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 : $30.00

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	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: 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) 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. *= Lab test workload (during a typical non-public holiday): • 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) **= Laboratory turnaround time (TAT) requirement: • 2 hours for A/E and inpatient samples, • Outpatient samples received at 11.00AM to be resulted 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 *Go-Live* 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** • Please provide description of STAT prioritization during peak sample saturation on the system's track. • STAT prioritization *throughout* the majority of the components of the TLA system is preferred.
16	• **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.** Note: • TAT defined as the period from registration time and result generated by analysers • Priority of samples is by: 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: - 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.

<table>
<tr><th>NO.</th><th>SPECIFICATIONS AND REQUIREMENTS</th></tr>
<tr><td>28</td><td>PRE-ANALYTICAL ASSESSMENT MODULE (RIPASH)</td></tr>
<tr><td>29</td><td>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.</td></tr>
<tr><td>30</td><td>ON-TRACK CENTRIFUGE MODULE (RIPASH)</td></tr>
<tr><td>31</td><td>Programmable settings</td></tr>
<tr><td>32</td><td>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.</td></tr>
<tr><td>33</td><td>Intelligent setting to optimize sample turnaround time.</td></tr>
<tr><td>34</td><td>Programmable waiting time to load and start centrifuge.</td></tr>
<tr><td>35</td><td>Automated load balancing centrifuge with rapid ascend and descend features.</td></tr>
<tr><td>36</td><td>Low noise with user defined spin time and easy maintenance.</td></tr>
<tr><td>37</td><td>Vendor to also provide one (1) unit <u>off-track refrigerated centrifuge</u> with minimum capacity of 4 samples. This is for samples requiring refrigerated centrifugation such as samples for Ammonia and Lactate tests.</td></tr>
<tr><td>38</td><td>Vendor to perform centrifuge speed and timer check of all centrifuges provided annually according to protocol provided by the laboratory.</td></tr>
<tr><td>39</td><td>DECAPPER (RIPASH)</td></tr>
<tr><td>40</td><td>Able to de-cap rubber or plastic caps of different types and sizes without creating hazardous aerosols</td></tr>
<tr><td>41</td><td>To de-cap samples prior to first analysis AND to de-cap samples from on-board storage for additional testing.</td></tr>
<tr><td>42</td><td>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.</td></tr>
<tr><td>43</td><td>ANALYZERS (RIPASH)</td></tr>
<tr><td>44</td><td>• 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).</td></tr>
<tr><td>45</td><td>• <u>RIPASH TEST MENU</u>
The analyzers must have the following test menu within the TLA system: -

<table>
<tr><th>No.</th><th>Test Name</th></tr>
<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>
</table>
</td></tr>
</table>

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
	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	• **THROUGHPUT (RIPASH)**
53	Vendor shall offer a suitable number of chemistry and immunoassay analyzers to achieve the following throughput: • 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): 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
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

NO.	SPECIFICATIONS AND REQUIREMENTS
	• 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.
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 ≥ 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	• **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: -

NO.	SPECIFICATIONS AND REQUIREMENTS
	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	All the PCs must have optimal storage, RAM, processor and updated operating system to handle heavy middleware, LIS and TLA track management software activity. Work activity that will be done on these PCs include but not limited to: - 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. 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.
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	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). Alternatively, vendor may generate the statistical analysis reports using data provided by the laboratory.
102	• **IN-DEPTH MIDDLEWARE & QC MANAGEMENT SOFWARE 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	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

NO.	SPECIFICATIONS AND REQUIREMENTS
	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.
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	**Vendor shall provide protocol for re-evaluation of results from a period of compromised analytical performance** • 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. Please describe how your middleware will be able to do this.
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.
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).

NO.	SPECIFICATIONS AND REQUIREMENTS
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	**AFTER SALES SUPPORT (RIPASH)**
140	**Two (2) technical staffs (unless stated otherwise) that shall work on-site according to the working hours below:** 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.** Vendor shall provide **replacement staff if any of the two staff is unable to attend to work.** **The staffs must be:** 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	**Technical staff job scope:** 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	**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.

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	All periodic maintenance 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	• **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 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	• **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.
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: 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	The vendor shall ensure that the maximum structural loading limits of all floors where TLA system is to be installed are not exceeded. 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). 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. 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.
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	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. • 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. 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
195	Please provide specification for power requirement. Vendor's TLA system must not exceed the laboratory's existing electric current capacity. 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. All the electrical wires shall be covered with PVC trunk properly for safety precautions.
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 ^{o}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; 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: - **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

<table>
<tr><th>NO.</th><th>SPECIFICATIONS AND REQUIREMENTS</th></tr>
<tr><td>215</td><td>The vendor guarantees that on completion of the installation, the IAS is free from any defects and is completely safe for operations</td></tr>
<tr><td>216</td><td>INITIAL METHOD VERIFICATION
Vendor must perform a complete method verification of all the tests across all mirror analyzers, including, but not limited to: -

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.

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.

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.</td></tr>
<tr><td>217</td><td>Vendor shall also present the verification study findings to senior laboratory representatives on submission of the verification study report.</td></tr>
<tr><td>218</td><td>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.</td></tr>
<tr><td>219</td><td>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.</td></tr>
<tr><td>220</td><td>The scope of testing and commissioning shall also include visual inspection for damage and/or corrosion of TLA system, safety, and neatness.</td></tr>
<tr><td>221</td><td>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.</td></tr>
<tr><td>222</td><td>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.</td></tr>
<tr><td>223</td><td>ANALYZERS FOR CLINICAL CHEMISTRY LAB (PIHMH)</td></tr>
<tr><td>224</td><td>• 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</td></tr>
<tr><td>225</td><td><u>PIHM Hospital TEST MENU</u>

<table>
<tr><th>No.</th><th>Test Name</th></tr>
<tr><td>1</td><td>Alanine Transaminase (ALT)</td></tr>
<tr><td>2</td><td>Albumin (ALB)</td></tr>
<tr><td>3</td><td>Alkaline Phosphatase (ALP)</td></tr>
<tr><td>4</td><td>Amylase</td></tr>
<tr><td>5</td><td>BILI DIRECT</td></tr>
<tr><td>6</td><td>BILI TOTAL</td></tr>
<tr><td>7</td><td>CO2C Bicarbonate</td></tr>
<tr><td>8</td><td>CRP16</td></tr>
</table></td></tr>
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<table>
<tr><th>NO.</th><th>SPECIFICATIONS AND REQUIREMENTS</th></tr>
<tr><td></td><td>
<table>
<tr><td>9</td><td>Calcium</td></tr>
<tr><td>10</td><td>Cholesterol</td></tr>
<tr><td>11</td><td>CL-C (Chloride)</td></tr>
<tr><td>12</td><td>CreaC (Creat)</td></tr>
<tr><td>13</td><td>GGT</td></tr>
<tr><td>14</td><td>Glucose</td></tr>
<tr><td>15</td><td>K-C (Potassium)</td></tr>
<tr><td>16</td><td>NA-C (Sodium)</td></tr>
<tr><td>17</td><td>Phosphate</td></tr>
<tr><td>18</td><td>Total Protein (TP)</td></tr>
<tr><td>19</td><td>Triglyceride</td></tr>
<tr><td>20</td><td>Uric Acid (UA)</td></tr>
<tr><td>21</td><td>HDL Cholesterol</td></tr>
<tr><td>22</td><td>Urea</td></tr>
<tr><td>23</td><td>Troponin I or Troponin T</td></tr>
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</td></tr>
<tr><td>226</td><td>All the assay kits must be CE & IVD - marked.</td></tr>
<tr><td>227</td><td>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.</td></tr>
<tr><td>228</td><td>Vendor shall provide the test methods and technology of the analyzers and a list of current users in the region.</td></tr>
<tr><td>229</td><td>INITIAL METHOD VERIFICATION
Vendor must perform a complete method verification of all the tests across all mirror analyzers, including, but not limited to: -

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.

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.

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.</td></tr>
<tr><td>230</td><td>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’.</td></tr>
<tr><td>231</td><td>Analyzers able to do intra-cup replicates.</td></tr>
</table>

NO.	SPECIFICATIONS AND REQUIREMENTS
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 (preferrable).

NO.	SPECIFICATIONS AND REQUIREMENTS
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: - 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
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	Weekly maintenance 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
	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	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 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.
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	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. • 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
	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 ^{o}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 sall 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 (clod 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
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 *ad hoc* verification studies including reagent lot verification **(except for initial method verification and method verification during assay method change / formula change).**

NO.	SPECIFICATIONS AND REQUIREMENTS
	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. ▪ ^ 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.* ▪ *Slow usage reagents for PIHM are Amylase, Calcium, Direct Bili & Phosphate*
374	Vendor to submit a sample 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	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. 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.
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	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: 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	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 (*Lembaga Tawaran Kecil*).
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	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.
385	**DELIVERY PERIOD:** Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order
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).

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)	Dilu ent for dilu tion

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)	Dilu ent for dilu tion

SECTION 3

FORMS TO BE USED

CONTENTS

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						

	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$)**	**TOTAL COSTS (B$)**
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						

	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$)**	**TOTAL COSTS (B$)**
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						

	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$)**	**TOTAL COSTS (B$)**
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						

	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$)**	**TOTAL COSTS (B$)**
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						

	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$)**	**TOTAL COSTS (B$)**
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						

	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$)**	**TOTAL COSTS (B$)**
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)

	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$)**	**TOTAL COSTS (B$)**
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						

	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$)**	**TOTAL COSTS (B$)**
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	VENDOR'S OFFER (PLEASE STATE) (Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy)
1	**GENERAL TLA REQUIREMENTS (RIPASH)**	
2	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: 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) 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. *= Lab test workload (during a typical non-public holiday): ▪ 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) **= Laboratory turnaround time (TAT) requirement: ▪ 2 hours for A/E and inpatient samples, ▪ Outpatient samples received at 11.00AM to be resulted by 4.30PM the same day.	**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**.

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)
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 *Go-Live* 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. 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.	

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)
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** ▪ Please provide description of STAT prioritization during peak sample saturation on the system's track. ▪ STAT prioritization *throughout* the majority of the components of the TLA system is preferred.	
16	▪ **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.** Note: ▪ TAT defined as the period from registration time and result generated by analysers ▪ Priority of samples is by: 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.	

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)
19	Have an initial loading capacity of ≥ 300 sample tubes of varying conditions (variable sample loading bays) as follows or equivalent: - 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: - 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	

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)
	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.	

<table>
<tr><th>NO.</th><th>SPECIFICATIONS AND REQUIREMENTS</th><th>VENDOR'S OFFER
(PLEASE STATE)
(Vendor's offer in Word format in a portable USB drive to be submitted together with the hardcopy)</th></tr>
<tr><td>43</td><td>ANALYZERS (RIPASH)</td><td></td></tr>
<tr><td>44</td><td>▪ 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).</td><td></td></tr>
<tr><td>45</td><td>- <u>RIPASH TEST MENU</u>
The analyzers must have the following test menu within the TLA system: -

<table>
<tr><th>No.</th><th>Test Name</th></tr>
<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>
<tr><td>13</td><td>Beta-HCG</td></tr>
<tr><td>14</td><td>Bicarbonate</td></tr>
<tr><td>15</td><td>Bili Direct (DBIL)</td></tr>
</table></td><td></td></tr>
</table>

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)
	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)	

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)
	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	

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)
	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)	

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)
	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	

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)
	affected by 'Hook Effect'.	
52	**THROUGHPUT (RIPASH)**	
53	Vendor shall offer a suitable number of chemistry and immunoassay analyzers to achieve the following throughput: - ▪ 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): - 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	

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)
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 ≥ 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: - 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	All the PCs must have optimal storage, RAM, processor and updated operating system to handle heavy middleware, LIS and TLA track management software activity. Work activity that will be done on these PCs include but not limited to: - 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. 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.	
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	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). Alternatively, vendor may generate the statistical analysis reports using data provided by the laboratory.	
102	**IN-DEPTH MIDDLEWARE & QC MANAGEMENT SOFWARE 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.	

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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	**Vendor shall provide protocol for re-evaluation of results from a period of compromised analytical performance** ▪ 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. Please describe how your middleware will be able to do this.	
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	**AFTER SALES SUPPORT (RIPASH)**	

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140	**Two (2) technical staffs (unless stated otherwise) that shall work on-site according to the working hours below:** **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.** Vendor shall provide **replacement staff if any of the two staff is unable to attend to work.** **The staffs must be:** 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	**Technical staff job scope:** 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	All periodic maintenance 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: 1. Power requirements 2. Water requirements 3. Heat generation 4. Measurements and weight of the TLA components	

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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.	
191	Onsite assessment can be arranged with prior notification and agreement of head of National Clinical Chemistry Reference Laboratory.	
192	The vendor shall ensure that the maximum structural loading limits of all floors where TLA system is to be installed are not exceeded. 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). 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. 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.	
193	Should the TLA system configuration requires moving the power outlets, work benches, desks, water pipes, waste pipes, lockers, biosafety cabinet and others,	

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	vendor shall be responsible to **relocate these items and bear the costs.**	
194	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. ▪ 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. 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	
195	Please provide specification for power requirement. Vendor's TLA system must not exceed the laboratory's existing electric current capacity. 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. All the electrical wires shall be covered with PVC trunk properly for safety precautions.	

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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 (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 ^{o}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: 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	**INITIAL METHOD VERIFICATION** Vendor must perform a complete method verification of all the tests across all mirror analyzers, including, but not limited to: - 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. 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. 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.	
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.	

<table>
<tr><th>NO.</th><th>SPECIFICATIONS AND REQUIREMENTS</th><th>VENDOR'S OFFER
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<tr><td>220</td><td>The scope of testing and commissioning shall also include visual inspection for damage and/or corrosion of TLA system, safety, and neatness.</td><td></td></tr>
<tr><td>221</td><td>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.</td><td></td></tr>
<tr><td>222</td><td>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.</td><td></td></tr>
<tr><td>223</td><td>ANALYZERS FOR CLINICAL CHEMISTRY LAB (PIHMH)</td><td></td></tr>
<tr><td>224</td><td>▪ 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</td><td></td></tr>
<tr><td>225</td><td><u>PIHM Hospital TEST MENU</u>

<table>
<tr><th>No.</th><th>Test Name</th></tr>
<tr><td>1</td><td>Alanine Transaminase (ALT)</td></tr>
<tr><td>2</td><td>Albumin (ALB)</td></tr>
<tr><td>3</td><td>Alkaline Phosphatase (ALP)</td></tr>
<tr><td>4</td><td>Amylase</td></tr>
<tr><td>5</td><td>BILI DIRECT</td></tr>
<tr><td>6</td><td>BILI TOTAL</td></tr>
<tr><td>7</td><td>CO2C Bicarbonate</td></tr>
<tr><td>8</td><td>CRP16</td></tr>
<tr><td>9</td><td>Calcium</td></tr>
<tr><td>10</td><td>Cholesterol</td></tr>
</table></td><td></td></tr>
</table>

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)
	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: - 1. Precision 2. Accuracy 3. Linearity	

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)
	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. 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. 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.	
230	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'.	
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.	

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)
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)**	

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)
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 (preferrable).	
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.	

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)
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.	

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)
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)	

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)
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	Weekly maintenance 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)	

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)
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	

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)
	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	

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)
330	**ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS (PIHMH)**	
331	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 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.	
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	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. ▪ 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	

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)
	water supply is directed from the water tanks to the site of testing sufficiently. 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 ^{o}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.	

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)
	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 sall 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 (clod 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	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 *ad hoc* 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)
	during assay method change / formula change). 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. ▪ ^ 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.* ▪ *Slow usage reagents for PIHM are Amylase, Calcium, Direct Bili & Phosphate*	
374	Vendor to submit a sample 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	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. 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.	
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	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: 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 (*Lembaga Tawaran Kecil*).	
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 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				

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.				

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

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_____

_____ Tenderer's official stamp:

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

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