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/169/2024/LAB(TC)	TO SUPPLY AND DELIVER REAGENTS AND CONSUMABLES FOR HBA_1C TESTING WITH EQUIPMENT RENTAL FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF FIVE(5) YEARS USAGE	5 YEARS	DEPARTMENT OF LABORATORY SERVICES	$100.00	27TH AUG 2024	*Mohammad Hanif bin Dr Haji Serbini* *National Clinical Chemistry Reference Laboratory* *Department of Laboratory Services* *Ministry of Health* *Negara Brunei Darussalam* *Contact No: 2242424 ext 6321* *email:* *hanif.serbini@moh.gov.bn*

NOMBOR TAWARAN: KK/169/2024/LAB(TC)

KEMENTERIAN KESIHATAN
NEGARA BRUNEI DARUSSALAM

TO SUPPLY AND DELIVER REAGENTS AND CONSUMABLES FOR HBA_1C TESTING WITH EQUIPMENT RENTAL FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF FIVE(5) YEARS USAGE

YURAN TAWARAN: $100.00

NOMBOR RESIT :

TARIKH TUTUP : HARI SELASA, 27HB OGOS 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/169/2024/LAB(TC)

INVITATION TO TENDER

TO SUPPLY AND DELIVER REAGENTS AND CONSUMABLES FOR HBA1C TESTING WITH EQUIPMENT RENTAL FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF FIVE (5) YEARS USAGE

DELIVERY PERIOD AFTER PO ISSUED	**PREFERABLY 4-8 WEEKS AND NO LONGER THAN 12 WEEKS**

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
1.	**HbA1c Reagent Test Kits** Inclusive of all reagents and consumables required for the measurement of HbA1c on HPLC analysers and POC or Compact benchtop analyser. This includes but not limited to: 1. Columns 2. Filters 3. Buffer solutions 4. Wash solutions 5. Calibrators 6. Third party Quality Controls (QCs) 7. Sample vials 8. Reagent cartridge for POC or Compact benchtop analyser 9. Third party Quality Control (QCs) for POC or Compact benchtop analyser	10, 000 Tests/Cartridge	10 Cartridges (100, 000 Tests)

***Cost per test should include the kit, control, calibrator and accessories/consumables required to run the test.**

NO.	SPECIFICATIONS AND REQUIREMENTS
1.0	**PROVISION OF EQUIPMENT**
1.1	Supply, deliver, install and commission free of charge to the government two (2) units of glycated haemoglobin analyzers to perform measurement of haemoglobin A1c (HbA1c). **Methodology**: High Performance Liquid Chromatography (HPLC).
1.2	Supply, deliver, install and commission free of charge to the government one (1) unit of point of care (POC) analyser or a compact benchtop analyser as an alternative instrument in the measurement of haemoglobin A1c (HbA1c). This instrument will have an alternative methodology to the abovementioned instrument. **Preferred Methodology**: Boronate Affinity or Boronate Fluorescene Quenching.
2.0	**EQUIPMENT SPECIFICATION**
2.1	**Overall Performance**
	2.1.1 A single sample entry point to the system is preferred. No sample preparation is required. If required, an automated mixing system of blood sample is included.
	2.1.2 The single-entry point must have the capacity in handling primary tubes as is specified below.
	2.1.3 STAT Sample port is available for loading of STAT samples.
	2.1.4 The system must be available daily with minimum daily start up time. Reagents can be loaded or replaced on the fly without disrupting routine sample loading or run.
	2.1.5 The system can be configured to automatic initialisation at pre-set time as desired by the laboratory.
	2.1.6 The system should be able to meet the laboratory's yearly workload for a period of 1 year with turnaround time (TAT) of less than 3 minutes for routine tests (400tests/day) allowing an average of 10% growth in tests per year. Turnaround time (TAT) is defined as from the time the specimen is ready for analysis to the time of releasing the result.
	2.1.7 The system must be able to load a minimum of 100 samples at one time and allow continuous sample loading. This should provide a reasonable free walk-away time.
	2.1.8 Vendor shall provide the system specifications being offered including the hardware offered. Please include the specifications brochure in the offer.
	2.1.9 Vendor shall provide a list of laboratory users currently using the system within the region.
	2.1.10 The system reports HbA1c values in both NGSP and IFCC units.
2.2	**Methodology**
	2.2.1 **HbA1c Analyser**: Preferred methodology is reversed phase cation exchange chromatography using High Performance Liquid Chromatography (HPLC) column.
	2.2.1.1 The methodology has minimal interferences from hemoglobin variants. 2.2.1.1.1 No interference from HbC, HbS, HbE and HbD traits. 2.2.1.1.2 No interference from HbF up to 30% 2.2.1.1.3 No interference from carbamylated Hb and labile HbA1c

NO.	SPECIFICATIONS AND REQUIREMENTS
	2.2.1.2 Please provide scientific studies detailing the interferences on the analyser.
	2.2.2 **POC or Compact Benchtop Analyser**: Methodology should be an alternative methodology to the abovementioned HPLC. Examples: Boronate Affinity, Boronate Fluorescence Quenching**,** Immunoassay or Enzymatic. **Preferred methodology** is **Boronate Affinity** or **Boronate Fluorescence Quenching**
	2.2.2.1 The analyser is able to measure HbA1c despite the presence of Hb variants in the sample.
	2.2.2.2 The analyser provides an alternative to HbA1c measurement when the sample cannot be analysed on the main HbA1c analyser. Preferrably the analyser doesn't have any interference from Hb variants. Vendor shall submit a scientific article on this.
	2.2.2.3 There is a minimal interference from Haemoglobin F. Please state the HbF concentrations which can cause interference on the analyser.
	2.2.2.4 Vendor shall submit scientific studies detailing the interferences on the analyser in their offer.
2.3	**Quality Performance**
	2.3.1 The system has a total analytical imprecision of less than 3.0%. Vendor shall provide a document stating this.
	2.3.2 A quality control interval setting is available to alert the laboratory users. This can be set at a pre-determined interval.
	2.3.3 Samples cannot be run or patient results are not released from the system when quality run exceeds the predetermined interval time.
	2.3.4 No or minimum carry over between samples. Vendor shall state, if any, special precautions or wash cycles required. If so, state in full details and state its turnaround time (TAT).
	2.3.5 The system preferably capable of measuring between 3.0 – 20.0%. Vendor shall state the reportable measuring range of the system.
2.4	**Calibration Traceability**
	2.4.1 The calibration system is traceable to the reference methods of both the National Glycohemoglobin Standardisation Program (NGSP) and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).
	2.4.2 The assay is certified by the NGSP. There is a documented traceability to the reference method of the Diabetes Control and Complications Trial (DCCT).
	2.4.3 A copy of NGSP and IFCC certifications should be submitted together with vendor's offer. Failure to do so is a non-compliance of abovementioned specifications.
	2.4.4. A copy of NGSP and IFCC certificates shall be supplied to the laboratory annually.
2.5	**Autoverification**
	2.5.1 The system is able to do autoverification according to established rules. The predefined rules implemented shall be agreed upon by the laboratory.
	2.5.2 Any results with warnings, flags or violation of the predefined rules are to be held on the system.
	2.5.3 All flagged results are to be held on the system and manually released by laboratory user.

NO.	SPECIFICATIONS AND REQUIREMENTS
	2.5.4 The system shall have the capability in configuration of predefined rules in reviewing each chromatogram.
	2.5.5 For chromatograms which do not violate the predefined rules, the results will be automatically transmitted to Laboratory Information System (LIS). This minimises hands-on time on the analyser in reviewing each chromatogram.
	2.5.6 The predefined autoverification rules allow individual chromatogram review step to be skipped.
	2.5.7 The system is able to transmit any predefined comments to the Laboratory Information System (LIS).
	2.5.8 There is an audit trail in the computer system that identifies all test results that were autoverified and the date/time of autoverification.
	2.5.9 The system allows rapid suspension of autoverification if there is any issue with the system.
	2.5.10 A log record of autoverification activities can be extracted from the analyser.
2.6	**POC or Compact Benchtop Analyser**
	2.6.1 The analyser reports in both NGSP (%) and IFCC (mmol/mol).
	2.6.2 A hardcopy of results can be printed out.
	2.6.3 A softcopy of results can be saved and backed-up on a computer. Automatic upload of results to a computer is preferred.
	2.6.4 No sample or reagent preparation required.
	2.6.5 Sample barcode scanner is available for safer and faster entry.
	2.6.6 Minimal or no maintenance required.
	2.6.7 Quality Control (QC) Data management is available on the analyser. If no QC data management is available on the analyser, the QC data can be entered and recorded on a separate QC data management software. The QC data management software is able to produce Levey Jennings (LJ) graphs.
	2.6.8 Vendor shall state the measurement time required for one sample
	2.6.9 Calibration of the reagent cartridge is traceable to IFCC and NGSP.
	2.6.10 A large storage or memory capacity to store calibration, quality control and patient results records.
	2.6.11 Analyser is cleared or approved by FDA or CE.
	2.6.12 Vendor shall provide the number of laboratory users using the analyser. There should be a minimum of 5 other laboratory users using the analyser.
	2.6.13 A connection between POC or Compact Benchtop analyser and the LIS for the transmission of patient results.
3.0	**TECHNICAL SPECIFICATIONS**

NO.	SPECIFICATIONS AND REQUIREMENTS
3.1	**Main System**
	3.1.1 It is envisaged that the system will be using a data manager or a middleware software linked to LIS. This can be used for data back-up, data retrieval and data monitoring.
	3.1.2 A bidirectional connection between analyser and LIS is required.
	3.1.3 LIS connection must be included, the analyser is either interfaced to our LIS or linked via middleware. This is inclusive of all required costs including for autoverification.
	3.1.4 The system shall provide a contingency procedure in the event of a LIS breakdown or downtime. Vendor shall state in details the contingency procedure available.
	3.1.5 The system, including the data manager, should be protected by an un-interrupted power supply (UPS). Please state how long the UPS will support the analyser/system while operating at full capacity.
	3.1.6 An on-board trouble-shooting guide should be available.
	3.1.7 Vendor shall list out in details the daily and periodic maintenance including the time required to perform the maintenance and the time required to restart analysis
	3.1.8 Vendor shall describe how operator-changeable parameters are backed up. Please state if password protection of these parameters is included.
	3.1.9 Patient data and quality control (QC) data back-up should be done at regular intervals. Minimum frequency of data back-up is once a month.
	3.1.10 All chromatograms shall be backed-up onto a separate computer at regular intervals. The back-up is preferred in real time.
3.2	**Reagent System**
	3.2.1 Calibration Curve Stability: Preferably a minimum of 14 days. Please provide information for the test
	3.2.2 Each reagent cartridge and buffer solutions have RFID tag.
	3.2.3. Washing solutions, buffer solutions, eluents, columns, filters and any other reagents are not lot sensitive. There should be minimal or no shifts in quality control (QC) between lot changes.
	3.2.4 State the shelf life of individual test reagents and the handlings of short shelf-life reagents. The vendor is to replace any reagents with near expiry date.
	3.2.5 Ready to use reagents and consumables are preferred.
	3.2.6 A reagent inventory should be kept and updated in real time.
	3.2.7 Material Safety Data Sheet (MSDS) shall be provided by the principal company.
	3.2.8 There should be a minimal change in lot numbers of reagents, cartridges and solutions supplied.
	3.2.9 All reagents and consumables required for testing shall be supplied by vendor. No capped quantity of reagents and consumables supply shall be set by vendor.
3.3	**Sampling System**

NO.	SPECIFICATIONS AND REQUIREMENTS
	3.3.1 System is able to recognize the laboratory sample barcode format. Please include examples of acceptable barcode labels.
	3.3.2 Able to sample primary sample tubes (4.0 mL). Sampling system uses a level sensing mechanism. Indicate an alternative procedure for samples tubes without barcodes.
	3.3.3 Indicate the minimum sample volume required for analysis.
	3.3.4 System is able to process small volume samples such as paediatric samples. For insufficient sample volume, indicate if there is any alternative procedure.
	3.3.5 System is able to load 100 samples at one time.
	3.3.6 System allows continuous sample loading.
3.4	**Quality Management System**
	3.4.1 On board Quality Control (QC) software on the analyser is provided.
	3.4.2 On board QC software includes a Levey Jennings (LJ) graph view.
	3.4.3 Westgard warning rules and alerts are available on the analyser.
	3.4.4 The analyser provides a QC failure rule whereby when the QC violates the rule, the analyser will stop analyzing samples or hold the results until the QC values have been reviewed and troubleshooting has been done.
	3.4.5 QC data management system is provided. Example: BioRAD Unity software. Please state the QC data management system provided.
	3.4.6 The QC data is automatically transmitted from the analyser to the QC data management system.
	3.4.7 The QC data management software provides the tools in monitoring the reliability, precision and performance of the laboratory testing. This includes peer to peer review and inter-instrument comparison.
	3.4.8 QC data from POC or Compact benchtop analyser can be recorded on the QC data management software. This includes LJ graph view.
3.5	**Laboratory Information System (LIS) Interface**
	3.5.1 The cost of interfacing between the analyser and/or middleware and the LIS will be borne by the vendor
	3.5.2 A personal computer (PC) shall be provided by the vendor for the LIS interface and middleware.
4.0	**SERVICE AND AFTER SALES SUPPORT**
4.1	All reagent test kits / consumables supplied throughout this tender shall have a minimum expiry date of **twelve (12) months on delivery**. Should the reagent or consumable be urgently needed, provision of a reagent test kit or consumable with expiry date of less than twelve (12) 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 twelve (12) 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 such as those containing red blood cells, list down all such items and

NO.	SPECIFICATIONS AND REQUIREMENTS
	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. State the proposed plan in ensuring there is a continuous support to the laboratory in application and technical issues. 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 analyzers. Any breakdown should be quickly attended to within 2 hours. There should not be any disruptions to the laboratory workflow due to breakdown of instruments.
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 should any replacement is required during preventive and breakdown maintenance.
4.10	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. Report of the verification study shall be submitted to the User for approval by the Director of Laboratory Services.
4.11	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).
4.12	Support is provided by a dedicated application specialist in troubleshooting any issues. This includes but not limited to analytical issues.
4.13	In the event that equipment cannot be repaired, vendor shall provide a replacement. The downtime of the equipment shall be kept to a minimum to prevent a disruption to the laboratory service.
5.0	**ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS**
5.1	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.

NO.	SPECIFICATIONS AND REQUIREMENTS
5.2	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.
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. Vendor shall perform and verify that electrical safety testing complies with laboratory requirement on rental equipment upon installation and provide the report for user acceptance. 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	Temperature and humidity requirement: preferably 22 – 28 ^{o}C and up to 80% relative humidity.
5.5	Floor area and drainage requirements: preferably adaptable to present facilities.
5.6	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.
5.7	Low generation of hazardous chemical or biological waste.
5.8	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
5.9	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	**MISCELLANEOUS**
6.1	**Accessories**
	Accessories such as, but not limited to, sample racks, waste bottles and sample tube adaptors shall be provided by the vendor.
6.2	**Storage Facility**
	A trolley or a bench shall be provided to store the two HbA1c analysers and the PC provided. This is sufficient for the storage of accessories and waste bottles of both analysers.
6.3	**Personal Computer (PC)**
	A PC shall be provided for LIS interface, middleware and patient results back-up. The computer specifications should meet the minimum requirements set by Brunei E-Government National Centre (EGNC). The memory capacity and speed should be sufficient in backing-up patient data and interfacing to LIS.

NO.	SPECIFICATIONS AND REQUIREMENTS
6.4	**Printer**
	A printer shall be provided for the purpose of patient results printing. The printer may be connected to PC and/or analyser. This includes the supply of ink cartridge toner.
6.5	**Method Validation**
	6.5.1 A method validation is required for every newly installed instrument according to ISO15189 and the department's protocol. It is also required when the instrument has been moved at a significant distance. Vendor shall assist the laboratory in performing the method validation according to the laboratory's protocol.
	6.5.2 Vendor shall submit in their offer a proposed timeline outlining the method validation program upon installation of the equipment.
	6.5.3 A method validation shall be performed on the two HbA1c analysers and POC or Compact benchtop analyser.
	6.5.4 A method validation report shall be submitted to the laboratory for review within the timeline proposed.
6.6	**Internal Quality Control (IQC) Materials**
	6.6.1 Vendor shall provide a third-party Quality Control (QC) material to the laboratory for the two HbA1c analysers and POC or Compact benchtop analyser.
	6.6.2 Vendor shall ensure the long expiry date of the QC material to minimise frequency of QC lot change.
	6.6.3 Please state the QC material proposed and submit QC brochure
7.0	**LITERATURE**
7.1	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.
7.2	To supply the laboratory with one (1) set of Material Safety Data Sheet (MSDS)
7.3	To supply hardcopy of maintenance log with list of details of daily, weekly or scheduled maintenance
7.4	To provide a library of chromatograms for reference or comparison purposes.
8.0	**TRAINING**
8.1	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.
8.2	Certificate of competence is to be issued to all trainees after completion of training.
8.3	The successful tenderer needs to ensure the key users are updated on any relevant information related to the laboratory testing. **They shall provide TWO off-site training for two (2) key users.** 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.**

NO.	SPECIFICATIONS AND REQUIREMENTS
8.4	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.
9	**FINANCIAL AGREEMENT**
9.1	A rental agreement is required over a period of five (5) 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 five (5) years contract.
9.2	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.
9.3	Buffer stock of the test kit including reagents, consumables and accessories should be available at the local representative as contingency.
9.4	The equipment supplied should include reagents, consumables, calibrators, maintenance record sheet, maintenance cleaning kit and quality control for initially setting up of the instruments.
9.5	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.
9.6	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.
9.7	**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: 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*).
10	**DELIVERY PERIOD:** Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order
11	**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).

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 Clinical Chemistry Reference Laboratory	
Lab/Section/Unit Ref No.:	DLS/PU/NCCRL/2024/14	
Person to Contact	Name : Mohammad Hanif Bin Dr Haji Serbini	
	E-mail : hanif.serbini@moh.gov.bn	
	Tel. No. : 2242424 ext. 6321	Fax No.: 2220869
FOR ADMINISTRATION USE ONLY		
PPM/PROC Ref. No.	PPM/PROC/2024/>50K/013(NCCRL)	
Advertisement Ref. No.		Date:

SECTION 3

FORMS TO BE USED

CONTENTS

SCHEDULE 1

TENDER FORM

To:

TENDER REFERENCE NO: KK/169/2024/LAB(TC)

INVITATION TO TENDER
TO SUPPLY AND DELIVER REAGENTS AND CONSUMABLES FOR HBA1C TESTING WITH EQUIPMENT RENTAL FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF FIVE (5) YEARS USAGE

TENDER OF (*name of tenderer*) _____

Company/Business Registration No _____

Tender Closing Date _____

DELIVERY PERIOD	

NO.	**USER'S REQUIREMENTS**			**VENDOR'S OFFER**					
	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.	**HbA1c Reagent Test Kits** Inclusive of all reagents and consumables required for the measurement of HbA1c on HPLC analysers and	10, 000 Tests/Cartridge	10 Cartridges (100, 000 Tests)						

NO.	USER'S REQUIREMENTS			VENDOR'S OFFER					
	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$)	TOTAL COSTS (B$)
	POC or Compact benchtop analyser. This includes but not limited to: 1. Columns 2. Filters 3. Buffer solutions 4. Wash solutions 5. Calibrators 6. Third party Quality Controls (QCs) 7. Sample vials 8. Reagent cartridge for POC or Compact benchtop analyser 9. Third party Quality Control (QCs) for POC or Compact benchtop analyser								

***Cost per test should include the kit, control, calibrator and accessories/consumables required to run the test.**

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
1.0	**PROVISION OF EQUIPMENT**	
1.1	Supply, deliver, install and commission free of charge to the government two (2) units of glycated haemoglobin analyzers to perform measurement of haemoglobin A1c (HbA1c). **Methodology**: High Performance Liquid Chromatography (HPLC).	
1.2	Supply, deliver, install and commission free of charge to the government one (1) unit of point of care (POC) analyser or a compact benchtop analyser as an alternative instrument in the measurement of haemoglobin A1c (HbA1c). This instrument will have an alternative methodology to the abovementioned instrument. **Preferred Methodology**: Boronate Affinity or Boronate Fluorescene Quenching.	
2.0	**EQUIPMENT SPECIFICATION**	
2.1	**Overall Performance**	
	2.1.1 A single sample entry point to the system is preferred. No sample preparation is required. If required, an automated mixing system of blood sample is included.	
	2.1.2 The single-entry point must have the capacity in handling primary tubes as is specified below.	
	2.1.3 STAT Sample port is available for loading of STAT samples.	
	2.1.4 The system must be available daily with minimum daily start up time. Reagents can be loaded or replaced on the fly without disrupting routine sample loading or run.	
	2.1.5 The system can be configured to automatic initialisation at pre-set time as desired by the laboratory.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	2.1.6 The system should be able to meet the laboratory's yearly workload for a period of 1 year with turnaround time (TAT) of less than 3 minutes for routine tests (400tests/day) allowing an average of 10% growth in tests per year. Turnaround time (TAT) is defined as from the time the specimen is ready for analysis to the time of releasing the result.	
	2.1.7 The system must be able to load a minimum of 100 samples at one time and allow continuous sample loading. This should provide a reasonable free walk-away time.	
	2.1.8 Vendor shall provide the system specifications being offered including the hardware offered. Please include the specifications brochure in the offer.	
	2.1.9 Vendor shall provide a list of laboratory users currently using the system within the region.	
	2.1.10 The system reports HbA1c values in both NGSP and IFCC units.	
2.2	**Methodology**	
	2.2.1 **HbA1c Analyser**: Preferred methodology is reversed phase cation exchange chromatography using High Performance Liquid Chromatography (HPLC) column.	
	2.2.1.1 The methodology has minimal interferences from hemoglobin variants. 2.2.1.1.1 No interference from HbC, HbS, HbE and HbD traits. 2.2.1.1.2 No interference from HbF up to 30% 2.2.1.1.3 No interference from carbamylated Hb and labile HbA1c	
	2.2.1.2 Please provide scientific studies detailing the interferences on the analyser.	
	2.2.2 **POC or Compact Benchtop Analyser**: Methodology should be an alternative methodology to the abovementioned HPLC. Examples: Boronate Affinity, Boronate Fluorescence Quenching**,** Immunoassay or Enzymatic. **Preferred methodology** is **Boronate Affinity** or **Boronate Fluorescence Quenching**	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	2.2.2.1 The analyser is able to measure HbA1c despite the presence of Hb variants in the sample.	
	2.2.2.2 The analyser provides an alternative to HbA1c measurement when the sample cannot be analysed on the main HbA1c analyser. Preferrably the analyser doesn't have any interference from Hb variants. Vendor shall submit a scientific article on this.	
	2.2.2.3 There is a minimal interference from Haemoglobin F. Please state the HbF concentrations which can cause interference on the analyser.	
	2.2.2.4 Vendor shall submit scientific studies detailing the interferences on the analyser in their offer.	
2.3	**Quality Performance**	
	2.3.1 The system has a total analytical imprecision of less than 3.0%. Vendor shall provide a document stating this.	
	2.3.2 A quality control interval setting is available to alert the laboratory users. This can be set at a pre-determined interval.	
	2.3.3 Samples cannot be run or patient results are not released from the system when quality run exceeds the predetermined interval time.	
	2.3.4 No or minimum carry over between samples. Vendor shall state, if any, special precautions or wash cycles required. If so, state in full details and state its turnaround time (TAT).	
	2.3.5 The system preferably capable of measuring between 3.0 – 20.0%. Vendor shall state the reportable measuring range of the system.	
2.4	**Calibration Traceability**	
	2.4.1 The calibration system is traceable to the reference methods of both the National Glycohemoglobin Standardisation Program (NGSP) and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).	
	2.4.2 The assay is certified by the NGSP. There is a documented traceability to the reference method of the Diabetes Control and Complications Trial (DCCT).	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	2.4.3 A copy of NGSP and IFCC certifications should be submitted together with vendor's offer. Failure to do so is a non-compliance of abovementioned specifications.	
	2.4.4. A copy of NGSP and IFCC certificates shall be supplied to the laboratory annually.	
2.5	**Autoverification**	
	2.5.1 The system is able to do autoverification according to established rules. The predefined rules implemented shall be agreed upon by the laboratory.	
	2.5.2 Any results with warnings, flags or violation of the predefined rules are to be held on the system.	
	2.5.3 All flagged results are to be held on the system and manually released by laboratory user.	
	2.5.4 The system shall have the capability in configuration of predefined rules in reviewing each chromatogram.	
	2.5.5 For chromatograms which do not violate the predefined rules, the results will be automatically transmitted to Laboratory Information System (LIS). This minimises hands-on time on the analyser in reviewing each chromatogram.	
	2.5.6 The predefined autoverification rules allow individual chromatogram review step to be skipped.	
	2.5.7 The system is able to transmit any predefined comments to the Laboratory Information System (LIS).	
	2.5.8 There is an audit trail in the computer system that identifies all test results that were autoverified and the date/time of autoverification.	
	2.5.9 The system allows rapid suspension of autoverification if there is any issue with the system.	
	2.5.10 A log record of autoverification activities can be extracted from the analyser.	
2.6	**POC or Compact Benchtop Analyser**	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	2.6.1 The analyser reports in both NGSP (%) and IFCC (mmol/mol).	
	2.6.2 A hardcopy of results can be printed out.	
	2.6.3 A softcopy of results can be saved and backed-up on a computer. Automatic upload of results to a computer is preferred.	
	2.6.4 No sample or reagent preparation required.	
	2.6.5 Sample barcode scanner is available for safer and faster entry.	
	2.6.6 Minimal or no maintenance required.	
	2.6.7 Quality Control (QC) Data management is available on the analyser. If no QC data management is available on the analyser, the QC data can be entered and recorded on a separate QC data management software. The QC data management software is able to produce Levey Jennings (LJ) graphs.	
	2.6.8 Vendor shall state the measurement time required for one sample	
	2.6.9 Calibration of the reagent cartridge is traceable to IFCC and NGSP.	
	2.6.10 A large storage or memory capacity to store calibration, quality control and patient results records.	
	2.6.11 Analyser is cleared or approved by FDA or CE.	
	2.6.12 Vendor shall provide the number of laboratory users using the analyser. There should be a minimum of 5 other laboratory users using the analyser.	
	2.6.13 A connection between POC or Compact Benchtop analyser and the LIS for the transmission of patient results.	
3.0	**TECHNICAL SPECIFICATIONS**	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
3.1	**Main System**	
	3.1.1 It is envisaged that the system will be using a data manager or a middleware software linked to LIS. This can be used for data back-up, data retrieval and data monitoring.	
	3.1.2 A bidirectional connection between analyser and LIS is required.	
	3.1.3 LIS connection must be included, the analyser is either interfaced to our LIS or linked via middleware. This is inclusive of all required costs including for autoverification.	
	3.1.4 The system shall provide a contingency procedure in the event of a LIS breakdown or downtime. Vendor shall state in details the contingency procedure available.	
	3.1.5 The system, including the data manager, should be protected by an un-interrupted power supply (UPS). Please state how long the UPS will support the analyser/system while operating at full capacity.	
	3.1.6 An on-board trouble-shooting guide should be available.	
	3.1.7 Vendor shall list out in details the daily and periodic maintenance including the time required to perform the maintenance and the time required to restart analysis	
	3.1.8 Vendor shall describe how operator-changeable parameters are backed up. Please state if password protection of these parameters is included.	
	3.1.9 Patient data and quality control (QC) data back-up should be done at regular intervals. Minimum frequency of data back-up is once a month.	
	3.1.10 All chromatograms shall be backed-up onto a separate computer at regular intervals. The back-up is preferred in real time.	
3.2	**Reagent System**	
	3.2.1 Calibration Curve Stability: Preferably a minimum of 14 days. Please provide information for the test	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	3.2.2 Each reagent cartridge and buffer solutions have RFID tag.	
	3.2.3. Washing solutions, buffer solutions, eluents, columns, filters and any other reagents are not lot sensitive. There should be minimal or no shifts in quality control (QC) between lot changes.	
	3.2.4 State the shelf life of individual test reagents and the handlings of short shelf-life reagents. The vendor is to replace any reagents with near expiry date.	
	3.2.5 Ready to use reagents and consumables are preferred.	
	3.2.6 A reagent inventory should be kept and updated in real time.	
	3.2.7 Material Safety Data Sheet (MSDS) shall be provided by the principal company.	
	3.2.8 There should be a minimal change in lot numbers of reagents, cartridges and solutions supplied.	
	3.2.9 All reagents and consumables required for testing shall be supplied by vendor. No capped quantity of reagents and consumables supply shall be set by vendor.	
3.3	**Sampling System**	
	3.3.1 System is able to recognize the laboratory sample barcode format. Please include examples of acceptable barcode labels.	
	3.3.2 Able to sample primary sample tubes (4.0 mL). Sampling system uses a level sensing mechanism. Indicate an alternative procedure for samples tubes without barcodes.	
	3.3.3 Indicate the minimum sample volume required for analysis.	
	3.3.4 System is able to process small volume samples such as paediatric samples. For insufficient sample volume, indicate if there is any alternative procedure.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	3.3.5 System is able to load 100 samples at one time.	
	3.3.6 System allows continuous sample loading.	
3.4	**Quality Management System**	
	3.4.1 On board Quality Control (QC) software on the analyser is provided.	
	3.4.2 On board QC software includes a Levey Jennings (LJ) graph view.	
	3.4.3 Westgard warning rules and alerts are available on the analyser.	
	3.4.4 The analyser provides a QC failure rule whereby when the QC violates the rule, the analyser will stop analyzing samples or hold the results until the QC values have been reviewed and troubleshooting has been done.	
	3.4.5 QC data management system is provided. Example: BioRAD Unity software. Please state the QC data management system provided.	
	3.4.6 The QC data is automatically transmitted from the analyser to the QC data management system.	
	3.4.7 The QC data management software provides the tools in monitoring the reliability, precision and performance of the laboratory testing. This includes peer to peer review and inter-instrument comparison.	
	3.4.8 QC data from POC or Compact benchtop analyser can be recorded on the QC data management software. This includes LJ graph view.	
3.5	**Laboratory Information System (LIS) Interface**	
	3.5.1 The cost of interfacing between the analyser and/or middleware and the LIS will be borne by the vendor	
	3.5.2 A personal computer (PC) shall be provided by the vendor for the LIS interface and middleware.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
4.0	**SERVICE AND AFTER SALES SUPPORT**	
4.1	All reagent test kits / consumables supplied throughout this tender shall have a minimum expiry date of **twelve (12) months on delivery**. Should the reagent or consumable be urgently needed, provision of a reagent test kit or consumable with expiry date of less than twelve (12) 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 twelve (12) 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 such as those containing red blood cells, 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. State the proposed plan in ensuring there is a continuous support to the	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	laboratory in application and technical issues. 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 analyzers. Any breakdown should be quickly attended to within 2 hours. There should not be any disruptions to the laboratory workflow due to breakdown of instruments.	
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 should any replacement is required during preventive and breakdown maintenance.	
4.10	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. Report of the verification study shall be submitted to the User for approval by the Director of Laboratory Services.	
4.11	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).	
4.12	Support is provided by a dedicated application specialist in troubleshooting any issues. This includes but not limited to analytical issues.	
4.13	In the event that equipment cannot be repaired, vendor shall provide a replacement. The downtime of the equipment shall be kept to a minimum to prevent a disruption to the laboratory service.	
5.0	**ENVIRONMENTAL AND INFRASTRUCTURE REQUIREMENTS**	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
5.1	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.	
5.2	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.	
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. Vendor shall perform and verify that electrical safety testing complies with laboratory requirement on rental equipment upon installation and provide the report for user acceptance. 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	Temperature and humidity requirement: preferably 22 – 28 ^{o}C and up to 80% relative humidity.	
5.5	Floor area and drainage requirements: preferably adaptable to present facilities.	
5.6	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.	
5.7	Low generation of hazardous chemical or biological waste.	
5.8	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)
	Proper guidelines to disinfect the liquid waste that is acceptable to ISO 15189 shall be provided	
5.9	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	**MISCELLANEOUS**	
6.1	**Accessories**	
	Accessories such as, but not limited to, sample racks, waste bottles and sample tube adaptors shall be provided by the vendor.	
6.2	**Storage Facility**	
	A trolley or a bench shall be provided to store the two HbA1c analysers and the PC provided. This is sufficient for the storage of accessories and waste bottles of both analysers.	
6.3	**Personal Computer (PC)**	
	A PC shall be provided for LIS interface, middleware and patient results back-up. The computer specifications should meet the minimum requirements set by Brunei E-Government National Centre (EGNC). The memory capacity and speed should be sufficient in backing-up patient data and interfacing to LIS.	
6.4	**Printer**	
	A printer shall be provided for the purpose of patient results printing. The printer may be connected to PC and/or analyser. This includes the supply of ink cartridge toner.	
6.5	**Method Validation**	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	6.5.1 A method validation is required for every newly installed instrument according to ISO15189 and the department's protocol. It is also required when the instrument has been moved at a significant distance. Vendor shall assist the laboratory in performing the method validation according to the laboratory's protocol.	
	6.5.2 Vendor shall submit in their offer a proposed timeline outlining the method validation program upon installation of the equipment.	
	6.5.3 A method validation shall be performed on the two HbA1c analysers and POC or Compact benchtop analyser.	
	6.5.4 A method validation report shall be submitted to the laboratory for review within the timeline proposed.	
6.6	**Internal Quality Control (IQC) Materials**	
	6.6.1 Vendor shall provide a third-party Quality Control (QC) material to the laboratory for the two HbA1c analysers and POC or Compact benchtop analyser.	
	6.6.2 Vendor shall ensure the long expiry date of the QC material to minimise frequency of QC lot change.	
	6.6.3 Please state the QC material proposed and submit QC brochure	
7.0	**LITERATURE**	
7.1	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.	
7.2	To supply the laboratory with one (1) set of Material Safety Data Sheet (MSDS)	
7.3	To supply hardcopy of maintenance log with list of details of daily, weekly or scheduled maintenance	
7.4	To provide a library of chromatograms for reference or comparison purposes.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
8.0	**TRAINING**	
8.1	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.	
8.2	Certificate of competence is to be issued to all trainees after completion of training.	
8.3	The successful tenderer needs to ensure the key users are updated on any relevant information related to the laboratory testing. **They shall provide TWO off-site training for two (2) key users.** 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.**	
8.4	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.	
9	**FINANCIAL AGREEMENT**	
9.1	A rental agreement is required over a period of five (5) 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 five (5) years contract.	
9.2	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.	
9.3	Buffer stock of the test kit including reagents, consumables and accessories should be available at the local representative as contingency.	
9.4	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)
9.5	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.	
9.6	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.	
9.7	**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: 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*).	
10	**DELIVERY PERIOD:** Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order	**(Yes / No)** **(If No, please specify)**
11	**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).	

NO.	GENERAL SPECIFICATIONS	VENDOR'S OFFER (HBA1C ANALYSER)	VENDOR'S OFFER (POC OR COMPACT BENCHTOP ANALYSER)
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:**		
M	**Equipment Whole Life Support**		
N	**Dimensions (WxHxD) cm:**		

NO.	GENERAL SPECIFICATIONS	VENDOR'S OFFER (HBA1C ANALYSER)	VENDOR'S OFFER (POC OR COMPACT BENCHTOP ANALYSER)
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/169/2024/LAB(TC)

INVITATION TO TENDER

TO SUPPLY AND DELIVER REAGENTS AND CONSUMABLES FOR HBA1C TESTING WITH EQUIPMENT RENTAL FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF FIVE (5) YEARS USAGE

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	**HbA1c Reagent Test Kits** Inclusive of all reagents and consumables required for the measurement of HbA1c on HPLC analysers and POC or Compact benchtop analyser. This includes but not limited to: 1.Columns 2. Filters 3. Buffer solutions 4. Wash solutions 5. Calibrators 6. Third party Quality Controls (QCs) 7. Sample vials 8. Reagent cartridge for POC or Compact benchtop analyser 9. Third party Quality Control (QCs) for POC or Compact benchtop analyser			

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 : _____