REFERENCE OF TENDER	DESCRIPTION OF TENDER	TIME PERIOD OF TENDER	DEPARTMENT/ DIVISION/UNIT REQUESTING TENDER	FEES	CLOSING DATE NOT LATER THAN 2.00PM	FOCAL PERSON
KK/226/2024/LAB(TC)	TO SUPPLY AND DELIVER TESTING KITS FOR RAPID MOLECULAR RESISTANCE GENE DETECTION WITH RENTAL ANALYSER SYSTEM FOR THE NATIONAL MYCOBACTERIA REFERENCE LABORATORY AND NATIONAL CLINICAL MICROBIOLOGY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF THREE(3) YEARS	3 YEARS	DEPARTMENT OF LABORATORY SERVICES	$500.00	29TH OCT 2024	*Abdul Hafiz Aqillah bin Haji Mahri* *National Clinical Microbiology Reference Laboratory* *Department of Laboratory Services* *Ministry of Health* *Negara Brunei Darussalam* *Contact No: 2221821 ext: 136* *email: hafiz.mahri@moh.gov.bn*

NOMBOR TAWARAN: KK/226/2024/LAB(TC)

KEMENTERIAN KESIHATAN
NEGARA BRUNEI DARUSSALAM

TO SUPPLY AND DELIVER TESTING KITS FOR RAPID MOLECULAR RESISTANCE GENE DETECTION WITH RENTAL ANALYSER SYSTEM FOR THE NATIONAL MYCOBACTERIA REFERENCE LABORATORY AND NATIONAL CLINICAL MICROBIOLOGY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF THREE(3) YEARS

YURAN TAWARAN: $500.00

NOMBOR RESIT :

TARIKH TUTUP : HARI SELASA, 29HB OKTOBER 2024

JAM : 2.00 PETANG

KEPADA :

PENGERUSI LEMBAGA TAWARAN KECIL
PETI TAWARAN, TINGKAT BAWAH
BANGUNAN KEMENTERIAN KESIHATAN
COMMONWEALTH DRIVE
BANDAR SERI BEGAWAN BB 3910
NEGARA BRUNEI DARUSSALAM

(CLUSTERING)

SECTION 2

SPECIFICATIONS AND REQUIREMENTS

TENDER REFERENCE NO: KK/226/2024/LAB(TC)

INVITATION TO TENDER

TO SUPPLY AND DELIVER TESTING KITS FOR RAPID MOLECULAR RESISTANCE GENE DETECTION WITH RENTAL ANALYSER SYSTEM FOR THE NATIONAL MYCOBACTERIA REFERENCE LABORATORY AND NATIONAL CLINICAL MICROBIOLOGY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF THREE (3) YEARS

DELIVERY PERIOD	**PREFERABLY 4 – 8 WEEKS AND NO LATER THAN 12 WEEKS AFTER ISSUE OF PURCHASE ORDER**

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
1	**Rapid Molecular Test for Detection of *Mycobacterium tuberculosis* complex (MTBC) DNA and Rifampicin (RIF) resistance gene(s)** 1. Each kit shall contain: a. Utilises a cartridge based nucleic acid amplification test that detects RIF resistance [surrogate marker for multidrug resistance TB (MDR-TB)]. b. Single-use disposable assay cartridge that holds the samples, the PCR reagents and host the PCR process. c. Sample reagent bottles. d. Disposable transfer pipettes. 2. Assay cartridge shall also contain: a. Reagents for the <u>detection of MTBC and RIF resistance.</u> b. Sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor for the presence of inhibitor(s) in the PCR reaction and subsequent melt peak detection. c. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. 3. Unprocessed sputum samples or concentrated sediments prepared from induced or expectorated	50 TESTS/KIT	36 KITS

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
	sputum can be used as starting material. 4. Assay cartridge must be self-contained to minimize cross-contamination between samples. 5. Can be stored at 2 – 28^{o}C. 6. Cartridges must be compatible with the analyser described in 2.1. 7. Software and/or kits used to calibrate the analyser described in 2.1.		
2	**Rapid Molecular Test for Detection of *Mycobacterium tuberculosis* complex (MTBC) DNA and Extensively-Drug Resistance gene(s)** 1. Each kit shall contain: a. Utilises a cartridge based nucleic acid amplification test for further detection of extensively-drug resistance genes, i.e., detects resistance to isoniazid, ethionamide, fluorquinolones and second-line injectable (markers for extensively-drug resistance TB (XDR-TB). b. Single-use disposable assay cartridge that holds the samples, the PCR reagents and host the PCR process. c. Sample reagent bottles. d. Disposable transfer pipettes. 2. Assay cartridge shall contain: a. Reagents for the detection of <u>XDR MTB profile.</u> b. Sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor the presence of inhibitor(s) in the PCR reaction. c. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. 3. Unprocessed sputum samples, concentrated sediments prepared from sputum, or BD™ Mycobacterial Growth Indicator Tube (MGIT™) culture can be used as starting material. 4. Assay cartridge must be self-contained to minimize cross-contamination between samples. 5. Can be stored at 2-28^{o}C.	10 TESTS/KIT	1 KIT

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
	6. Cartridges must be compatible with the analyser described in 2.1. 7. Software and/or kits used to calibrate the analyser described in 2.1.		
3	**QC panel for *Mycobacterium tuberculosis* (MTB) and Mutations Associated with Multi-Drug Resistant MTB (MDR-TB).** 1. Use as a 3rd party quality control to monitor the nucleic acid detection of MTB and the mutations associated with multi-drug resistant MTB (MDR-TB). 2. Consists of three (3) positive controls that comprised of the following MTB gene segments: - *IS6110,* - *IS1081,* - *hsp65,* - *16S rRNA,* - *23S rRNA,* - *inhA,* - *katG*, - *rpoB;* and - one (1) negative control. 3. Can be stored at 2-8°C. 4. Tested and compatible to be used with analyser described in 2.1.	3 SETS OF POSITIVE AND NEGATIVE CONTROLS/KIT	4 KITS
4	**QC panel for Extensively Drug Resistant *Mycobacterium tuberculosis* (XDR-TB).** 1. Use as a 3rd party quality control to monitor analytical performance of the extraction, amplification and detection steps of *in-vitro* laboratory nucleic acid testing procedures for the qualitative detection of extensively drug resistant *M. tuberculosis* (XDR-TB). 2. Consists of two (2) positive controls that comprised of the following MTB gene segments: - *eis* promoter, - *fabG1,* - *gyrA,* - *gyrB,* - *inhA* promoter, - *katG,* - *oxyR-ahpC* - *rrs;* and - *One (*1) negative control. 3. Can be stored at 2-8°C. 4. Tested and compatible to be used with analyser described in 2.1.	5 SETS OF POSITIVE AND NEGATIVE CONTROLS/KIT	1 KIT

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
5	**Rapid Molecular Test for Detection and Differentiation of KPC, NDM, VIM, OXA-48 and IMP.** 1. Inclusive of all reagents and consumables required for qualitative test for the rapid detection and differentiation of KPC, NDM, VIM, OXA-48 and IMP gene sequences associated with carbapenem-non-susceptibility. This includes but not limited to: a. Individually wrapped and sterile specimen collection swab used for collection, transport and preservation of clinical specimens. b. Assay kit containing single-used disposable assay cartridges with integrated reaction tubes, sample reagent vials, disposable transfer pipettes, and package insert (IFU). c. Software and/or kits used to calibrate the analyser described in 2.1. 1. Utilises automated real-time polymerase chain reaction (PCR). 2. The assay kit can be performed on carbapenem-non-susceptible pure colonies of Enterobacteriaceae, *Acinetobacter baumannii*, or *Pseudomonas aeruginosa* grown on blood agar or MacConkey agar and on rectal and perirectal swab specimens. 3. Specimen collection swab - double regular size rayon swab with plastic applicator packaged with plastic round bottom tube containing Liquid Stuart medium. 4. The swab containing sample can be stored for up to 6 hours at room temperature and 7 days at 2-8°C before testing. 5. Assay cartridges shall contain built-in quality controls which includes: a. Sample processing control – to verify adequate processing of the sample. b. Probe check control – to verify bead rehydration, reaction tube filling, probe integrity, and dye stability. 6. Assay cartridges must be self-contained to minimize cross-contamination between samples. 7. Turnaround time: < 50 mins.	10 TESTS/KIT	200 KITS

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
	8. Assay cartridges can be stored at 2-28°C. 9. Must be compatible with the analyser described in 2.1.		
6	**Multivalent external controls (QC panel) for detection and differentiation of beta-lactamase gene sequences.** 1. Used as an external quality control to monitor the detection and differentiation of 5 beta-lactamase gene sequences (*bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP-1) 2. Includes external positive control which carries all 5 beta-lactamase gene sequences (KPC, NDM, VIM, OXA-48 and IMP) and external negative control which does not carry any beta lactamase gene sequences. 3. Can be stored refrigerated at 2-8°C. 4. Can be tested together with item 5 on the offered analyser described in 2.1.	6 SETS OF POSITIVE AND NEGATIVE CONTROLS/KIT	3 KITS

***Cost per test shall be stated for items 1, 2 & 5 and cost per kit shall be stated for items 3, 4 &**

<table>
<tr><th>NO.</th><th>SPECIFICATIONS AND REQUIREMENTS</th></tr>
<tr><td>1.0</td><td>PROVISION OF EQUIPMENT</td></tr>
<tr><td></td><td>1.1 Supply, deliver, install and commission free of charge to the Government FULLY AUTOMATED RAPID MOLECULAR DIAGNOSTIC ANALYSER FOR CARTRIDGE BASED NUCLEIC ACID AMPLIFICATION TEST FOR DETECTION OF RESISTANCE GENES IN MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) AND CARBAPENEM NON-SUSCEPTIBLE BACTERIA. This system shall include:
a. Two (2) units of 4-modules Processing Unit.
b. Two (2) units of barcode reader for scanning the barcode label of the assay cartridge.
c. Two (2) units of UPS for the system modules.
d. Two (2) units of PC/Laptop with Laser Printer and hard-drive (for pre and post analytical processes).</td></tr>
<tr><td>2.0</td><td>EQUIPMENT SPECIFICATION</td></tr>
<tr><td></td><td>2.1 <u>4-modules Processing Unit</u>
<table>
<tr><td>Technology</td><td>:</td><td>Fully automated and integrated real-time Polymerase Chain Reaction (RT-PCR).</td></tr>
<tr><td>Category</td><td>:</td><td>CBNAAT (Cartridge Based Nucleic Acid Amplification Test).</td></tr>
<tr><td>Capacity</td><td>:</td><td>4 cartridges/samples.</td></tr>
<tr><td>Dimensions</td><td>:</td><td>25-30 x 30-35 x 25-30 cm.</td></tr>
<tr><td>Power supply</td><td>:</td><td>100 – 240V, 50/60 Hz.</td></tr>
<tr><td>Heating ramp rate</td><td>:</td><td>10^{o} per second between a range of 50^{o}C to 95^{o}C.</td></tr>
<tr><td>Maximum Cooling rate</td><td>:</td><td>2.5^{o}C per second between 90^{o}C to 50^{o}C.</td></tr>
<tr><td>Programmable ramp rate</td><td>:</td><td>0.01^{o}C/s to 1.0^{o}C/s.</td></tr>
<tr><td>Data Storage</td><td>:</td><td>Unlimited, archive 4000 tests at a time.</td></tr>
<tr><td>Features</td><td>:</td><td>▪ Ability to perform detection of Mycobacterium tuberculosis complex DNA (MTBC) and drugs resistance genes simultaneously.
▪ Ability to perform detection of carbapenem non-susceptible bacteria.
▪ Ability to run 4 tests independently at any given time.
▪ Ability to produce results in <2 hour.
▪ Easy-to-use technology for all staff levels.</td></tr>
</table>
2.2 <u>Laptop with hard-drive, printer and scanner</u>
▪ Equipped with latest Windows software.
▪ Laser Printer – for double sided printing with free-of-charge supply of black ink cartridges and to be delivered as required.
▪ Hard-drive for further backup of information.</td></tr>
<tr><td>3.0</td><td>TECHNICAL SPECIFICATIONS</td></tr>
<tr><td>3.1</td><td>Main System
3.1.1 An onboard trouble-shooting guide should be available.
3.1.2 List details on daily and periodic maintenance including time required to perform the maintenance and to restart analysis.
3.1.3 Calibration and periodic temperature checks are available.
3.1.4 Capability for interfacing to LIS (i.e., BruHIMS) when required and to include update of middleware/ software as indicated by the system.</td></tr>
<tr><td>3.2</td><td>Reagent System
3.2.1 State the shelf-life of individual test reagents and the handlings of short- life reagents (willing to replace those reagents nearer to expiry date if not used up).
3.2.2 The operator should carry out nil or minimum reagent preparation.
3.2.3 A reagent inventory should be kept and updated in real- time.
3.2.4 Stock of the test kit and accessories should be available at the local representative as contingency.</td></tr>
</table>

NO.	SPECIFICATIONS AND REQUIREMENTS
4.0	**SERVICE AND AFTER SALES SUPPORT**
4.1	All reagent test kits supplied throughout this tender shall have a minimum expiry date of six **(6) months on delivery**. Should the reagent be urgently needed, provision of a reagent test kit or consumable with expiry date of less than six (6) months should be first agreed by the User of the particular laboratory before delivery is made.
4.2	Letter of Undertaking (LOU) shall be produced upon each delivery of test kit or consumable with expiry date of less than **six (6)** months and vendor shall declare in the LOU that unused, unopened, expired kits will be replaced accordingly. For items which are known to have short expiry date, list down all such items and vendor shall declare in this tender submission of such items and shall be exempted from submitting LOU upon delivery.
4.3	Staggered delivery every 3 months period directly to the User.
4.4	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.
4.5	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 mentioned in para 4.1 calculated from delivery date. 4. Leakage upon delivery.
4.6	Please supply details of the arrangement for 24-hour service support. There should preferably be remote diagnostic facility available. This should include the number of engineers and application specialist, their qualification/training with the system, response time during office hours, after office hours, weekdays and weekends.
4.7	The supplier SHALL be responsible for the preventive maintenance (Weekly, Monthly, and Quarterly as needed) and breakdown maintenance of the analyser(s). Any breakdown should be quickly attended to within the day.
4.8	A copy of service report must be submitted to the laboratory whenever service work is done on the instrument.
4.9	Spare parts SHALL be supplied by the supplier free of charge, should any replacement is required during preventive and breakdown maintenance.
4.10	Backup is particularly important for all aspects of the system. The proposed system should be provided with backup instruments and should be able to perform the same test parameters.
4.11	Vendor shall aid the user with verification of a comprehensive methods performance for all of the tests listed above including, but not limited to, precision, accuracy, linearity, sensitivity, specificity, carryover, limit of detection or as required by the User depending on the nature of testing and requirement of ISO 15189:2022. Report of the verification study shall be submitted to the User for approval by the Director of Laboratory Services.
4.12	All reagents and consumables used for troubleshooting and/or verification studies are borne by the supplier.
4.13	In the event of test results cannot be produced due to equipment failure or unavailable reagent supplies within the specified turnaround time, the vendor shall arrange and bear all costs for analysis of tests to an accredited laboratory (ISO 15189).
5.0	**ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS**
5.1	The system shall occupy space as per dimensions stated in 2.1. If any renovation (electrical and/or environmental) is required, costs shall be borne by Vendor.
5.2	Should any renovation is 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.

NO.	SPECIFICATIONS AND REQUIREMENTS
5.3	Power and water requirements: No or low water consumption. If water is required, state how much and what purity, with provision of water purification system included. Please provide specification for power requirement. All costs for installing electrical and water requirements shall be borne by the Vendor. All the electrical wires shall be covered with PVC trunk properly for safety precautions.
5.4	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.
5.5	Temperature and humidity requirement: preferably 22 – 28 ^{o}C and up to 80% relative humidity.
5.6	Floor area and drainage requirements: preferably adaptable to present facilities.
5.7	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.
5.8	Low generation of hazardous chemical or biological waste.
5.9	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.
5.10	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.
6.0	**IT System**
6.1	The two analyzers shall be interfaced to our LIS (i.e. BruHIMS) through a middleware which will be provided by the successful tenderer at no additional cost. a. The middleware shall include auto-validation rules or other necessary rules. b. User shall be able to view QC results through the middleware. c. Results should be retrievable through the middleware. d. The middleware shall act as mini-LIS should the LIS is down. e. The middleware should be connected to a COLORED laser printer for printing of results. f. The software features shall include the following modules; ▪ Test management ▪ Order entry ▪ Final report printing ▪ Turnaround time monitoring ▪ Quality control monitoring ▪ Quality assurance ▪ Equipment maintenance ▪ Historical reports
7.0	**MISCELLANEOUS**
7.1	If in any event where the laboratory needs to be relocated, the supplier is responsible to decontaminate, transport and recommission the equipments where applicable. This includes method validation of the instrument, connectivity to BruHIMS and resetting of the analysers to the new lab location.
8.0	**LITERATURE**

NO.	SPECIFICATIONS AND REQUIREMENTS
8.1	To supply one (1) CD or one (1) set of hard copy of the Operating Manual and Service Manual including circuit diagrams of the equipment shall be provided upon commissioning.
8.2	To supply the laboratory with one (1) set of Material Safety Data Sheet (MSDS)
8.3	To supply hardcopy of maintenance log with list of details of daily, weekly or scheduled maintenance
8.4	To provide Certificate of Analysis (CoA) for every batch of reagents and/or consumables delivered.
9.0	**TRAINING**
9.1	Training shall be provided, at no additional cost, as follows: 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.
9.2	Certificate of competence is to be issued to all trainees after completion of training.
9.3	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.**
9.4	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.
10	**FINANCIAL AGREEMENT**
10.1	A rental agreement is required over a period of **three (3)** years for the provision of the reagent kits as per estimated total costs for this contract. However, contract agreement shall be terminated when total expenditures of supplies exceed the estimated total costs regardless of **three (3)** years contract.
10.2	Supply of the test kit including reagents, consumables and accessories is based on the number of kits required in the Purchase Order according to an agreed schedule period.
10.3	Buffer stock of the test kit including reagents, consumables and accessories should be available at the local representative as contingency.
10.4	The equipment supplied should include reagents, consumables, calibrators, maintenance record sheet, maintenance cleaning kit and quality control for initially setting up of the instruments.
10.5	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.
10.6	All costs incurred for the supply and delivery of test kit including reagents, consumables and accessories, equipment and other accessories required by the tender will be borne by the successful vendor.
10.7	**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: i. When the testing is no longer required or relevant i.e. test is obsolete, to the laboratory or department. ii. When the item(s) set out in this tender is/are no longer required by the laboratory or the Department. iii. 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

NO.	SPECIFICATIONS AND REQUIREMENTS
	user for an open advertisement subject to approval by the Mini Tender Board (*Lembaga Tawaran Kecil*).
11	**DELIVERY PERIOD:** Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order
12	**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).

* 6 months validity required for <$50K or 12 months for >$50K

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.

DELIVERY PERIOD AFTER PO ISSUED	**Preferably 4-8 weeks and no longer than 12 weeks**	
Lab/Section/Unit	NATIONAL MYCOBACTERIA REFERENCE LABORATORY	
Lab/Section/Unit Ref No.:	DLS/PU/MYB/2023/>50K/03	
Person to Contact	Name : ABDUL HAFIZ AQILAH BIN HJ MAHRI	
	E-mail : hafiz.mahri@moh.gov.bn	
	Tel. No. : 2221821 ext. 136 or 8853606	Fax No.:
FOR ADMINISTRATION USE ONLY		
PPM/PROC Ref. No.	PPM/PROC/2024/>50K/035(MYB)	
Advertisement Ref. No.		Date:

SECTION 3

FORMS TO BE USED

CONTENTS

SCHEDULE 1

TENDER FORM

To:

TENDER REFERENCE NO: KK/226/2024/LAB(TC)

INVITATION TO TENDER
TO SUPPLY AND DELIVER TESTING KITS FOR RAPID MOLECULAR RESISTANCE GENE DETECTION WITH RENTAL ANALYSER SYSTEM FOR THE NATIONAL MYCOBACTERIA REFERENCE LABORATORY AND NATIONAL CLINICAL MICROBIOLOGY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF THREE (3) YEARS

TENDER OF (*name of tenderer*) _____

Company/Business Registration No _____

Tender Closing Date _____

USER'S REQUIREMENTS				**VENDOR'S OFFER**					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
1	**Rapid Molecular Test for Detection of *Mycobacterium tuberculosis* complex (MTBC) DNA and Rifampicin (RIF) resistance gene(s)** 1. Each kit shall contain: a. Utilises a cartridge based nucleic acid amplification test that detects RIF resistance	50 TESTS/KIT	36 KITS						

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	[surrogate marker for multidrug resistance TB (MDR-TB)]. b. Single-use disposable assay cartridge that holds the samples, the PCR reagents and host the PCR process. c. Sample reagent bottles. d. Disposable transfer pipettes. 2. Assay cartridge shall also contain: a. Reagents for the <u>detection of MTBC and RIF resistance.</u> b. Sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor for the presence of inhibitor(s) in the PCR reaction and subsequent melt peak detection. c. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. 3. Unprocessed sputum samples or								

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	concentrated sediments prepared from induced or expectorated sputum can be used as starting material. 4. Assay cartridge must be self-contained to minimize cross-contamination between samples. 5. Can be stored at 2 – 28^{o}C. 6. Cartridges must be compatible with the analyser described in 2.1. 7. Software and/or kits used to calibrate the analyser described in 2.1.								
2	**Rapid Molecular Test for Detection of *Mycobacterium tuberculosis* complex (MTBC) DNA and Extensively-Drug Resistance gene(s)** 1. Each kit shall contain: a. Utilises a cartridge based nucleic acid amplification test for further detection of extensively-drug resistance genes, i.e., detects resistance to isoniazid, ethionamide,	10 TESTS/KIT	1 KIT						

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	fluorquinolones and second-line injectable (markers for extensively-drug resistance TB (XDR-TB). b. Single-use disposable assay cartridge that holds the samples, the PCR reagents and host the PCR process. c. Sample reagent bottles. d. Disposable transfer pipettes. 2. Assay cartridge shall contain: a. Reagents for the detection of <u>XDR MTB profile.</u> b. Sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor the presence of inhibitor(s) in the PCR reaction. c. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.								

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	3. Unprocessed sputum samples, concentrated sediments prepared from sputum, or BD™ Mycobacterial Growth Indicator Tube (MGIT™) culture can be used as starting material. 4. Assay cartridge must be self-contained to minimize cross-contamination between samples. 5. Can be stored at 2-28^{o}C. 6. Cartridges must be compatible with the analyser described in 2.1. 7. Software and/or kits used to calibrate the analyser described in 2.1.								
3	**QC panel for *Mycobacterium tuberculosis* (MTB) and Mutations Associated with Multi-Drug Resistant MTB (MDR-TB).** 1. Use as a 3rd party quality control to monitor the nucleic acid detection of MTB and the mutations associated with multi-drug resistant MTB (MDR-TB).	3 SETS OF POSITIVE AND NEGATIVE CONTROLS/KIT	4 KITS						

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	2. Consists of three (3) positive controls that comprised of the following MTB gene segments: - *IS6110,* - *IS1081,* - *hsp65,* - *16S rRNA,* - *23S rRNA,* - *inhA*, - *katG*, - *rpoB;* and - one (1) negative control. 3. Can be stored at 2-8°C. 4. Tested and compatible to be used with analyser described in 2.1.								
4	**QC panel for Extensively Drug Resistant *Mycobacterium tuberculosis* (XDR-TB).** 1. Use as a 3rd party quality control to monitor analytical performance of the extraction, amplification and detection steps of *in-vitro* laboratory nucleic acid testing procedures for the qualitative detection of extensively drug resistant *M. tuberculosis* (XDR-TB). 2. Consists of two (2) positive	5 SETS OF POSITIVE AND NEGATIVE CONTROLS/KIT	1 KIT						

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	controls that comprised of the following MTB gene segments: - *eis* promoter, - *fabG1,* - *gyrA,* - *gyrB,* - *inhA* promoter, - *katG,* - *oxyR-ahpC* - *rrs;* and - *One (*1) negative control. 3. Can be stored at 2-8°C. Tested and compatible to be used with analyser described in 2.1.								
5	**Rapid Molecular Test for Detection and Differentiation of KPC, NDM, VIM, OXA-48 and IMP.** 1. Inclusive of all reagents and consumables required for qualitative test for the rapid detection and differentiation of KPC, NDM, VIM, OXA-48 and IMP gene sequences associated with carbapenem-non-susceptibility. This includes but not limited to: a. Individually wrapped and sterile specimen collection	10 TESTS/KIT	200 KITS						

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	swab used for collection, transport and preservation of clinical specimens. b. Assay kit containing single-used disposable assay cartridges with integrated reaction tubes, sample reagent vials, disposable transfer pipettes, and package insert (IFU). c. Software and/or kits used to calibrate the analyser described in 2.1. 1. Utilises automated real-time polymerase chain reaction (PCR). 2. The assay kit can be performed on carbapenem-non-susceptible pure colonies of Enterobacteriaceae, *Acinetobacter baumannii*, or *Pseudomonas aeruginosa* grown on blood agar or MacConkey agar and on rectal and perirectal swab specimens. 3. Specimen collection swab - double regular size rayon swab with plastic applicator packaged with plastic round bottom tube								

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
	containing Liquid Stuart medium. 4. The swab containing sample can be stored for up to 6 hours at room temperature and 7 days at 2-8°C before testing. 5. Assay cartridges shall contain built-in quality controls which includes: a. Sample processing control – to verify adequate processing of the sample. b. Probe check control – to verify bead rehydration, reaction tube filling, probe integrity, and dye stability. 6. Assay cartridges must be self-contained to minimize cross-contamination between samples. 7. Turnaround time: < 50 mins. 8. Assay cartridges can be stored at 2-28°C. 9. Must be compatible with the analyser described in 2.1.								

USER'S REQUIREMENTS				VENDOR'S OFFER					
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 UNIT* (B$)**	**TOTAL COSTS (B$)**
6	**Multivalent external controls (QC panel) for detection and differentiation of beta-lactamase gene sequences.** 1. Used as an external quality control to monitor the detection and differentiation of 5 beta-lactamase gene sequences (*bla*KPC, *bla*NDM, *bla*VIM, *bla*OXA-48, and *bla*IMP-1) 2. Includes external positive control which carries all 5 beta-lactamase gene sequences (KPC, NDM, VIM, OXA-48 and IMP) and external negative control which does not carry any beta lactamase gene sequences. 3. Can be stored refrigerated at 2-8°C. 4. Can be tested together with item 5 on the offered analyser described in 2.1.	6 SETS OF POSITIVE AND NEGATIVE CONTROLS/KIT	3 KITS						

***Cost per test shall be stated for items 1, 2 & 5 and cost per kit shall be stated for items 3, 4 & 6.**

<table>
<tr><th>NO.</th><th>SPECIFICATIONS AND REQUIREMENTS</th><th>VENDOR'S OFFER
(PLEASE STATE)</th></tr>
<tr><td>1.0</td><td>PROVISION OF EQUIPMENT</td><td></td></tr>
<tr><td></td><td>1.1 Supply, deliver, install and commission free of charge to the Government FULLY AUTOMATED RAPID MOLECULAR DIAGNOSTIC ANALYSER FOR CARTRIDGE BASED NUCLEIC ACID AMPLIFICATION TEST FOR DETECTION OF RESISTANCE GENES IN MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) AND CARBAPENEM NON-SUSCEPTIBLE BACTERIA. This system shall include:
a. Two (2) units of 4-modules Processing Unit.
b. Two (2) units of barcode reader for scanning the barcode label of the assay cartridge.
c. Two (2) units of UPS for the system modules.
d. Two (2) units of PC/Laptop with Laptop Printer and hard-drive (for pre and post analytical processes).</td><td></td></tr>
<tr><td>2.0</td><td>EQUIPMENT SPECIFICATION</td><td></td></tr>
<tr><td></td><td>2.1 <u>4-modules Processing Unit</u>
<table>
<tr><td>Technology</td><td>:</td><td>Fully automated and integrated real-time Polymerase Chain Reaction (RT-PCR).</td></tr>
<tr><td>Category</td><td>:</td><td>CBNAAT (Cartridge Based Nucleic Acid Amplification Test).</td></tr>
<tr><td>Capacity</td><td>:</td><td>4 cartridges/samples.</td></tr>
<tr><td>Dimensions</td><td>:</td><td>25-30 x 30-35 x 25-30 cm.</td></tr>
<tr><td>Power supply</td><td>:</td><td>100 – 240V, 50/60 Hz.</td></tr>
<tr><td>Heating ramp rate</td><td>:</td><td>10^{o} per second between a range of 50^{o}C to 95^{o}C.</td></tr>
<tr><td>Maximum Cooling rate</td><td>:</td><td>2.5^{o}C per second between 90^{o}C to 50^{o}C.</td></tr>
<tr><td>Programmable ramp rate</td><td>:</td><td>0.01^{o}C/s to 1.0^{o}C/s.</td></tr>
<tr><td>Data Storage</td><td>:</td><td>Unlimited, archive 4000 tests at a time.</td></tr>
<tr><td>Features</td><td>:</td><td>▪ Ability to perform detection of Mycobacterium tuberculosis complex DNA (MTBC) and drugs resistance genes simultaneously.</td></tr>
</table></td><td></td></tr>
</table>

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	▪ Ability to perform detection of carbapenem non-susceptible bacteria. ▪ Ability to run 4 tests independently at any given time. ▪ Ability to produce results in <2 hour. ▪ Easy-to-use technology for all staff levels. 2.2 **Laptop with hard-drive, printer and scanner** ▪ Equipped with latest Windows software. ▪ Laser Printer – for double sided printing with free-of-charge supply of black ink cartridges and to be delivered as required. ▪ Hard-drive for further backup of information.	
3.0	**TECHNICAL SPECIFICATIONS**	
3.1	**Main System** 3.1.1 An onboard trouble-shooting guide should be available. 3.1.2 List details on daily and periodic maintenance including time required to perform the maintenance and to restart analysis. 3.1.3 Calibration and periodic temperature checks are available. 3.1.4 Capability for interfacing to LIS (i.e., BruHIMS) when required and to include update of middleware/ software as indicated by the system.	
3.2	**Reagent System** 3.2.1 State the shelf-life of individual test reagents and the handlings of short- life reagents (willing to replace those reagents nearer to expiry date if not used up). 3.2.2 The operator should carry out nil or minimum reagent preparation. 3.2.3 A reagent inventory should be kept and updated in real- time. 3.2.4 Stock of the test kit and accessories should be available at the local representative as contingency.	
4.0	**SERVICE AND AFTER SALES SUPPORT**	
4.1	All reagent test kits supplied throughout this tender shall have a minimum expiry date of six **(6) months on delivery**. Should the reagent be urgently needed, provision of a reagent test kit or consumable with expiry date of	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	less than six (6) months should be first agreed by the User of the particular laboratory before delivery is made.	
4.2	Letter of Undertaking (LOU) shall be produced upon each delivery of test kit or consumable with expiry date of less than **six (6)** months and vendor shall declare in the LOU that unused, unopened, expired kits will be replaced accordingly. For items which are known to have short expiry date, list down all such items and vendor shall declare in this tender submission of such items and shall be exempted from submitting LOU upon delivery.	
4.3	Staggered delivery every 3 months period directly to the User.	
4.4	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.	
4.5	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 mentioned in para 4.1 calculated from delivery date. 4. Leakage upon delivery.	
4.6	Please supply details of the arrangement for 24-hour service support. There should preferably be remote diagnostic facility available. This should include the number of engineers and application specialist, their qualification/training with the system, response time during office hours, after office hours, weekdays and weekends.	
4.7	The supplier SHALL be responsible for the preventive maintenance (Weekly, Monthly, and Quarterly as needed) and breakdown maintenance of the analyser(s). Any breakdown should be quickly attended to within the day.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
4.8	A copy of service report must be submitted to the laboratory whenever service work is done on the instrument.	
4.9	Spare parts SHALL be supplied by the supplier free of charge, should any replacement is required during preventive and breakdown maintenance.	
4.10	Backup is particularly important for all aspects of the system. The proposed system should be provided with backup instruments and should be able to perform the same test parameters.	
4.11	Vendor shall aid the user with verification of a comprehensive methods performance for all of the tests listed above including, but not limited to, precision, accuracy, linearity, sensitivity, specificity, carryover, limit of detection or as required by the User depending on the nature of testing and requirement of ISO 15189:2022. Report of the verification study shall be submitted to the User for approval by the Director of Laboratory Services.	
4.12	All reagents and consumables used for troubleshooting and/or verification studies are borne by the supplier.	
4.13	In the event of test results cannot be produced due to equipment failure or unavailable reagent supplies within the specified turnaround time, the vendor shall arrange and bear all costs for analysis of tests to an accredited laboratory (ISO 15189).	
5.0	**ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS**	
5.1	The system shall occupy space as per dimensions stated in 2.1. If any renovation (electrical and/or environmental) is required, costs shall be borne by Vendor.	
5.2	Should any renovation is 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.	
5.3	Power and water requirements: No or low water consumption. If water is required, state how much and what purity, with provision of water purification system included. Please provide specification for power requirement. All costs for installing electrical and water requirements shall be borne by the Vendor. All the electrical wires shall be covered with PVC trunk properly for safety precautions.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
5.4	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.	
5.5	Temperature and humidity requirement: preferably 22 – 28 ^{o}C and up to 80% relative humidity.	
5.6	Floor area and drainage requirements: preferably adaptable to present facilities.	
5.7	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.	
5.8	Low generation of hazardous chemical or biological waste.	
5.9	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.	
5.10	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.	
6.0	**IT System**	
6.1	The two analyzers shall be interfaced to our LIS (i.e. BruHIMS) through a middleware which will be provided by the successful tenderer at no additional cost. a. The middleware shall include auto-validation rules or other necessary rules.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	b. User shall be able to view QC results through the middleware. c. Results should be retrievable through the middleware. d. The middleware shall act as mini-LIS should the LIS is down. e. The middleware should be connected to a COLORED laser printer for printing of results. f. The software features shall include the following modules; ▪ Test management ▪ Order entry ▪ Final report printing ▪ Turnaround time monitoring ▪ Quality control monitoring ▪ Quality assurance ▪ Equipment maintenance ▪ Historical reports	
7.0	**MISCELLANEOUS**	
7.1	If in any event where the laboratory needs to be relocated, the supplier is responsible to decontaminate, transport and recommission the equipments where applicable. This includes method validation of the instrument, connectivity to BruHIMS and resetting of the analysers to the new lab location.	
8.0	**LITERATURE**	
8.1	To supply one (1) CD or one (1) set of hard copy of the Operating Manual and Service Manual including circuit diagrams of the equipment shall be provided upon commissioning.	
8.2	To supply the laboratory with one (1) set of Material Safety Data Sheet (MSDS)	
8.3	To supply hardcopy of maintenance log with list of details of daily, weekly or scheduled maintenance	
8.4	To provide Certificate of Analysis (CoA) for every batch of reagents and/or consumables delivered.	
9.0	**TRAINING**	
9.1	Training shall be provided, at no additional cost, as follows:	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	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.	
9.2	Certificate of competence is to be issued to all trainees after completion of training.	
9.3	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.**	
9.4	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.	
10	**FINANCIAL AGREEMENT**	
10.1	A rental agreement is required over a period of **three (3)** years for the provision of the reagent kits as per estimated total costs for this contract. However, contract agreement shall be terminated when total expenditures of supplies exceed the estimated total costs regardless of **three (3)** years contract.	
10.2	Supply of the test kit including reagents, consumables and accessories is based on the number of kits required in the Purchase Order according to an agreed schedule period.	
10.3	Buffer stock of the test kit including reagents, consumables and accessories should be available at the local representative as contingency.	
10.4	The equipment supplied should include reagents, consumables, calibrators, maintenance record sheet, maintenance cleaning kit and quality control for initially setting up of the instruments.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
10.5	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.	
10.6	All costs incurred for the supply and delivery of test kit including reagents, consumables and accessories, equipment and other accessories required by the tender will be borne by the successful vendor.	
10.7	**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: i. When the testing is no longer required or relevant i.e. test is obsolete, to the laboratory or department. ii. When the item(s) set out in this tender is/are no longer required by the laboratory or the Department. iii. 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*).	
11	**DELIVERY PERIOD:** Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order	
12	**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).	

* 6 months validity required for <$50K or 12 months for >$50K

NO.	GENERAL SPECIFICATIONS	VENDOR'S OFFER
A	**Model & Brand**	
B	**Country of Origin**	
C	**Total Price Per Test (CIF): B$**	
D	**Price Ranking:**	(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:**	
M	**Equipment Whole Life Support**	
N	**Dimensions (WxHxD) cm:**	

NO.	GENERAL SPECIFICATIONS	VENDOR'S OFFER
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.

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/226/2024/LAB(TC)

INVITATION TO TENDER
TO SUPPLY AND DELIVER TESTING KITS FOR RAPID MOLECULAR RESISTANCE GENE DETECTION WITH RENTAL ANALYSER SYSTEM FOR THE NATIONAL MYCOBACTERIA REFERENCE LABORATORY AND NATIONAL CLINICAL MICROBIOLOGY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF THREE (3) 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)
1	Rapid Molecular Test for Detection of *Mycobacterium tuberculosis* complex (MTBC) DNA and Rifampicin (RIF) resistance gene(s)			
2	Rapid Molecular Test for Detection of *Mycobacterium tuberculosis* complex (MTBC) DNA and Extensively-Drug Resistance gene(s)			
3	QC panel for *Mycobacterium tuberculosis* (MTB) and Mutations Associated with Multi-Drug Resistant MTB (MDR-TB)			
4	QC panel for Extensively Drug Resistant *Mycobacterium tuberculosis* (XDR-TB)			
5	Rapid Molecular Test for Detection and Differentiation of KPC, NDM, VIM, OXA-48 and IMP			
6	Multivalent external controls (QC panel) for detection and differentiation of beta-lactamase gene sequences			

We understand as stated in the Instructions to Tenderers that Tenders without samples shall not be considered.

Tenderer's official stamp:

_____
[signature of authorized officer of Tenderer]
Name:
Designation:
Date:

FOR OFFICE USE

Date of receipt : _____

Receiving Officer : _____