852">Albumin</td></tr> <tr><td data-bbox="277 852 389 903">5</td><td data-bbox="389 852 1270 903">Alkaline Phosphatase (ALP)</td></tr> <tr><td data-bbox="277 903 389 954">6</td><td data-bbox="389 903 1270 954">Alpha-1 Antitrypsin (A1AT)</td></tr> <tr><td data-bbox="277 954 389 1005">7</td><td data-bbox="389 954 1270 1005">Alpha-fetoprotein (AFP)</td></tr> <tr><td data-bbox="277 1005 389 1056">8</td><td data-bbox="389 1005 1270 1056">Amikacin</td></tr> <tr><td data-bbox="277 1056 389 1107">9</td><td data-bbox="389 1056 1270 1107">Aminotransferase (AST)</td></tr> <tr><td data-bbox="277 1107 389 1158">10</td><td data-bbox="389 1107 1270 1158">Ammonia</td></tr> <tr><td data-bbox="277 1158 389 1209">11</td><td data-bbox="389 1158 1270 1209">Amylase</td></tr> <tr><td data-bbox="277 1209 389 1260">12</td><td data-bbox="389 1209 1270 1260">Beta-2 Microglobulin (B2M)</td></tr> <tr><td data-bbox="277 1260 389 1311">13</td><td data-bbox="389 1260 1270 1311">Beta-HCG</td></tr> <tr><td data-bbox="277 1311 389 1362">14</td><td data-bbox="389 1311 1270 1362">Bicarbonate</td></tr> <tr><td data-bbox="277 1362 389 1390">15</td><td data-bbox="389 1362 1270 1390">Bili Direct (DBIL)</td></tr> </tbody> </table> | No. | Test Name | 1 | 25-OH Vitamin D | 2 | Acetaminophen | 3 | Alanine Transaminase (ALT) | 4 | Albumin | 5 | Alkaline Phosphatase (ALP) | 6 | Alpha-1 Antitrypsin (A1AT) | 7 | Alpha-fetoprotein (AFP) | 8 | Amikacin | 9 | Aminotransferase (AST) | 10 | Ammonia | 11 | Amylase | 12 | Beta-2 Microglobulin (B2M) | 13 | Beta-HCG | 14 | Bicarbonate | 15 | Bili Direct (DBIL) | |
| No. | Test Name | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | 25-OH Vitamin D | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Acetaminophen | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | Alanine Transaminase (ALT) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | Albumin | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 | Alkaline Phosphatase (ALP) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | Alpha-1 Antitrypsin (A1AT) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7 | Alpha-fetoprotein (AFP) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8 | Amikacin | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 9 | Aminotransferase (AST) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10 | Ammonia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 11 | Amylase | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12 | Beta-2 Microglobulin (B2M) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 13 | Beta-HCG | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 14 | Bicarbonate | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 15 | Bili Direct (DBIL) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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|-----|---------------------------------|--|---|
| 16 | | Bili Total (TBIL) | |
| 17 | | CA-125 | |
| 18 | | CA15-3 | |
| 19 | | CA19-9 | |
| 20 | | Calcium | |
| 21 | | Carbamazepine | |
| 22 | | Carcinoembryonic antigen (CEA) | |
| 23 | | Ceruloplasmin | |
| 24 | | Chloride | |
| 25 | | Cholinesterase | |
| 26 | | Complement Component 3 (C3) | |
| 27 | | Complement Component 4 (C4) | |
| 28 | | Cortisol | |
| 29 | | C-peptide | |
| 30 | | C-Reactive Protein (CRP) | |
| 31 | | Creatine Kinase | |
| 32 | | Creatine Kinase-MB (CKMB) | |
| 33 | | Creatinine | |
| 34 | | Cyclosporine | |
| 35 | | Digoxin | |
| 36 | | Dehydroepiandrosterone sulfate (DHEAS) | |

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|-----|---------------------------------|-----------------------------------|---|
| 37 | | Estradiol (E2) | |
| 38 | | Ferritin | |
| 39 | | Folic Acid | |
| 40 | | Follicle Stimulating Hormone | |
| 41 | | Free Prostate Surface Antigen | |
| 42 | | Free Thyroxine (FT4) | |
| 43 | | Free Triiodothyronine (FT3) | |
| 44 | | Gamma Glutamyl Transferase (GGT) | |
| 45 | | Gentamicin | |
| 46 | | Glucose | |
| 47 | | Haptoglobin | |
| 48 | | HDL Cholesterol | |
| 49 | | Immunoglobulin A | |
| 50 | | Immunoglobulin G | |
| 51 | | Immunoglobulin M | |
| 52 | | Insulin | |
| 53 | | intact parathyroid hormone (iPTH) | |
| 54 | | Iron | |
| 55 | | Lactate | |
| 56 | | Lactate Dehydrogenase (LDH) | |
| 57 | | Lithium | |

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|-----|-------------------------------------|---|
| 58 | Luteinizing Hormone | |
| 59 | Magnesium | |
| 60 | Methotrexate | |
| 61 | Microalbumin | |
| 62 | NT-proBNP | |
| 63 | Phenobarbital | |
| 64 | Phenytoin | |
| 65 | Phosphate | |
| 66 | Potassium (K) | |
| 67 | Procalcitonin | |
| 68 | Progesterone | |
| 69 | Prolactin | |
| 70 | Protein Urine & CSF | |
| 71 | Rheumatoid Factor | |
| 72 | Salicylate | |
| 73 | Sex Hormone Binding Globulin (SHBG) | |
| 74 | Sodium (Na) | |
| 75 | Tacrolimus | |
| 76 | Testosterone | |
| 77 | Theophylline | |
| 78 | Thyroid Stimulating Hormone (TSH) | |

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|-----|--|--------------------------------|---|
| | 79 | Total Cholesterol | |
| | 80 | Total Prostate Surface Antigen | |
| | 81 | Total Protein | |
| | 82 | Transferrin | |
| | 83 | Triglyceride | |
| | 84 | Troponin I or Troponin T | |
| | 85 | Urea | |
| | 86 | Uric Acid | |
| | 87 | Valproic Acid | |
| | 88 | Vancomycin | |
| | 89 | Vitamin B12 | |
| 46 | All the assay kits must be CE & IVD - marked. | | |
| 47 | Vendor shall declare any use of third-party reagents for any of the assays above. Third party reagents must have documented test validation report that was performed on the analyzer model used in this tender. | | |
| 48 | Vendor shall describe any limitations to the possibility of using third party reagents. | | |
| 49 | Reagents to require minimum or nil preparations. | | |
| 50 | Vendor shall provide the test methods of the assays. The information shall be submitted in Appendix G. | | |
| 51 | Minimal 'Hook Effect' in the immunoassays. Please declare any assay affected / potentially affected by 'Hook Effect'. Kindly include claims from the manufacturer with regard to the 'Hook Effect' and the manufacturer's protocol or recommendation for re-testing samples potentially | | |

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| | affected by 'Hook Effect'. | |
| 52 | THROUGHPUT (RIPASH) | |
| 53 | Vendor shall offer a suitable number of chemistry and immunoassay analyzers to achieve the following throughput: - <ul style="list-style-type: none"> ▪ Perform and complete 1,530 immunoassay tests and 25,000 chemistry tests in about 4.5 hours (include time from the sample first introduced on the track) ▪ High no. of testing capacity at a time (~>330 tests at a time for chemistry tests and ~>70 tests at a time for immunoassay tests). ▪ The main objective for requiring high throughput is to be able to load A/E and inpatient samples on the track even during peak hours while still achieving <2 hours TAT. | |
| 54 | Short analysis time for critical tests (see below): - <ol style="list-style-type: none"> 1. Na+, K+, Cl- 2. Urea 3. Troponin T/ Troponin I (<20 mins) 4. Creatinine (Please provide the analysis runtime of the tests above) | |
| 55 | Analyzers able to do intra-cup replicates. | |
| 56 | Analyzers able to do auto-dilution and also user defined manual dilution factors that can be programmed into the system. | |
| 57 | Vendor shall perform dilution verification of all the programmable auto-dilution every two years. | |
| 58 | Analyzers must have minimum carryover between samples for all tests | |
| 59 | There must be random access with stat capability to the analyzers (off-track). | |
| 60 | The analysers must have user friendly touch colour monitor screens. | |
| 61 | Analyzers must be able provide result printout for individual patient sample with analyzer ID stated | |

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| 62 | Analyzer able to perform serum haemolytic, icteric and lipemic (HIL) check by measurement of absorbance and auto-translatable into semi-quantitative HIL index. | |
| 63 | The analyser must be able to provide a countdown of tests remaining of reagent kit on board and their due calibration date. | |
| 64 | The analyser must have automated notification when a new lot require calibration | |
| 65 | The analyser must have automated notification of impending calibration expiry | |
| 66 | The analysers must have a minimal daily maintenance with short or no analyser downtime. | |
| 67 | Vendor shall perform initial verification of the HIL measurements/index | |
| 68 | Vendor shall provide comprehensive HIL interference rules and guidelines from the Manufacturer to implement for sample rejection by tests for all tests (eg. H-index of +1: - to reject LDH result etc.). - Data to be provided in excel and word format in a comprehensive summary tabular format. | |
| 69 | Vendor shall provide the list of all interfering substances that may affect test results for each test - Data to be provided in excel format in a comprehensive summary tabular form). | |
| 70 | Analyzers or the TLA system must have sample volume sensing/detection and comparison with required volume. 1. Provide description of sample volume check especially for low volume samples (i.e. fail-safe system for low volume samples already inside the track). 2. Describe how the sample probe will be prevented from contamination by serum separator gel for such cases. | |
| 71 | Analyzers or TLA system must be able to detect fibrin or solids in serums. ▪ Describe the detection method and the fail-safe feature for samples with fibrin/solids already inside the track. | |
| 72 | Analyzers able to analyse serum, plasma, urine, CSF, body fluid and supernatant. | |

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| 73 | Vendor shall provide the list the minimum sample volumes required to run each test (refer to test menu). - Data to be provided in excel format in a comprehensive summary tabular form. | |
| 74 | Provide list of sample stability by tests in tabular form (excel) | |
| 75 | Any IQC violation will automatically trigger deactivation of the offending test and disable the offending cartridge until user intervention allows reactivation. | |
| 76 | RE-CAPPER OR RE-SEALER (RIPASH) | |
| 77 | Tubes will be resealed or recapped prior to storage to prevent serum evaporation | |
| 78 | Able to recap/reseal all primary tubes and any secondary tubes compatible to the analyzers provided by vendor. | |
| 79 | SAMPLE OUTPUT MODULE (RIPASH) | |
| 80 | The system should be able to sort samples into variable output lane / tray categories as follows: 1. Priority output lane: 1. For samples that failed to be aliquoted due to fibrin or low sample volume 2. Sample with unreadable barcode. 2. Incomplete output lane: 1. When reagents are not onboard / disabled / samples not registered by Laboratory information system (LIS). 3. Complete output lane: When on-track refrigerator is down (buffer lane). | |
| 81 | Sorting area for ≥ 200 samples (Customizable quantity for each lane category). | |
| 82 | ON-TRACK REFRIGERATED SAMPLE STORAGE MODULE (RIPASH) | |
| 83 | Automated refrigerated stockyard capable of holding $\geq 10,000$ sample tubes. | |
| 84 | Auto retrieval and reloading of sample to analyser for test add-on or batch testing (sample automatically routed to analyser). | |
| 85 | Automated dispensing of expired samples with user-defined criteria for its disposal. | |
| 86 | Auto-charting of temperature with alert | |

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| 87 | Annual temperature spatial distribution check of the fridge shall be performed by vendor. | |
| 88 | SAMPLE TRACK TRANSPORT SYSTEM (RIPASH) | |
| 89 | The transport system must be equipped with intelligent sample process management system to ensure optimum TAT. | |
| 90 | The sample track shall have an efficient land system to avoid jams in sample transport | |
| 91 | The sample track should Individual sample carriers with Radio Frequency Identification (RFID) or similar for efficient routing and sample trail log for traceability. | |
| 92 | Ability to cross lanes for samples requiring destination re-routing / prioritization. | |
| 93 | INFORMATION TECHNOLOGY (RIPASH) | |
| 94 | There should be remote diagnostics facilities available | |
| 95 | INTERFACING (RIPASH) | |
| 96 | Analyzers must be interfaced bi-directionally to Bru-HIMS through a middleware provided by the vendor. Vendor shall obtain approval from MOH Bru-HIMS for interfacing and to ensure vendor comply to interfacing requirements. The cost of setting up the interface and other maintenance costs are to be borne by the vendor. | |
| 97 | SOFTWARE COMPONENTS: MIDDLEWARE, TRACK MANAGEMENT, SERVER STORAGE AND CLIENT WORKSTATION PCs (RIPASH) | |
| 98 | Vendors to provide four (4) client workstation PCs that are equipped with: - <ol style="list-style-type: none"> 1. Keyboard and mouse 2. Barcode scanner 3. Analyzer Middleware 4. Access to TLA track management. 5. Microsoft Office subscription for the period of the tender contract. 6. QC Management Software 7. Antivirus software for the period of the tender contract. | |

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| 99 | <p>All the PCs must have optimal storage, RAM, processor and updated operating system to handle heavy middleware, LIS and TLA track management software activity.</p> <p>Work activity that will be done on these PCs include but not limited to: -</p> <ol style="list-style-type: none"> 1. Result review on analyzer middleware for. 2. Tracking samples and managing TLA components on the TLA track management software. 3. Registering patient samples and reviewing laboratory results on the Laboratory Information System software. 4. QC management. <p>The above activities are heavy workload items as the TLA system is expected to process thousands of patient samples per day. Should the PCs start to lag and affect the laboratory work, vendor shall upgrade the PCs to ensure smooth operation.</p> | |
| 100 | <p>Vendor must maintain the internal server (if required by the TLA system) also having sufficient storage to cater the period of tender contract.</p> | |
| 101 | <p>Vendor to provide statistical analysis software for evaluating the analyzer performances such as precision, linearity, inter-instrument correlation, limit of blank, limit of detection, limit of quantitation, and reference range verification for two (2) users access (RIPASH and PIHMH).</p> <p>Alternatively, vendor may generate the statistical analysis reports using data provided by the laboratory.</p> | |
| 102 | <p>IN-DEPTH MIDDLEWARE & QC MANAGEMENT SOFTWARE SPECIFICATIONS (RIPASH)</p> | |
| 103 | <p>Able to auto-calculate estimated Glomerular Filtration Rate (eGFR) using the CKD-EPI equation. The eGFR result can be transmitted to LIS.</p> | |
| 104 | <p>Able to generate measurement of uncertainty (MU).</p> | |
| 105 | <p>Analyzer middleware must have the ability to perform test result auto-validation based on delta check, alert limit, reference range, instrument analytical range, HIL index and user defined rules.</p> | |

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| 106 | Vendor to provide guideline and provide assistance to the lab for the implementation of test result auto-validation. | |
| 107 | The middleware can flag and alert samples if they are haemolysed, lipemic and icteric using HIL index. Middleware must be able to hold tests that are affected by the haemolysed/icteric/lipemic samples depending on the HIL index. | |
| 108 | Middleware must be able to hold critical tests results, automatic repeat testing followed by user intervention before results can be released. Middleware also must be able to flag results that are only critical to certain locations only e.g. Troponin critical results only applicable for A/E locations. | |
| 109 | Middleware must be able to trigger auto-dilution and rerun samples with results higher than the analytical measuring range (AMR) where applicable. | |
| 110 | Middleware must be able to auto rerun samples for subsequent test (reflex test) based on user defined rules such as FT4 and FT3 when TSH result is abnormal | |
| 111 | Middleware must be able to flag samples whose delta check alerted. Subsequently requires user intervention prior to release of the results. | |
| 112 | Middleware contains an overview page for held/blocked results for: - 1. Critical results 2. Auto-dilution 3. Haemolysed, Icteric, Lipemic samples 4. Tests with QC violation. | |
| 113 | The middleware is able to do moving averages for patient results (preferrable). | |
| 114 | During interruption of Bru-HIMS (LIS) service, the middleware must be able is to act a temporary laboratory information system (LIS) i.e. sample processing & result reporting resumes independently of actual LIS. Once Bru-HIMS (LIS) is back on live, the results from the pre-generated specimen IDs should be able to be transmitted back to the actual specimen ID on Bru-HIMS. Please describe and give details on how the middleware can perform this. | |
| 115 | Analyzer middleware must be able to produce result printout for individual patient sample with complete patient and sample identifiers, ordering location and reference range. This is required as a back-up should the LIS is down and cannot be used to generate patient sample result report. | |

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| 116 | Vendor to configure on the laboratory's reference ranges of lab test results into the middleware. | |
| 117 | Able to and assist laboratory to generate monthly turnaround time (TAT) by test and by location. | |
| 118 | Able to and assist laboratory to generate monthly statistics by tests and by specimen types. | |
| 119 | <p>Vendor shall provide protocol for re-evaluation of results from a period of compromised analytical performance</p> <ul style="list-style-type: none"> ▪ Middleware must be able to conveniently and quickly trigger mass re-testing of all affected samples in the situation of a compromised analytical performance from the time of last QC in-control. ▪ Vendor must also provide a solution on how to extract the original test run result and the rerun result for comparative analysis. ▪ The above must be able to be done in a systematic and convenient way in order to perform corrective actions and amend released lab results swiftly such as in cases of hundreds of results affected. <p>Please describe how your middleware will be able to do this.</p> | |
| 120 | Vendor to cover the costs of installation, maintenance and upgrades of the middleware throughout the contract period | |
| 121 | QUALITY CONTROL MANAGEMENT (RIPASH) | |
| 122 | Vendor must provide a QC Management Software that allows periodic IQC performance review. | |
| 123 | QC management software must be linked to the Middleware to allow automated submission of QC results. Any QC violation will automatically trigger test result to be put on hold. Vendor to cover all connection and maintenance costs for the link. | |
| 124 | QC Management software is able to generate Levy-Jennings Chart Plot for periodic review. | |
| 125 | QC Management software is able to generate running QC CV% data for periodic review. Periodic QC performance data (Mean, SD and CV%) is exportable to excel format. | |

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| 126 | Vendor must assist in configuring new lot QC data on the QC management software. | |
| 127 | Vendor must provide third party QC material and the laboratory shall be given online access to peer IQC performance database for comparison. Please provide details of IQC materials provided and the peer IQC database. | |
| 128 | Must be barcoded QC materials | |
| 129 | The IQC supplied shall have minimal lot to lot changes | |
| 130 | QC materials requiring minimum preparation prior to use | |
| 131 | QC materials preferred to have long shelf life (≥ 12 months). | |
| 132 | Please list out QC materials stability for all tests. To provide in excel format. | |
| 133 | The QC Management Software to be connected to middleware and includes auto upload of QC data to QC peer review module. | |
| 134 | Vendor to cover the costs of installation, maintenance and upgrades of the QC software throughout the contract period | |
| 135 | MONITOR (RIPASH) | |
| 136 | Vendor to provide high wall-mounted flat screen monitor for real time monitoring of TAT of STAT samples (A/E samples and inpatient samples, TAT < 2 hours). | |
| 137 | PRINTERS (RIPASH) | |
| 138 | Vendor to provide printers (inclusive of print cartridge costs) as follows: - 1. Black ink printers connected to each analyzer or each single line of connected analyzer modules and middleware to print sample results and other data (E.g. IQC points, calibration results & etc.). 2. One (1) colour printer for printing monthly QC Levy-Jennings charts from analyzer's middleware or QC Management software. | |
| 139 | <u>AFTER SALES SUPPORT (RIPASH)</u> | |

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| 140 | <p>Two (2) technical staffs (unless stated otherwise) that shall work on-site according to the working hours below:</p> <ol style="list-style-type: none"> 1. Monday – Thursday, from 7.45am – 12.15 pm & 1.30pm – 4.30pm. Ramadan month: 8.00am – 2.00pm. 2. Saturday, only one (1) staff is required to work at 7.45am – 12.15 pm & 1.30pm – 4.30pm. Ramadan month: 8.00am – 2.00pm. 3. Only one (1) staff is required to attend to work during public holidays (Fridays, Sundays and National holidays) from 7.45am – 12.15pm & 1.30pm – 4.30pm. Ramadan month: 8.00am – 2.00pm. <p>Vendor shall provide replacement staff if any of the two staff is unable to attend to work.</p> <p>The staffs must be:</p> <ol style="list-style-type: none"> 1. Local or PR 2. Have educational qualification minimum of Higher National Technical Education Certificate (HNTec) or equivalent in Laboratory Sciences or related fields. Higher qualification is an advantage. 3. Fully trained and competent to perform the job scope in Clause 141. 4. Working experience in related field is preferred. | |
| 141 | <p>Technical staff job scope:</p> <ol style="list-style-type: none"> 1. Daily maintenance of the analyzers including topping-up reagents, supplies, disposing onboard wastes, running calibration, running IQC and troubleshooting IQC according to laboratory protocol. 2. Preparation of reagents for use on the analyzers if required. 3. Load patient samples onto the TLA system. 4. Any other daily maintenance of the TLA system as required. 5. Monthly QC data extraction (LJ Chart and CV%) according to Laboratory's template. 6. Stock check and monitoring including forecasting usage. 7. New reagent lot verification. 8. New QC lot comparison. 9. General quality monitoring of the TLA system such as fridge temperature, | |

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| | extract test statistics, test turnaround time, incident statistics e.g. hemolyzed samples and etc. 10. Assist laboratory during LIS downtime. 11. Assist laboratory to re-test samples that has compromised results and to extract results for re-evaluation. | |
| 142 | ENGINEER SUPPORT (RIPASH) | |
| 143 | Vendor must provide ≥ 2 dedicated engineers based in Brunei Darussalam for hardware service support 24/7 throughout the contract period. Please submit list of engineers expected to work under this project and their period of working experience in related field. | |
| 144 | Answering call and inquiries from laboratory staff inclusive of public holidays (less than 30 minutes) | |
| 145 | Present themselves in the laboratory (≤ 2 hours of responding to the call) | |
| 146 | Local engineers to maintain and have access to remote support from regional office. | |
| 147 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. | |
| 148 | Vendor shall provide to end user, one (1) softcopy and one (1) hard copy of the maintenance log schedule listing out details of daily, weekly and other periodic scheduled preventive maintenance. | |
| 149 | <u>All periodic maintenance</u> of all automation systems including analysers is to be carried out by vendor. | |
| 150 | Engineer to perform scheduled preventive maintenance during off-peak hours (such as Fridays and Sundays) and the downtime for scheduled preventive maintenance should be < 8 hours, allowing the other mirror analyzers operational during this time. | |
| 151 | Scheduled replacement of hardware (≤ 6 hours during off peak) | |
| 152 | Vendor must keep buffer stock of necessary spare hardware parts in Brunei such as but not limited to sample probes and reagent probes to ensure downtime is kept to | |

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| | a minimum. | |
| 153 | Vendor shall maintain complete records of service maintenance work done which must have countersignature by end user. A copy must be available to laboratory head when and if requested. | |
| 154 | CORRECTIVE MAINTENANCE RESPONSE TIME (NON-URGENT TEST E.G. IRON TEST) (RIPASH): | |
| 155 | To trouble shoot and replace locally available spare parts (≤6 hours) | |
| 156 | Waiting for spare part from overseas affecting only partially of total service (< 72 hours) | |
| 157 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. | |
| 158 | CORRECTIVE MAINTENANCE RESPONSE TIME (URGENT TESTS E.G. POTASSIUM, TROPONIN, B-HCG) (RIPASH) | |
| 159 | To trouble shoot and resolve corrective issue (≤3 hours). | |
| 160 | The end user reserves the right to broaden the urgent test menu as and when required. | |
| 161 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. | |
| 162 | APPLICATION SPECIALIST SUPPORT (RIPASH) | |
| 163 | Vendor must provide ≥ 2 dedicated application specialists based in Brunei Darussalam for hardware service support 24/7 throughout the contract period | |
| 164 | The application specialist must be fully trained and capable to handle all issues pertaining to the test's applications both chemistry and immunochemistry tests as well as having the knowledge, experience and skills to perform method verification as required by ISO15189. | |
| 165 | The application specialist is responsible to perform method verification of all 89 tests to be done on analysers, including HIL index and auto-dilution verification during commissioning of the analyzer and preparation of the method verification | |

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| | report. Therefore, during the period of commissioning, the project may need more application specialists to perform the initial method verification (such as 3 or 4 personnel) than after the commissioning phase (≥ 2 personnel). | |
| 166 | Answering call & queries from laboratory staff inclusive of public holidays (≤ 30 minutes). | |
| 167 | Present themselves in the laboratory (≤ 2 hours of responding to the call). | |
| 168 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. | |
| 169 | The application specialist responsibility also includes assisting in monitoring results, re-establishing QC ranges, troubleshooting of Internal QC and External Quality Assurance Program Results, and assisting in preparation for ISO 15189 Assessments. | |
| 170 | Continued support by Application specialist to update, customise, and validate auto verification rules, tests software, and middleware functions | |
| 171 | All troubleshooting and corrective actions performed by the engineer and application team must address and resolve the root cause of the issue as much as possible. Monitoring and further testing must be done by the vendor should the root cause is not identified. | |
| 172 | All service work by engineer and application team must be recorded in service reports in complete details and to be verified by laboratory personnel. Lab personnel may request for further corrective action / troubleshooting should the current action done deemed inadequate. | |
| 173 | CONTINUOUS SUPPORT (RIPASH) | |
| 174 | Vendor must supply the following in a tabular format (excel): 1. Analytical measuring range of each test 2. Linearity range of each test. 3. Reference range of each test. 4. Manufacturer's claim total within laboratory (total) precision of each test. 5. LOB, LOD & LOQ claim of each test. | |
| 175 | Engineer to perform all periodic scheduled preventive maintenance of the TLA components including attending to breakdowns / issues. | |

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| 176 | Application specialists must perform reagent lot verification of all incoming new lot reagents according to laboratory's protocol. | |
| 177 | Application specialists must perform annual linearity verification of all tests using linearity kits or patient samples provided by the lab | |
| 178 | Application specialists must perform method verification should there be any change of method or formulation of the assays. The vendor shall cover the cost of the consumables, calibration material and reagents. | |
| 179 | Annual temperature spatial distribution check of the on-track fridge to be performed by Application specialists/Engineer. | |
| 180 | Application specialists/Engineer to perform centrifuge speed and timer check of all centrifuges provided annually according to protocol provided by the laboratory. | |
| 181 | Application specialists to perform dilution verification of all the programmable auto-dilution every two years. | |
| 182 | Application specialists to provide immediate remote and onsite assistance should there be any issues with the bidirectional connectivity between middleware and LIS throughout the period of the tender contract. | |
| 183 | Engineer to perform periodic maintenance including parts replacement of water purification systems as required by the manufacturer's recommendations and to perform annual sterilization and as when needed. | |
| 184 | Application specialists to perform back up of analyzer data (lab results, IQC data, calibration data) on a biweekly basis or as agreed by the user later on depending on how long the analyzer can operate optimally before it lags due to memory space. | |
| 185 | To generate annual measurement of uncertainty report of all tests either from the middleware or QC management software. | |
| 186 | Application specialist must assist senior lab personnel in any other periodical method verification as required by ISO 15189 | |
| 187 | ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS (RIPASH) | |
| 188 | Please summarize the data sheet of the proposed TLA system to include the following information: <ol style="list-style-type: none"> 1. Power requirements 2. Water requirements 3. Heat generation 4. Measurements and weight of the TLA components | |

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| 189 | <p>Vendor to ensure all environmental requirements for optimal TLA system operations are fulfilled before installation, testing and commissioning. Should any renovation be required, Vendor shall comply with the Ministry's procedure for infection control risk assessment (ICRA), implementation and monitoring as set out in the document titled Construction and/or Renovation, Maintenance, Repair and Demolition in the Health Care Setting. Vendor is required to liaise with RIPAS Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation</p> <p>The system shall occupy space not more than the present system in the laboratory. If any renovation (electrical and/or environmental) is required, costs shall be borne by Vendor.</p> | |
| 190 | <p>Prior to the proposed renovation work, vendor is required to conduct an onsite assessment of current site.</p> | |
| 191 | <p>Onsite assessment can be arranged with prior notification and agreement of head of National Clinical Chemistry Reference Laboratory.</p> | |
| 192 | <p>The vendor shall ensure that the maximum structural loading limits of all floors where TLA system is to be installed are not exceeded.</p> <p>Vendor shall appoint a certified chartered engineer to assess the site's structural loading capacity against the proposed TLA system to be installed (Please state your appointed engineer and proof of qualification/certification).</p> <p>Should the maximum structural loading limits of the floors be exceeded, vendor must provide reinforcements to the floor to sustain the load of the TLA components. The vendor shall also ensure the floor site conforms to TLA system's manufacturer's specification.</p> <p>Any floor structural strengthening work to the TLA floor must not affect the area below the TLA floor (Breast Imaging Centre) including no interruption to their power supply, dust pollution and etc. Breast Imaging Centre area is designated as off-limits for any construction/renovation activities.</p> | |
| 193 | <p>Should the TLA system configuration requires moving the power outlets, work benches, desks, water pipes, waste pipes, lockers, biosafety cabinet and others,</p> | |

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| | vendor shall be responsible to relocate these items and bear the costs. | |
| 194 | <p>Water requirements: Low water consumption. If water is required, state how much and what purity, with provision of water purification system included. All costs for installing water requirements shall be borne by the Vendor.</p> <ul style="list-style-type: none"> ▪ Vendor to provide two (2) water tank to ensure system is able to run at least 4 hours when external water supply is unavailable. ▪ Vendor to supply the appropriate quantity of water purifier / de-ionizer systems according to TLA manufacturer's recommendations (including supply of contingency units if the first set of units failed) with appropriate filters to produce water that meets requirement for clinical lab diagnostic use. ▪ Vendor must perform water sterilization periodically and to perform filter change as needed. Water resistivity and sterility must meet manufacturer's requirement and to perform the maintenance/servicing if fall below the standard. Any other required maintenance and repair work needed for the water systems shall be borne by vendor. ▪ Vendor to install sediment filters prior to the purification systems. ▪ Vendor to provide and install water pumps and piping as required to ensure water supply is directed from the water tanks to the site of testing sufficiently. <p>Vendor is required to liaise with RIPAS Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation</p> | |
| 195 | <p>Please provide specification for power requirement. Vendor's TLA system must not exceed the laboratory's existing electric current capacity.</p> <p>All costs for installing electrical requirements shall be borne by the Vendor. Vendor shall install dedicated power sockets for the TLA system direct to the nearest Distribution Board (DB). A qualified electrician shall be appointed by the vendor to perform all the electrical works.</p> <p>All the electrical wires shall be covered with PVC trunk properly for safety precautions.</p> | |

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| 196 | <p>Electrical Safety – Vendor shall test for and maintain the electrical safety of all equipment and accessory devices installed throughout their usage period. This include conducting electrical safety testing upon installation & during preventive maintenance (at least every six (6) months) using calibrated device. Electrical safety testing report shall be submitted to the laboratory for acceptance.</p> | |
| 197 | <p>Vendor shall supply, install, test and commission additional Cat6A UTP cable with uPVC conduit/casing and faceplate to the hospital network point if the existing points are not enough and located far away from the TLA system.</p> <p>This is to establish connectivity between the supplied TLA system and its accessory devices/machines/PCs to the hospital's Laboratory Information System (LIS) network.</p> | |
| 198 | <p>Before commencing any site preparation or installation, the Vendor is required to contact and consult the RIPAS Hospital Estate Department. This is mandatory to confirm that all work meets departmental regulations and receives Estate's approval.</p> | |
| 199 | <p>Temperature and humidity requirement: preferably 22 – 28 °C and up to 80% relative humidity.</p> | |
| 200 | <p>Floor area and drainage requirements: preferably adaptable to present facilities.</p> | |
| 201 | <p>Heat and noise generation: preferably less than 7,000 BTU per unit and ≤ 65 dBA at the front of the unit while at full operation.</p> | |
| 202 | <p>Vendor shall provide and install one (1) air conditioning (AC) unit – 4.0 horsepower inclusive of maintenance and repair as needed. This is to ensure sufficient cooling of the environment from the heat generated by the TLA system and as contingency if RIPAS Hospital's central air conditioning is down.</p> | |
| 203 | <p>Low generation of hazardous chemical or biological waste.</p> | |
| 204 | <p>If biological liquid waste is generated, the supplier shall provide the following for suitable waste containers:</p> <ul style="list-style-type: none"> i. Two waste containers shall be capped, have an inlet and outlet, easy to handle and do not hold more than 15L of liquid waste | |

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| | ii. When the production of waste liquid is more than 15L/day, a direct waste pipe shall be installed. A pre-dilution container shall be provided with easy access to add disinfectant and dispose of waste liquid. A preventive pipe shall be installed to prevent overflowing liquid waste from the waste containers. Proper guidelines to disinfect the liquid waste that is acceptable to ISO 15189 shall be provided. | |
| 205 | The successful vendor shall keep the area behind of the equipment tidy and clean at all times. All wires and cables shall be properly covered using PVC trunk, flexible wire and cable cover or equivalent that is acceptable to the laboratory. | |
| 206 | Any steps to switch on or off any main electrical or plumbing supply must require prior consent from in charge of Estate Department, RIPAS Hospital | |
| 207 | Any environmental impact of site preparation work (e.g. dust, sound, vibration and waste removal) must be minimal to both the public and the laboratory staff. | |
| 208 | All necessary precautions must be taken by vendor to ensure minimal disruption to current laboratory services during site preparation, installation, testing and commissioning phase. | |
| 209 | Workers are required to wear RIPAS Hospital issued temporary workers pass at all times when on work site | |
| 210 | INSTALLATION, TESTING AND COMMISSIONING (RIPASH) | |
| 211 | The vendor will be represented by suitable qualified and competent staff for all the necessary installation, testing and commissioning work. The following may be required: 1. Project Supervisor / Manager 2. Application Specialists 3. Engineers 4. IT specialist | |
| 212 | The vendor shall ensure any temporary modifications to door or windows to create passage of components of TLA system to site is subsequently restored to original condition. | |
| 213 | The vendor shall ensure all work are carried out with minimal disruption to lab Services | |

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| 214 | The vendor shall ensure that the safety and security of the staff, patients, contents, and premises are not compromised in the installation process | |
| 215 | The vendor guarantees that on completion of the installation, the IAS is free from any defects and is completely safe for operations | |
| 216 | <p>INITIAL METHOD VERIFICATION Vendor must perform a complete method verification of all the tests across all mirror analyzers, including, but not limited to: -</p> <ol style="list-style-type: none"> 1. Precision 2. Accuracy 3. Linearity 4. Limit of blank, limit of detection and limit of quantitation. 5. Carryover 6. Inter-instrument comparison between all new analyzers and existing analyzers. 7. Inter-instrument comparison between new analyzers. 8. Reference range verification 9. verification of the HIL measurements/index 10. Verification of auto-dilutions that are available on the analyzers. <p>Vendor must perform the method verification according to protocols that meets the requirement of ISO15189 and the laboratory's internal requirement depending on the nature of testing with the total cost borne by the vendor including the costs of reagents, calibrators, IQC, linearity kits and consumables.</p> <p>Report of the verification study shall be submitted to the Head of Section and then for final approval by the Director of Department of Laboratory Services.</p> | |
| 217 | Vendor shall also present the verification study findings to senior laboratory representatives on submission of the verification study report. | |
| 218 | Senior laboratory representative may request vendor to re-do any study that failed the set acceptable criteria or deemed inadequate and request changes to report template/format. | |
| 219 | Final report to be submitted in both softcopy and two (2) hardcopy format. All raw results from the analyzers must be attached together with the report. | |

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| 220 | The scope of testing and commissioning shall also include visual inspection for damage and/or corrosion of TLA system, safety, and neatness. | | | | | | | | | | | | | | | | | | | | | | | |
| 221 | Application specialists are required to run and obtain 20 IQC data points per level of all the tests using the QC lot that is expected to be used on the Go-Live date just prior to the Go-Live date. This is required for establishment of QC target means and CV goals. | | | | | | | | | | | | | | | | | | | | | | | |
| 222 | Vendor to assist the lab to perform a mock/trial run of the TLA system before the Go-live date using dummy samples. The lab orders are to be replicated as close as possible. | | | | | | | | | | | | | | | | | | | | | | | |
| 223 | ANALYZERS FOR CLINICAL CHEMISTRY LAB (PIHMH) | | | | | | | | | | | | | | | | | | | | | | | |
| 224 | <ul style="list-style-type: none"> ▪ Vendor must provide Chemistry and Immunoassay analyzers that covers the PIHMH test menu (see below). ▪ One (1) Chemistry analyzer and one (1) immunoassay analyzer. ▪ The same brand as the analyzers offered for the TLA system | | | | | | | | | | | | | | | | | | | | | | | |
| 225 | <p><u>PIHM Hospital TEST MENU</u></p> <table border="1" data-bbox="280 847 1270 1391"> <thead> <tr> <th data-bbox="280 847 392 898">No.</th> <th data-bbox="392 847 1270 898">Test Name</th> </tr> </thead> <tbody> <tr> <td data-bbox="280 898 392 949">1</td> <td data-bbox="392 898 1270 949">Alanine Transaminase (ALT)</td> </tr> <tr> <td data-bbox="280 949 392 1000">2</td> <td data-bbox="392 949 1270 1000">Albumin (ALB)</td> </tr> <tr> <td data-bbox="280 1000 392 1051">3</td> <td data-bbox="392 1000 1270 1051">Alkaline Phosphatase (ALP)</td> </tr> <tr> <td data-bbox="280 1051 392 1102">4</td> <td data-bbox="392 1051 1270 1102">Amylase</td> </tr> <tr> <td data-bbox="280 1102 392 1153">5</td> <td data-bbox="392 1102 1270 1153">BILI DIRECT</td> </tr> <tr> <td data-bbox="280 1153 392 1204">6</td> <td data-bbox="392 1153 1270 1204">BILI TOTAL</td> </tr> <tr> <td data-bbox="280 1204 392 1256">7</td> <td data-bbox="392 1204 1270 1256">CO2C Bicarbonate</td> </tr> <tr> <td data-bbox="280 1256 392 1307">8</td> <td data-bbox="392 1256 1270 1307">CRP16</td> </tr> <tr> <td data-bbox="280 1307 392 1358">9</td> <td data-bbox="392 1307 1270 1358">Calcium</td> </tr> <tr> <td data-bbox="280 1358 392 1391">10</td> <td data-bbox="392 1358 1270 1391">Cholesterol</td> </tr> </tbody> </table> | No. | Test Name | 1 | Alanine Transaminase (ALT) | 2 | Albumin (ALB) | 3 | Alkaline Phosphatase (ALP) | 4 | Amylase | 5 | BILI DIRECT | 6 | BILI TOTAL | 7 | CO2C Bicarbonate | 8 | CRP16 | 9 | Calcium | 10 | Cholesterol | |
| | No. | Test Name | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | Alanine Transaminase (ALT) | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | Albumin (ALB) | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | Alkaline Phosphatase (ALP) | | | | | | | | | | | | | | | | | | | | | | |
| | 4 | Amylase | | | | | | | | | | | | | | | | | | | | | | |
| | 5 | BILI DIRECT | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | BILI TOTAL | | | | | | | | | | | | | | | | | | | | | | |
| | 7 | CO2C Bicarbonate | | | | | | | | | | | | | | | | | | | | | | |
| | 8 | CRP16 | | | | | | | | | | | | | | | | | | | | | | |
| | 9 | Calcium | | | | | | | | | | | | | | | | | | | | | | |
| | 10 | Cholesterol | | | | | | | | | | | | | | | | | | | | | | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | VENDOR'S OFFER (PLEASE STATE) (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|--|---|-----------------|----|---------------|----|-----|----|---------|----|-----------------|----|---------------|----|-----------|----|--------------------|----|--------------|----|----------------|----|-----------------|----|------|----|--------------------------|--|
| | <table border="1"> <tr><td data-bbox="280 320 389 363">11</td><td data-bbox="389 320 1270 363">CL-C (Chloride)</td></tr> <tr><td data-bbox="280 363 389 406">12</td><td data-bbox="389 363 1270 406">CreaC (Creat)</td></tr> <tr><td data-bbox="280 406 389 450">13</td><td data-bbox="389 406 1270 450">GGT</td></tr> <tr><td data-bbox="280 450 389 493">14</td><td data-bbox="389 450 1270 493">Glucose</td></tr> <tr><td data-bbox="280 493 389 536">15</td><td data-bbox="389 493 1270 536">K-C (Potassium)</td></tr> <tr><td data-bbox="280 536 389 579">16</td><td data-bbox="389 536 1270 579">NA-C (Sodium)</td></tr> <tr><td data-bbox="280 579 389 622">17</td><td data-bbox="389 579 1270 622">Phosphate</td></tr> <tr><td data-bbox="280 622 389 665">18</td><td data-bbox="389 622 1270 665">Total Protein (TP)</td></tr> <tr><td data-bbox="280 665 389 708">19</td><td data-bbox="389 665 1270 708">Triglyceride</td></tr> <tr><td data-bbox="280 708 389 751">20</td><td data-bbox="389 708 1270 751">Uric Acid (UA)</td></tr> <tr><td data-bbox="280 751 389 794">21</td><td data-bbox="389 751 1270 794">HDL Cholesterol</td></tr> <tr><td data-bbox="280 794 389 837">22</td><td data-bbox="389 794 1270 837">Urea</td></tr> <tr><td data-bbox="280 837 389 880">23</td><td data-bbox="389 837 1270 880">Troponin I or Troponin T</td></tr> </table> | 11 | CL-C (Chloride) | 12 | CreaC (Creat) | 13 | GGT | 14 | Glucose | 15 | K-C (Potassium) | 16 | NA-C (Sodium) | 17 | Phosphate | 18 | Total Protein (TP) | 19 | Triglyceride | 20 | Uric Acid (UA) | 21 | HDL Cholesterol | 22 | Urea | 23 | Troponin I or Troponin T | |
| 11 | CL-C (Chloride) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12 | CreaC (Creat) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 13 | GGT | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 14 | Glucose | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 15 | K-C (Potassium) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 16 | NA-C (Sodium) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 17 | Phosphate | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 18 | Total Protein (TP) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 19 | Triglyceride | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 20 | Uric Acid (UA) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 21 | HDL Cholesterol | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 22 | Urea | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 23 | Troponin I or Troponin T | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 226 | All the assay kits must be CE & IVD - marked. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 227 | Vendor to declare any use of third-party reagents for any of the assays above. Third party reagents must have documented test validation report that was performed on the analyzer model used in this tender. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 228 | Vendor shall provide the test methods and technology of the analyzers and a list of current users in the region. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 229 | INITIAL METHOD VERIFICATION Vendor must perform a complete method verification of all the tests across all mirror analyzers, including, but not limited to: - <ol style="list-style-type: none"> 1. Precision 2. Accuracy 3. Linearity | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| | <p>4. Limit of blank, limit of detection and limit of quantitation. 5. Carryover 6. Inter-instrument comparison between all new analyzers and existing analyzers. 7. Inter-instrument comparison between new analyzers. 8. Reference range verification 9. verification of the HIL measurements/index 10. Verification of auto-dilutions that are available on the analyzers.</p> <p>Vendor must perform the method verification according to protocols that meets the requirement of ISO15189 and the laboratory's internal requirement depending on the nature of testing with the total cost borne by the vendor including the costs of reagents, calibrators, IQC, linearity kits and consumables.</p> <p>Report of the verification study shall be submitted to the Head of Section and then for final approval by the Director of Department of Laboratory Services.</p> | |
| 230 | <p>Minimal 'Hook Effect' in the immunoassays.</p> <p>Please declare any assay affected / potentially affected by 'Hook Effect'. Kindly include claims from the manufacturer with regard to the 'Hook Effect' and the manufacturer's protocol or recommendation for re-testing samples potentially affected by 'Hook Effect'.</p> | |
| 231 | Analyzers able to do intra-cup replicates. | |
| 232 | Analyzers able to do auto-dilution and also user defined manual dilution factors that can be programmed into the system. | |
| 233 | Vendor to perform dilution verification of all the programmable auto-dilution every two years. | |
| 234 | Analyzers must have minimum carryover between samples for all tests | |
| 235 | There must be random access with stat capability to the analyzers. | |
| 236 | The analysers must have user friendly touch colour monitor screens. | |

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| 237 | Analyzers must be able provide result printout for individual patient sample with analyzer ID stated | |
| 238 | The analyser should provide a countdown of tests remaining of reagent kit on board and their due calibration date. | |
| 239 | The analyser should have automated notification when a new lot reagent require calibration | |
| 240 | The analyser should have automated notification of impending calibration expiry | |
| 241 | The analyser should have option to override calibrator/reagent expiry | |
| 242 | Analyzer able to perform serum haemolytic, icteric and lipemic (HIL) check by measurement of absorbance and auto-translatable into semi-quantitative HIL index. | |
| 243 | Vendor to perform initial verification of the HIL measurements/index | |
| 244 | Vendor to provide comprehensive HIL interference rules and guidelines from the Manufacturer to implement for sample rejection by tests for all tests (eg. H-index of +1: - to reject LDH result etc.). - Data to be provided in excel and word format in a comprehensive summary tabular format. | |
| 245 | Vendor to provide the list of all interfering substances that may affect test results for each test - Data to be provided in excel format in a comprehensive summary tabular form). | |
| 246 | Analyzers have sample volume sensing/detection and comparison with required volume. | |
| 247 | Analyzers able to detect fibrin or solids in serums. | |
| 248 | Analyzers able to analyse serum, plasma, urine, CSF, body fluid and supernatant. | |
| 249 | List the minimum sample volumes required to run each test (refer to test menu). - Data to be provided in excel format in a comprehensive summary tabular form). | |
| 250 | Provide list of sample stability by tests in tabular form (excel) | |
| 251 | INTERFACING (PIHMH) | |

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| 252 | Analyzers must be interfaced bi-directionally to Bru-HIMS through a middleware provided by the vendor. Vendor shall obtain approval from MOH Bru-HIMS for interfacing and to ensure vendor comply to interfacing requirements. The cost of setting up the interface and other maintenance costs are to be borne by the vendor. | |
| 253 | MIDDLEWARE & WORKSTATION (PIHMH) | |
| 254 | Able to auto-calculate estimated Glomerular Filtration Rate (eGFR) using the CKD-EPI equation. The eGFR result can be transmitted to LIS. | |
| 255 | Able to generate measurement of uncertainty (MU). | |
| 256 | Analyzer middleware must have the ability to perform test result auto-validation based on delta check, alert limit, reference range, instrument analytical range, HIL index and user defined rules. | |
| 257 | Vendor to provide guideline and provide assistance to the lab for the implementation of test result auto-validation. | |
| 258 | The middleware can flag and alert samples if they are haemolysed, lipemic and icteric using HIL index. Middleware must be able to hold tests that are affected by the haemolysed/icteric/lipemic samples depending on the HIL index. | |
| 259 | Middleware must be able to hold critical tests results, automatic repeat testing followed by user intervention before results can be released. | |
| 260 | Middleware must be able to trigger auto-dilution and rerun samples with results higher than the analytical measuring range (AMR) where applicable. | |
| 261 | Middleware must be able to flag samples whose delta check alerted. Subsequently requires user intervention prior to release of the results. | |
| 262 | Middleware contains an overview page for held/blocked results for: - <ol style="list-style-type: none"> 1. Critical results 2. Auto-dilution 3. Haemolysed, Icteric, Lipemic samples Tests with QC violation. | |
| 263 | The middleware is able to do moving averages for patient results (preferable). | |
| 264 | During interruption of Bru-HIMS (LIS) service, the middleware must be able is to act a temporary laboratory information system (LIS) i.e. sample processing & result reporting resumes independently of actual LIS. | |

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| 265 | Analyzer middleware must be able to produce result printout for individual patient sample with complete patient and sample identifiers, ordering location and reference range. This is required as a back-up should the LIS is down and cannot be used to generate patient sample result report. | |
| 266 | Vendor to configure on the laboratory's reference ranges of lab test results into the middleware. | |
| 267 | Able to and assist laboratory to generate monthly turnaround time (TAT) by test and by location. | |
| 268 | Able to and assist laboratory to generate monthly statistics by tests and by specimen types. | |
| 269 | Vendor to cover the costs of installation, maintenance and upgrades of the middleware throughout the contract period | |
| 270 | Vendors to provide one (1) client workstation PCs that are equipped with: - 1. Keyboard and mouse 2. Barcode scanner 3. Analyzer Middleware 4. Microsoft Office subscription for the period of the tender contract. 5. QC Management Software 6. Antivirus software for the period of the tender contract. | |
| 271 | QUALITY CONTROL (PIHMH) | |
| 272 | Vendor must provide a QC management software to allow periodic review of QC performance. | |
| 273 | Must be bar coded QC materials | |
| 274 | The IQC supplied should have minimal lot to lot changes | |
| 275 | QC materials requiring minimum preparation prior to use | |
| 276 | QC materials preferred to have long shelf life (≥ 12 months). | |
| 277 | Please list out QC materials stability for all tests. To provide in excel format. | |

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| 278 | QC management software must be linked to the Middleware to allow automated submission of QC results. Any QC violation will automatically trigger test result to be put on hold. Vendor to cover all connection and maintenance costs for the link. | |
| 279 | QC Management software is able to generate Levy-Jennings Chart Plot for periodic review. | |
| 280 | QC Management software is able to generate running QC CV% data for periodic review. Periodic QC performance data (Mean, SD and CV%) is exportable to excel format. | |
| 281 | Vendor must assist in configuring new lot QC data on the QC management software. | |
| 282 | Vendor must provide third party QC material and the laboratory should be given online access to peer IQC performance database for comparison. Please provide details of IQC materials provided and the peer IQC database. | |
| 283 | The QC Management Software to be connected to middleware and includes auto upload of QC data to QC peer review module. | |
| 284 | Vendor to cover the costs of installation, maintenance and upgrades of the QC software throughout the contract period | |
| 285 | PRINTERS (PIHMH) | |
| 286 | Vendor to provide printers (inclusive of print cartridge costs) as follows: - Black ink printers connected to each analyzer or each single line of connected analyzer modules including middleware to print sample results and other data (e.g., IQC points, calibration results & etc.). | |
| 287 | AFTER SALES SUPPORT (PIHMH) | |
| 288 | ENGINEER SUPPORT (PIHMH) | |
| 289 | Vendor must provide ≥ 1 dedicated engineer based in Brunei Darussalam for hardware service support 24/7 throughout the contract period. | |
| 290 | Answering call and inquiries from laboratory staff inclusive of public holidays (less than 30 minutes) | |
| 291 | Present themselves in the laboratory (≤ 2 hours of responding to the call) | |

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| 292 | Local engineers to maintain and have access to remote support from regional office. | |
| 293 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. | |
| 294 | Vendor shall provide to end user, one (1) softcopy and one (1) hard copy of the maintenance log schedule listing out details of daily, weekly and other periodic scheduled preventive maintenance. | |
| 295 | <u>Weekly maintenance</u> of all automation systems including analysers is to be carried out by vendor. | |
| 296 | Engineer to perform scheduled preventive maintenance during off-peak hours and the downtime for scheduled preventive maintenance should be < 8 hours. | |
| 297 | Scheduled replacement of hardware (≤6 hours during off peak) | |
| 298 | Vendor must keep buffer stock of necessary spare hardware parts in Brunei such as but not limited to sample probes and reagent probes to ensure downtime is kept to a minimum. | |
| 299 | Vendor shall maintain complete records of service maintenance work done which must have countersignature by end user. A copy must be available to laboratory head when and if requested. | |
| 300 | CORRECTIVE MAINTENANCE RESPONSE TIME (NON-URGENT TEST E.G. IRON TEST) (PIHMH): - | |
| 301 | To trouble shoot and replace locally available spare parts (≤6 hours) | |
| 302 | Waiting for spare part from overseas affecting only partially of total service (< 72 hours) | |
| 303 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. | |
| 304 | CORRECTIVE MAINTENANCE RESPONSE TIME (URGENT TESTS E.G. POTASSIUM, TROPONIN) (PIHMH) | |
| 305 | To trouble shoot and resolve corrective issue (≤3 hours) | |

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| 306 | The end user reserves the right to broaden the urgent test menu as and when required | |
| 307 | If not resolvable within the agreed time frame, vendor shall be responsible to send affected tests to a comparable laboratory for testing with all costs (including transport) associated with this exercise borne by the vendor. | |
| 308 | APPLICATION SPECIALIST SUPPORT (PIHMH) | |
| 309 | Vendor must provide ≥ 1 dedicated application specialists based in Brunei Darussalam for hardware service support 24/7 throughout the contract period | |
| 310 | The application specialist must be fully trained and capable to handle all issues pertaining to the test's applications both chemistry and immunochemistry tests as well as having the knowledge, experience and skills to perform method verification as required by ISO15189. | |
| 311 | The application specialist is responsible to perform method verification of all tests to be done on analysers, including HIL index and auto-dilution verification during commissioning of the analyzer and preparation of the method verification report. | |
| 312 | Answering call & queries from laboratory staff inclusive of public holidays (≤ 30 minutes). | |
| 313 | Present themselves in the laboratory (≤ 2 hours of responding to the call). | |
| 314 | Vendor to supply laboratory management with a systematic workaround for unresolved issues and to escalate the issue to regional and/or main headquarter including flying overseas engineers in for assistance as necessary. | |
| 315 | The application specialist responsibility also includes assisting in monitoring results, re-establishing QC ranges, troubleshooting of Internal QC and External Quality Assurance Program Results, and assisting in preparation for ISO 15189 Assessments. | |
| 316 | All troubleshooting and corrective actions performed by the engineer and application team must address and resolve the root cause of the issue as much as possible. Monitoring and further testing must be done by the vendor should the root cause is not identified. | |
| 317 | All service work by engineer and application team must be recorded in service reports in complete details and to be verified by laboratory personnel. Lab personnel may request for further corrective action / troubleshooting should the | |

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| | current action done deemed inadequate. | |
| 318 | CONTINUOUS SUPPORT (PIHMH) | |
| 319 | Vendor must supply the following in a tabular format (excel): - 1. Analytical measuring range of each test 2. Linearity range of each test. 3. Reference range of each test. 4. Manufacturer's claim total within laboratory (total) precision of each test. 5. LOB, LOD & LOQ claim of each test. | |
| 320 | Engineer to perform all periodic scheduled preventive maintenance of the analyzers including attending to breakdowns / issues. | |
| 321 | Application specialists must perform reagent lot verification of all incoming new lot reagents according to laboratory's protocol. | |
| 322 | Application specialists must perform annual linearity verification of all tests using linearity kits or patient samples provided by the lab | |
| 323 | Application specialists must perform method verification should there be any change of method or formulation of the assays. The vendor shall cover the cost of the consumables, calibration material and reagents. | |
| 324 | Application specialists to perform dilution verification of all the programmable auto-dilution every two years. | |
| 325 | To generate annual measurement of uncertainty report of all tests either from the middleware or QC management software. | |
| 326 | Application specialists to provide immediate remote and onsite assistance should there be any issues with the bidirectional connectivity between middleware and LIS throughout the period of the tender contract. | |
| 327 | Engineer to perform periodic maintenance including parts replacement of water purification systems as required by the manufacturer's recommendations and to perform annual sterilization and as when needed. | |
| 328 | Application specialists to perform back up of analyzer data (lab results, IQC data, calibration data) on a monthly basis or as agreed by the user later on depending on how long the analyzer can operate optimally before it lags due to memory space. | |
| 329 | Application specialist must assist senior lab personnel in any other periodical method verification as required by ISO 15189 | |

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| 330 | ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS (PIHMH) | |
| 331 | <p>Vendor to ensure all environmental requirements for optimal operation of the analyzers are fulfilled before installation, testing and commissioning. Should any renovation be required, Vendor shall comply with the Ministry's procedure for infection control risk assessment (ICRA), implementation and monitoring as set out in the document titled Construction and/or Renovation, Maintenance, Repair and Demolition in the Health Care Setting. Vendor is required to liaise with PIHM Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation</p> <p>The system shall occupy space not more than the present system in the laboratory. If any renovation (electrical and/or environmental) is required, costs shall be borne by Vendor.</p> | |
| 332 | Prior to the proposed renovation work, vendor is required to conduct an onsite assessment of current site. | |
| 333 | Onsite assessment can be arranged with prior notification and agreement of head of PIHM Hospital Laboratory. | |
| 334 | <p>Water requirements: Low water consumption. If water is required, state how much and what purity, with provision of water purification system included. All costs for installing water requirements shall be borne by the Vendor.</p> <ul style="list-style-type: none"> ▪ Vendor to provide one (1) water tank to ensure system is able to run at least 4 hours when external water supply is unavailable. ▪ Vendor to supply the appropriate quantity of water purifier / de-ionizer systems according to manufacturer's recommendations if with appropriate filters to produce water that meets requirement for clinical lab diagnostic use. ▪ Vendor must perform water sterilization periodically and to perform filter change as needed. Water resistivity and sterility must meet manufacturer's requirement and to perform the maintenance/servicing if fall below the standard. Any other required maintenance and repair work needed for the water systems shall be borne by vendor. ▪ Vendor to install sediment filters prior to the purification systems. ▪ Vendor to provide and install water pumps and piping as required to ensure | |

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| | <p>water supply is directed from the water tanks to the site of testing sufficiently.</p> <p>Vendor is required to liaise with PIHM Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation</p> | |
| 335 | <p>Please provide specification for power requirement.</p> <p>All costs for installing electrical requirements shall be borne by the Vendor. All the electrical wires shall be covered with PVC trunk properly for safety precautions. Vendor is required to liaise with PIHM Hospital Estate Department prior to any site preparation and installation to ensure the work are in compliance with the department's regulation.</p> | |
| 336 | <p>Electrical Safety – Vendor shall test for and maintain the electrical safety of all equipment and accessory devices installed throughout their usage period. This include conducting electrical safety testing upon installation & during preventive maintenance (at least every six (6) months) using calibrated device. Electrical safety testing report shall be submitted to the laboratory for acceptance.</p> | |
| 337 | <p>Temperature and humidity requirement: preferably 22 – 28 °C and up to 80% relative humidity.</p> | |
| 338 | <p>Floor area and drainage requirements: preferably adaptable to present facilities.</p> | |
| 339 | <p>Heat and noise generation: preferably less than 7,000 BTU per unit and ≤ 65 dBA at the front of the unit while at full operation.</p> | |
| 340 | <p>Low generation of hazardous chemical or biological waste.</p> | |
| 341 | <p>If biological liquid waste is generated, the supplier shall provide the following for suitable waste containers;</p> <ul style="list-style-type: none"> i. Two waste containers shall be capped, have an inlet and outlet, easy to handle and do not hold more than 15L of liquid waste. ii. When the production of waste liquid is more than 15L/day, a direct waste pipe shall be installed. A pre-dilution container shall be provided with easy access to add disinfectant and dispose of waste liquid. A preventive pipe shall be installed to prevent overflowing liquid waste from the waste containers. | |

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| | Proper guidelines to disinfect the liquid waste that is acceptable to ISO 15189 shall be provided. | |
| 342 | The successful vendor shall keep the area behind of the equipment tidy and clean at all times. All wires and cables shall be properly covered using PVC trunk, flexible wire and cable cover or equivalent that is acceptable to the laboratory. | |
| 343 | Any environmental impact of site preparation work (e.g. dust, sound, vibration and waste removal) must be minimal to both the public and the laboratory staff. | |
| 344 | All necessary precautions must be taken by vendor to ensure minimal disruption to current laboratory services during site preparation, installation, testing and commissioning phase. | |
| 345 | Workers are required to wear PIHM Hospital issued temporary workers pass at all times when on work site | |
| 346 | SUPPLY OF REAGENTS AND CONSUMABLES (RIPASH & PIHMH) | |
| 347 | All reagents must remain stable throughout the shelf life when stored at their stated temperature. | |
| 348 | All reagents must have a long shelf life from the date of acceptance. Any loss incurred from expired reagents and expired onboard stability of the reagents will be borne by vendor as the laboratory will only be charged based on tests performed statistics. | |
| 349 | Staggered delivery of reagents and consumables shall be according to user's schedule. | |
| 350 | Delivery shall be direct to National Clinical Chemistry Reference Laboratory (NCCRL), RIPAS Hospital for P.O. generated by NCCRL. | |
| 351 | Delivery shall be direct to Clinical Chemistry Laboratory PIHM Hospital (Temburong) for P.O. generated by PIHMH Lab. | |
| 352 | Should the reagents require inversion on their arrival at the laboratory, vendor to perform the inversion after the Delivery Order and the reagents are cross-checked and before arranging the reagents in the storage space. | |
| 353 | On delivery, vendor is also required to arrange reagents in the store sites (cold room, freezer, fridge or dry store room) according to "First-In, First-Out" (FIFO) i.e. the older, nearing expiry date stocks to be arranged at the frontmost whereas the newer, longer expiry date stocks on the aftmost part of the shelves. | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | VENDOR'S OFFER (PLEASE STATE) (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) |
|-----|--|---|
| 354 | Reagent kit size for all tests must be fit for purpose to optimise cost savings. | |
| 355 | The reagents supplied should have minimal lot to lot changes. | |
| 356 | The IQC materials supplied should have minimal lot to lot changes i.e. enough stock to use until nearing IQC material expiry date. | |
| 357 | Vendor shall provide documentation evidence that the transport and storage of the reagents and calibrators are in accordance to temperature requirements of manufacturers. | |
| 358 | Vendor to assist the laboratory to manage reagent usage especially for reagents with short onboard stability to ensure low wastage. | |
| 359 | Delivery and storage of reagents to the laboratory by vendor should be such that there is optimum use of the limited laboratory storage facilities (< 1-2 months usage at the laboratory storage space) | |
| 360 | Vendor shall keep their buffer stock (> 3 months usage) at the local representative for the laboratory's use as contingency to ensure minimal interruption of the laboratory services. However, the laboratory is not obliged to purchase any or the whole of the buffer stock. Please describe your storage space that can be allocated for this project. | |
| 361 | Any defect and contaminations occurring along the line should be replaced by the next shipment or at the earliest shipment. | |
| 362 | Should there be any discontinuity of reagents due to non-compliance in the manufacturing of reagents; the vendor must be able to provide an alternative so that the test requests are still available for the customers. | |
| 363 | LITERATURE (RIPASH & PIHMH) | |
| 364 | To supply one (1) softcopy and one (1) set of hard copy of the Operating Manual and Service Manual including circuit diagrams of the equipment shall be provided upon commissioning. | |
| 365 | To supply the laboratory with one (1) set of Material Safety Data Sheet (MSDS) for all reagents, bulk solutions, calibrators and IQC materials. | |
| 366 | To supply one (1) hardcopy and one (1) softcopy of maintenance log with list of details of daily, weekly and other periodic scheduled preventive maintenance. | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | VENDOR'S OFFER (PLEASE STATE) (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) |
|-----|--|---|
| 367 | TRAINING (RIPASH & PIHMH) | |
| 368 | On-site training for ALL staff members expected to handle the machine. Please ensure that adequate time is allocated such that training will take place in small groups to minimize staff shortage in the laboratory. | |
| 369 | Certificate of competence is to be issued to all trainees after completion of training. | |
| 370 | <p>The successful tenderer needs to ensure the key users are updated on any relevant information related to the laboratory testing. They shall provide ONE off-site training for two (2) key users per year of contract.</p> <p>All expenses for attending the training shall be borne by the vendor; full registration, air ticket, daily allowance, accommodation, transport to and from the airport and place of training. Training may be in the form of operator's training, workshop, congress, international conference including 3rd-party conference, or other forms of training that is deemed appropriate and relevant.</p> | |
| 371 | Inviting speakers from overseas to give talks or presentations to the users on topics related to the laboratory testing as part of users' continuous education. Certificate of attendance is to be issued to all trainees after completion of training. | |
| 372 | FINANCIAL AGREEMENT (RIPASH & PIHMH) | |
| 373 | <p>The cost of testing must be charged based on the test count (test performed) accumulated at the end of each month. Vendor must extract a <u>test count statistic</u> from the TLA system (RIPASH) and the analyzer system (PIHMH) which will be used for invoicing.</p> <p><u>Test count definition:</u> Includes tests performed for:</p> <ol style="list-style-type: none"> 1. Completed results from patient samples (including reruns), 2. Completed results from Internal Quality Control runs. 3. Completed results from Calibration runs. 4. Completed results from EQA sample runs. 5. and other periodic and <i>ad hoc</i> verification studies including reagent lot verification (except for initial method verification and method verification | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | VENDOR'S OFFER (PLEASE STATE) (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) |
|-----|---|---|
| | <p>during assay method change / formula change).</p> <p>Note: Cost per test should also account for expected test wastage due to limited/short reagent shelf life/onboard stability especially for slow usage reagents.</p> <ul style="list-style-type: none"> ▪ ^ Slow usage reagents for NCCRL are: <i>Aceta, A1AT, AST, B2M, Carbamazepine, Ceruloplasmin, Cholinesterase, C-Peptide, Digoxin, Dehydroepiandrosterone sulfate (DHEAS), LDH, Lithium, MTX, Phenytoin, Phenobarbital, Salicylate, Sex Hormone Binding Globulin (SHBG), Theophylline, Valproic Acid.</i> ▪ <i>Slow usage reagents for PIHM are Amylase, Calcium, Direct Bili & Phosphate</i> | |
| 374 | <p>Vendor to submit <u>a sample of a generated monthly test count statistic report</u> together with the tender contract offer document. The data can be extracted either from the TLA software / middleware / analyzer.</p> | |
| 375 | <p>A rental agreement of the TLA components and its accessories at RIPAS Hospital and the immunoassay and chemistry analyzers at PIHM Hospital is required over a period of seven (7) years including the provision of the reagent kits, internal quality controls, calibrators, consumables and other accessories, two (2) on-site technical staff including after sales services indicated in detail above for performing the estimated total no. of tests in this contract.</p> <p>The total costs are to be absorbed to the cost per test which will be charged based on the test count accumulated at the end of each month. However, contract agreement shall be terminated when estimated total no. of tests is exceeded.</p> | |
| 376 | <p>Supply of the test kit including reagent, internal quality controls, calibrators, consumables and other accessories is based on the number of tests required in the Purchase Order according to an agreed schedule period.</p> | |
| 377 | <p>Should there be any discontinuity of reagents due to non-compliance in the manufacturing of reagents; the vendor must be able to provide an alternative so that the test requests are still available for the customers.</p> | |
| 378 | <p>All costs incurred for the supply and delivery of test kit including reagents, consumables and accessories, equipment and other accessories & support services required by the tender will be borne by the successful vendor.</p> | |
| 379 | <p>User shall have the rights to refuse delivery of items that do not meet the acceptance criteria such as, but not limited to, the following:</p> <ol style="list-style-type: none"> 1. Tampered or damaged box | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | VENDOR'S OFFER (PLEASE STATE) (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) |
|-----|---|---|
| | 2. Leakage upon delivery 3. Items stored pre-delivery not in accordance to manufacturer's instructions 4. Expiry date not meeting requirement | |
| 380 | User shall have the rights to return any items, and to be replaced at no extra cost, if found not meeting the acceptance criteria upon opening a pack such as, but not limited to, the following: 1. Tampered or damaged packaging 2. Evident of leakage or damaged products 3. Expired products that are evidently less than the requirement calculated from delivery date 4. Leakage upon delivery | |
| 381 | EXIT CLAUSE: The tender contract shall be automatically terminated even though tender has not yet expired and this shall be in effect due to, but not limited to, the following: 1. When the testing is no longer required or relevant i.e. test is obsolete, to the laboratory or department. 2. When the item(s) set out in this tender is/are no longer required by the laboratory or the Department. 3. When the approved budget allocation for this tender contract has been used up before the tender contract expires whereby a renewal of tender shall be submitted by the user for an open advertisement subject to approval by the Mini Tender Board (<i>Lembaga Tawaran Kecil</i>). | |
| 382 | OTHERS | |
| 383 | Should the laboratory is being relocated, vendor must assist in the relocation of the TLA components and its accessories. This also applies to the analyzers in PIHM Lab if needed. | |
| 384 | Should there be any discontinuity of testing due to non-compliance in the analytical system (analyzer breakdown, IQC failures & etc.); the vendor must be able to provide an alternative so that the test requests are still available for the customers. e.g. Providing logistics to transport samples to other laboratory (reference laboratory or district laboratory and vice versa or private laboratory for urgent tests). All cost incurred to be borne by vendor. | |

| NO. | SPECIFICATIONS AND REQUIREMENTS | VENDOR'S OFFER (PLEASE STATE) (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy) |
|------------|--|---|
| 385 | DELIVERY PERIOD: Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order | (Yes / No) (If No, please specify) |
| 386 | PRICE VALIDITY: The quotation shall remain valid for 12 MONTHS from the final date for the submission of the quotation and no supplier may withdraw his/her quotation within that period. The Government reserves the right to extend this period if deemed necessary provided that such extension to the quotation validity period shall have written consent of the supplier(s). | |

Appendix C
(Data to be submitted in excel form in USB device)

| No. | GENERAL SPECIFICATIONS* | VENDOR'S OFFER for National Clinical Chemistry Reference Laboratory, RIPAS Hospital | | |
|-----|------------------------------------|--|---------------------|-----------------------|
| | | TLA Track System | Chemistry Analyzers | Immunoassay Analyzers |
| A | Model & Brand | | | |
| B | Country of Origin | | | |
| C | Total Price Per Test (CIF): B\$ | | | |
| D | Price Ranking: | (leave blank) | (leave blank) | (leave blank) |
| E | Where marketed | | | |
| F | Year of Manufacture | | | |
| G | Warranty: | | | |
| H | Delivery Time: | | | |
| I | Power Requirements: | | | |
| J | Battery Back-up: | | | |
| K | International Safety Standard: | | | |
| L | Technical Support: | | | |

| No. | GENERAL SPECIFICATIONS* | VENDOR'S OFFER for National Clinical Chemistry Reference Laboratory, RIPAS Hospital | | |
|-----|-----------------------------------|--|---------------------|-----------------------|
| | | TLA Track System | Chemistry Analyzers | Immunoassay Analyzers |
| M | Equipment Whole Life Support | | | |
| N | Dimensions (WxHxD) cm: | | | |
| O | Weight (kg): | | | |
| P | User Manuals | | | |
| Q | Service Manuals | | | |
| R | Spare-parts & Consumables Listing | | | |
| S | Technical Training On-Site: | | | |
| T | Site Requirements: | | | |

*To all participating companies, please fill in the table above along with your other documents during submission of tender.

Appendix D
(Data to be submitted in excel form in USB device)

| No. | GENERAL SPECIFICATIONS* | VENDOR'S OFFER for Clinical Chemistry Laboratory, PIHM Hospital | |
|-----|---------------------------------|--|-----------------------|
| | | Chemistry Analyzers | Immunoassay Analyzers |
| A | Model & Brand | | |
| B | Country of Origin | | |
| C | Total Price Per Test (CIF): B\$ | | |
| D | Price Ranking: | (leave blank) | (leave blank) |
| E | Where marketed | | |
| F | Year of Manufacture | | |
| G | Warranty: | | |
| H | Delivery Time: | | |
| I | Power Requirements: | | |
| J | Battery Back-up: | | |
| K | International Safety Standard: | | |
| L | Technical Support: | | |

| No. | GENERAL SPECIFICATIONS* | VENDOR'S OFFER for Clinical Chemistry Laboratory, PIHM Hospital | |
|-----|-----------------------------------|--|-----------------------|
| | | Chemistry Analyzers | Immunoassay Analyzers |
| M | Equipment Whole Life Support | | |
| N | Dimensions (WxHxD) cm: | | |
| O | Weight (kg): | | |
| P | User Manuals | | |
| Q | Service Manuals | | |
| R | Spare-parts & Consumables Listing | | |
| S | Technical Training On-Site: | | |
| T | Site Requirements: | | |

*To all participating companies, please fill in the table above along with your other documents during submission of tender.

Appendix G
Summary of Test Characteristics for RIPAS Hospital Test Menu
(Data to be submitted in excel form in USB device)

| No. | Assay Name | Reagent Packaging size | Reagent Preparation requirement | Reagent/Product Code | Test Method | Testing time | Specimen type | Specimen tube type | Sample volume required | Specimen stability | Reference ranges from IFU | Analytical Measuring Range | LOQ | LOD | LOB | Manufacturer's Claim Total Within Lab Precision. | Recommended sample dilution factors (Please state if they are manual / onboard auto dilutions) | Diluent for dilution | |
|-----|------------|------------------------|---------------------------------|----------------------|-------------|--------------|---------------|--------------------|------------------------|--------------------|---------------------------|----------------------------|-----|-----|-----|--|---|----------------------|--|
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |

Appendix H
Summary of Test Characteristics for PIHM Hospital Test Menu
(Data to be submitted in excel form in USB device)

| No. | Assay Name | Reagent Packaging size | Reagent Preparation requirement | Reagent/Product Code | Test Method | Testing time | Specimen type | Specimen tube type | Sample volume required | Specimen stability | Reference ranges from IFU | Analytical Measuring Range | LOQ | LOD | LOB | Manufacturer's Claim Total Within Lab Precision. | Recommended sample dilution factors (Please state if they are manual / onboard auto dilutions) | Diluent for dilution | |
|-----|------------|------------------------|---------------------------------|----------------------|-------------|--------------|---------------|--------------------|------------------------|--------------------|---------------------------|----------------------------|-----|-----|-----|--|---|----------------------|--|
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |

1. We offer and undertake on your acceptance of our Tender to supply and deliver the above mentioned goods in accordance with your Invitation To Tender.
2. Our Tender is fully consistent with and does not contradict or derogate from anything in your Invitation To Tender. We have not qualified or changed any of the provisions of your Invitation To Tender.
3. We shall execute a formal agreement in the appropriate form set out in Section 4 – Contract of the Invitation to Tender together with such further terms and conditions, if any, agreed between the Government and us.
4. OUR OFFER IS VALID FOR **TWELVE (12)** CALENDER MONTHS FROM THE TENDER CLOSING DATE.
5. When requested by you, we shall extend the validity of this offer.
6. We further undertake to give you any further information which you may require.

Dated this _____ day of _____, 20 _____

[Signature of authorised officer of Tenderer]
Name:
Designation:

Tenderer's official stamp:

SCHEDULE 2 - INFORMATION SUMMARY

- 2.1 Tenderers shall provide in this Schedule the following information:
- a. Management summary
 - b. Company profile (including Contractor and sub-contractor(s), if any)
 - c. Years of experience (as of the Tender Closing Date) of the Contractor and sub-contractor(s) in the:
 - ***Supply & Delivery Of Laboratory Equipment, Test Kits and Consumables.***
 - d. Other information which is considered relevant

SCHEDULE 3 – SUB-CONTRACTS

- 3.1 Tenderers shall complete Table 3.1 with information about all the companies involved in the provision of the services and items specified in this tender. This shall include details about the Contractor and each sub-contractor involved, as well as their respective responsibilities.
- 3.2 Tenderers shall also indicate in Table 3.1 any alliance relationship established with each sub-contractor. An alliance is defined as a formal and binding business relationship between the allied parties.

Table 3.1 - Responsibility Table

| Company Name | Responsibility Description | Alliance Relationship between Contractor and Sub-contractor(s) | | |
|--------------------------|----------------------------|--|------------------|----------------------|
| | | Alliance Exists? (Y/N) | Date Established | Alliance Description |
| Contractor | | | | |
| | | Not Applicable | Not Applicable | Not Applicable |
| Sub-contractor(s) | | | | |
| | | | | |

SCHEDULE 4 – COMPANY’S BACKGROUND

- 4.1 Each of the companies involved in this tender, including Contractor and sub-contractor(s) (if any), shall provide information on the company’s background, scope of operations, financial standing and certified copy of its Certificate of Incorporation or Certificate of Registration (as the case may be).

SCHEDULE 5 – REFERENCES

5.1 Tenderers shall submit a list of customers in Table 5.1 to whom the Contractor has provided similar services and items as specified in this tender in the recent 5 years as of the Tender Closing Date.

Table 5.1 - References of previous customers

| Customer Name and Address | Customer Type (Govt or Quasi Govt)* | Contact Person | Title | Contact Number, Fax Number and E-mail Address |
|---------------------------|-------------------------------------|----------------|-------|---|
| | | | | |

***Note: Tenderers shall indicate whether the customer is a Government or Quasi Government organisation. A Quasi Government is defined as an organisation which (1) is managed and controlled by the Government; or (2) has at least 50% shares being held by the Government. Please leave the column blank if the customer is neither a Government or Quasi Government organisation.**

5.2 The Ministry of Health shall treat all the information submitted under this schedule in strict confidence.

5.3 The Ministry of Health reserves the right to contact the references for tender assessment purposes.

SCHEDULE 6 - SUBMISSION OF SAMPLE

- 6.1 Tenderers shall submit the Submission of Sample form below in respect of the items specified in this tender.
- 6.2 Samples of the items to be submitted shall be:
- a) identical in packing and manufacture to the items to be offered by the Tenderer; and
 - b) marked with the corresponding item number of the tender.

SUBMISSION OF SAMPLE FORM

To:

TENDER REFERENCE NO.: KK/61/2026/LAB(TC)

INVITATION TO TENDER

TO SUPPLY, DELIVER AND COMMISSION A LABORATORY AUTOMATION SYSTEM ON EQUIPMENT RENTAL BASIS FOR ROUTINE CHEMISTRY TESTING, INCLUDING REAGENTS AND CONSUMABLES FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY (RIPAS HOSPITAL) AND CLINICAL CHEMISTRY LABORATORY (PIHM HOSPITAL), DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF SEVEN (7) YEARS

SUBMISSION OF SAMPLE FORM OF (NAME OF TENDERER)

| NO. | TEST/REAGENT NAME | SAMPLE SUBMITTED (indicate with ✓) | SAMPLE NOT SUBMITTED (indicate with ✕) | OFFERED/ NOT OFFERED (indicate as appropriate) |
|------------|--|--|--|---|
| | APPENDIX A: SUMMARY OF UNIT PRICE OF REAGENT KIT (RIPAS HOSPITAL) | | | |
| | TOTAL LABORATORY AUTOMATION SYSTEM FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, RIPAS HOSPITAL | | | |
| 1 | 25-OH Vitamin D | | | |
| 2 | Acetaminophen | | | |
| 3 | Alanine Transaminase (ALT) | | | |
| 4 | Albumin | | | |
| 5 | Alkaline Phosphatase (ALP) | | | |
| 6 | Alpha-1 Antitrypsin (A1AT) | | | |
| 7 | Alpha-fetoprotein (AFP) | | | |
| 8 | Amikacin | | | |
| 9 | Aminotransferase (AST) | | | |
| 10 | Ammonia | | | |
| 11 | Amylase | | | |
| 12 | Beta-2 Microglobulin (B2M) | | | |

| NO. | TEST/REAGENT NAME | SAMPLE SUBMITTED (indicate with ✓) | SAMPLE NOT SUBMITTED (indicate with ✕) | OFFERED/ NOT OFFERED (indicate as appropriate) |
|------------|-----------------------------------|--|---|---|
| 13 | Beta-HCG | | | |
| 14 | Bicarbonate | | | |
| 15 | Bili Direct (DBIL) | | | |
| 16 | Bili Total (TBIL) | | | |
| 17 | CA-125 | | | |
| 18 | CA15-3 | | | |
| 19 | CA19-9 | | | |
| 20 | Calcium | | | |
| 21 | Calcium Urine | | | |
| 22 | Carbamazepine | | | |
| 23 | Carcinoembryonic antigen (CEA) | | | |
| 24 | Ceruloplasmin | | | |
| 25 | Chloride | | | |
| 26 | Chloride Urine | | | |
| 27 | Cholinesterase | | | |
| 28 | Complement Component 3 (C3) | | | |
| 29 | Complement Component 4 (C4) | | | |
| 30 | Cortisol | | | |
| 31 | C-peptide | | | |
| 32 | C-Reactive Protein (CRP) | | | |
| 33 | Creatine Kinase | | | |
| 34 | Creatine Kinase-MB (CKMB) | | | |
| 35 | Creatinine | | | |
| 36 | Creatinine Urine | | | |

| NO. | TEST/REAGENT NAME | SAMPLE SUBMITTED (indicate with ✓) | SAMPLE NOT SUBMITTED (indicate with ✕) | OFFERED/ NOT OFFERED (indicate as appropriate) |
|------------|--|---|---|---|
| 37 | Cyclosporine | | | |
| 38 | Digoxin | | | |
| 39 | Dehydroepiandrosterone sulfate (DHEAS) | | | |
| 40 | Estradiol (E2) | | | |
| 41 | Ferritin | | | |
| 42 | Folic Acid | | | |
| 43 | Follicle Stimulating Hormone | | | |
| 44 | Free Prostate Surface Antigen | | | |
| 45 | Free Thyroxine (FT4) | | | |
| 46 | Free Triiodothyronine (FT3) | | | |
| 47 | Gamma Glutamyl Transferase (GGT) | | | |
| 48 | Gentamicin | | | |
| 49 | Glucose | | | |
| 50 | Haptoglobin | | | |
| 51 | HDL Cholesterol | | | |
| 52 | Immunoglobulin A | | | |
| 53 | Immunoglobulin G | | | |
| 54 | Immunoglobulin M | | | |
| 55 | Insulin | | | |
| 56 | intact parathyroid hormone (iPTH) | | | |
| 57 | Iron | | | |
| 58 | Lactate | | | |
| 59 | Lactate Dehydrogenase (LDH) | | | |
| 60 | Lithium | | | |

| NO. | TEST/REAGENT NAME | SAMPLE SUBMITTED (indicate with ✓) | SAMPLE NOT SUBMITTED (indicate with ✕) | OFFERED/ NOT OFFERED (indicate as appropriate) |
|------------|-------------------------------------|---|---|---|
| 61 | Luteinizing Hormone | | | |
| 62 | Magnesium | | | |
| 63 | Magnesium Urine | | | |
| 64 | Methotrexate | | | |
| 65 | Microalbumin | | | |
| 66 | NT-proBNP | | | |
| 67 | Phenobarbital | | | |
| 68 | Phenytoin | | | |
| 69 | Phosphate | | | |
| 70 | Phosphate Urine | | | |
| 71 | Potassium (K) | | | |
| 72 | Potassium Urine | | | |
| 73 | Procalcitonin | | | |
| 74 | Progesterone | | | |
| 75 | Prolactin | | | |
| 76 | Protein Urine / CSF | | | |
| 77 | Rheumatoid Factor | | | |
| 78 | Salicylate | | | |
| 79 | Sex Hormone Binding Globulin (SHBG) | | | |
| 80 | Sodium (Na) | | | |
| 81 | Sodium Urine | | | |
| 82 | Tacrolimus | | | |
| 83 | Testosterone | | | |
| 84 | Theophylline | | | |

| NO. | TEST/REAGENT NAME | SAMPLE SUBMITTED (indicate with ✓) | SAMPLE NOT SUBMITTED (indicate with ✕) | OFFERED/ NOT OFFERED (indicate as appropriate) |
|-----|---|---------------------------------------|---|--|
| 85 | Thyroid Stimulating Hormone (TSH) | | | |
| 86 | Total Cholesterol | | | |
| 87 | Total Prostate Surface Antigen | | | |
| 88 | Total Protein | | | |
| 89 | Transferrin | | | |
| 90 | Triglyceride | | | |
| 91 | Troponin I or Troponin T | | | |
| 92 | Urea | | | |
| 93 | Urea Urine | | | |
| 94 | Uric Acid | | | |
| 95 | Uric Acid Urine | | | |
| 96 | Valporic Acid | | | |
| 97 | Vancomycin | | | |
| 98 | Vitamin B12 | | | |
| | APPENDIX B: SUMMARY OF UNIT PRICE OF REAGENT KIT (PIHM HOSPITAL) | | | |
| | CHEMISTRY - IMMUNOASSAY ANALYZERS FOR CLINICAL CHEMISTRY LABORATORY, PIHM HOSPITAL | | | |
| 1 | Alanine Transaminase (ALT) | | | |
| 2 | Albumin (ALB) | | | |
| 3 | Alkaline Phosphatase (ALP) | | | |
| 4 | Amylase | | | |
| 5 | BILI DIRECT | | | |
| 6 | BILI TOTAL | | | |
| 7 | CO2C Bicarbonate | | | |

| NO. | TEST/REAGENT NAME | SAMPLE SUBMITTED (indicate with ✓) | SAMPLE NOT SUBMITTED (indicate with ✕) | OFFERED/ NOT OFFERED (indicate as appropriate) |
|------------|--------------------------|--|---|---|
| 8 | CRP16 | | | |
| 9 | Calcium | | | |
| 10 | Cholesterol | | | |
| 11 | CL-C (Chloride) | | | |
| 12 | CreaC (Creat) | | | |
| 13 | GGT | | | |
| 14 | Glucose | | | |
| 15 | K-C (Potassium) | | | |
| 16 | NA-C (Sodium) | | | |
| 17 | Phosphate | | | |
| 18 | Total Protein (TP) | | | |
| 19 | Triglyceride | | | |
| 20 | Uric Acid (UA) | | | |
| 21 | HDL Cholesterol | | | |
| 22 | Urea | | | |
| 23 | Troponin I or Troponin T | | | |

SCHEDULE 7
LETTER OF DECLARATION