

SPECIFICATIONS AND REQUIREMENTS

QUOTATION REFERENCE NO:	JPKAS/IKLAN/26-27/05
TENDER NAME:	TO SUPPLY AND DELIVER MALARIA RAPID DIAGNOSTIC TEST (RDT) KITS FOR HEALTH SCREENING CENTRE, DEPARTMENT OF ENVIRONMENTAL HEALTH SERVICES

DELIVERY PERIOD AFTER PO ISSUED	2 WEEKS AT STAGGERED DELIVERY EVERY 2 MONTHS
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NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE
1	MALARIA RAPID DIAGNOSTIC TEST - To include all necessary consumables and reagents required to run the test such as droppers and buffers.	25 TESTS PER BOX OR EQUIVALENT	60,000 TESTS


 15/9

NO.	SPECIFICATIONS AND REQUIREMENTS
1	Quotation shall include supply and delivery of malaria kits.
2	Vendor to provide one (1) pack of test strip for SAMPLE with tender document.
3	All malaria kits supplied throughout this tender shall have a minimum expiry date of one (1) year on delivery. Should the reagent be urgently needed, provision of a reagent test kit with expiry date of less than one (1) year should be first agreed by Haematology Laboratory before delivery is made.
4	Vendor shall ensure temperature during delivery of the test kits is between 15-30°C. Record of temperature during delivery shall be made available when requested.
5	Certification of quality control of every Lot of test kit shall be provided for every delivery (batch) that indicates analytical sensitivity, analytical specificity, and accuracy and of the test method.
6	Methodology of the malaria kit should comply with ISO 13485 certification, (globally recognized system for the design, development and manufacture of medical devices).
7	Procedure for testing should be easy to be used by the healthcare professional.
8	Test method shall have indication of CE marked or FDA approved. Documentation of conformity shall be provided with tender document.
9	Test kits shall be packaged in a primary and secondary boxes that indicate name or trade name of test included, batch/lot number included, expiry date/shelf life included and name of manufacturer
10	WHO-prequalified RDT will be preferred or must comply with; a. Able to detect all four human malaria mainly <i>P. falciparum</i> and <i>P. vivax</i> b. The panel detection score must be at least 75% at 200 parasites/ μL for both <i>P. falciparum</i> and <i>P. vivax</i>. c. False positive rate should be less than 10% d. The invalid rate should be less than 5%
11	Each test kit should be individually/single packed complete with sample transfer device/dropper and product insert.
12	Each test kit should be in a cassette format. For Quality Control - must has its own built-in quality control indicator
13	Result should be able to be read at 10 minutes or less. Less time will be preferred.
14	Lot testing for Quality Control will be done by Haematology lab during the course of one year and if during this time, the kit failed the test, it is the responsibility of the vendor to replace new kits.
15	Vendor shall provide the following on-site training at no additional cost during tenure of 1 (one) year contract and to submit the evidence of training conducted to the POCT Section: • New users training • Refresher training or continuous education to update the users

DELIVERY PERIOD AFTER PO ISSUED	2 WEEKS AT STAGGERED DELIVERY EVERY 2 MONTHS (UPON USER'S REQUEST)		
Unit	Foreign Workers Health Screening Centre Berakas		
Lab/Section/Unit Ref No.:	JPKAS/UPP/QTN/23-24/6		
Person to Contact	Name	SITI JUSRINA JUMA'AT / DK HANI MASTIKA BINTI PG SULAIMAN	
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JPKAS/IKLAN/26-27/05

TO SUPPLY AND DELIVER MALARIA RAPID DIAGNOSTIC TEST (RDT) KITS FOR FOREIGN WORKERS HEALTH SCREENING CENTRE, DEPARTMENT OF ENVIRONMENTAL HEALTH SERVICES

15/19.

QUOTATION FORM

QUOTATION REFERENCE NO:	JPKAS/IKLAN/26-27/05
QUOTATION NAME:	TO SUPPLY AND DELIVER MALARIA RAPID DIAGNOSTIC TEST (RDT) KITS FOR HEALTH SCREENING CENTRE, DEPARTMENT OF ENVIRONMENTAL HEALTH SERVICES

USER'S REQUIREMENTS				VENDOR'S OFFER					
NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE REQUIRED	ITEM DESCRIPTIONS AND SPECIFICATIONS	PART/ CATALOGUE NUMBER AND BRAND	PACKAGING SIZE	TOTAL QUANTITY OFFERED/ YEAR	*COST PER UNIT (B\$)	TOTAL COSTS (B\$)
1	MALARIA RAPID DIAGNOSTIC TEST To include all necessary consumables and reagents required to run the test such as droppers and buffers.	25 TESTS PER BOX OR EQUIVALENT	60,000 TESTS						

JPKAS/IKLAN/26-27/05

TO SUPPLY AND DELIVER MALARIA RAPID DIAGNOSTIC TEST (RDT) KITS FOR HEALTH SCREENING CENTRE, DEPARTMENT OF ENVIRONMENTAL HEALTH SERVICES


15/9

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
1	Quotation shall include supply and delivery of malaria kits.	
2	Vendor to provide one (1) pack of test strip for SAMPLE with quotation document.	
3	All malaria kits supplied throughout this tender shall have a minimum expiry date of one (1) year on delivery. Should the reagent be urgently needed, provision of a reagent test kit with expiry date of less than one (1) year should be first agreed by Foreign Workers Health Screening Centre before delivery is made.	
4	Vendor shall ensure temperature during delivery of the test kits is between 15-30°C. Record of temperature during delivery shall be made available when requested.	
5	Certification of quality control of every Lot of test kit shall be provided for every delivery (batch) that indicates analytical sensitivity, analytical specificity, and accuracy and of the test method.	
6	Methodology of the malaria kit should comply with ISO 13485 certification, (globally recognized system for the design, development and manufacture of medical devices).	
7	Procedure for testing should be easy to be used by the healthcare professional.	
8	Test method shall have indication of CE marked or FDA approved. Documentation of conformity shall be provided with tender document.	
9	Test kits shall be packaged in a primary and secondary boxes that indicate name or trade name of test included, batch/lot number included, expiry date/shelf life included and name of manufacturer	

JPKAS/KLAN/26-27/05

TO SUPPLY AND DELIVER MALARIA RAPID DIAGNOSTIC TEST (RDT) KITS FOR HEALTH SCREENING CENTRE, DEPARTMENT OF ENVIRONMENTAL HEALTH SERVICES

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NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
10	WHO-prequalified RDT will be preferred or must comply with; - Able to detect all four human malaria mainly <i>P. falciparum</i> and <i>P. vivax</i> - The panel detection score must be at least 75% at 200 parasites/ μL for both <i>P. falciparum</i> and <i>P. vivax</i>. - False positive rate should be less than 10% - The invalid rate should be less than 5%	
11	Each test kit should be individually/single packed complete with sample transfer device/dropper and product insert.	
12	Each test kit should be in a cassette format. For Quality Control - must has its own built-in quality control indicator	
13	Result should be able to be read at 15 minutes or less. Less time will be preferred.	
14	Lot testing for Quality Control will be done by Haematology lab during the course of one year and if during this time, the kit failed the test, it is the responsibility of the vendor to replace new kits.	
15	Vendor shall provide the following on-site training at no additional cost during tenure of 1 (one) year contract and to submit the evidence of training conducted to the POCT Section: - New users training - Refresher training or continuous education to update the users	
16	Delivery Period shall be 2 weeks at staggered delivery every two months (Upon user's request)	

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