REFERENCE OF TENDER	DESCRIPTION OF TENDER	TIME PERIOD OF TENDER	DEPARTMENT/ DIVISION/UNIT REQUESTING TENDER	FEES	CLOSING DATE NOT LATER THAN 12.00AM	FOCAL PERSON
KK/86/2024/LAB(TC)	TO SUPPLY AND DELIVER OSMOMETER REAGENTS AND CONSUMABLES 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	21ST MAY 2024	*Siti Mahirah binti Awang Mahmud* *National Clinical Chemistry Reference Laboratory* *Department of Laboratory Services* *Ministry Of Health* *Negara Brunei Darussalam* *Contact No: 2242424 Ext 6321* *e-mail: mahirah.mahmud@moh.gov.bn*

NOMBOR TAWARAN : KK/86/2024/LAB(TC)

KEMENTERIAN KESIHATAN
NEGARA BRUNEI DARUSSALAM

TO SUPPLY AND DELIVER OSMOMETER REAGENTS AND CONSUMABLES 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, 21HB MAY 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/86/2024/LAB(TC)

INVITATION TO TENDER

TO SUPPLY AND DELIVER OSMOMETER REAGENTS AND CONSUMABLES 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	50 mOsm Calibration Standard	10 x 2ml / Box	9 Boxes
2	850 mOsm Calibration Standard	10 x 2ml / Box	9 Boxes
3	2000 mOsm Calibration Standard	10 x 2ml / Box	6 Boxes
4	Automated Osmo Calibration Set	4 x 2ml / Box	4 Boxes
5	3-Level Osmometer Control for Serum	9 x 3ml / Box	15 Boxes
6	2-Level Osmometer Control for Urine	8 x 3 ml / Box	10 Boxes
7	290 mOsm Reference Solution	10 x 2 ml / Box	4 Boxes
8	Osmometer Maintenance Kit	Per Box	8 Boxes
9	Sample Tips, Chamber Cleaners and Plunger Wire	1 x 500 / Packs	8 Packs
10	Inserts, Small Volume, Package Of 100	100 pieces / Pack	1 Pack

***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**
	Supply, deliver, install and commission free of charge to the government two (2) units of Osmometer analysers to perform measurement of Osmolality. **1 of the unit will be the main analyser with LIS connectivity and the other unit will act as a back-up analyser.**
2.0	**EQUIPMENT SPECIFICATION**
2.1	**Main Analyser**: 2.1.1 A single sample entry point to the system is preferred. No sample preparation is required. 2.1.2 The single-entry point must have the capacity in handling primary tubes as is specified below. 2.1.3 The system must be able to load a minimum of 10 samples at one time and allow continuous sample loading. This should provide a reasonable free walk-away time. 2.1.4 The system must be available daily with minimum daily start up time. It is preferred that the reagents can be loaded or replaced on the fly without disrupting routine sample loading or run. 2.1.5 It is preferred that 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 5 years 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 Please provide the system specifications being offered including the hardware offered. 2.1.8 Please provide a list of laboratory users currently using the system in the region. 2.1.9 The methodology required will be Freezing Point Depression. 2.1.10 Please provide scientific studies detailing the interferences or limitations on the analysers, including the effect of hemolysis, icterus and lipemia on sample results. 2.1.11 The system reports Osmolality in mOsm/kg H_2O unit. 2.1.12 The system preferably capable of measuring between 0 to 2000 mOsm/kg. Please state the reportable measuring range of the system.
2.2	**Quality Performance:** 2.2.1 The system has a total analytical imprecision of less than 2 mOsm/kg SD from the mean. Provide a document stating this. 2.2.2 It is preferred that a quality control interval setting is available to alert the laboratory users. This should be set at a pre-determined interval. 2.2.3 It is preferred that the results are not released from the system when quality run exceeds the predetermined interval time. 2.2.4 No or minimum carry over between samples. State if there are any special precautions or wash cycles required. If so, state in full details and state its turnaround time (TAT). 2.2.5 Please provide the Certificate of Analysis that contains all the required information on the standards, confirming that all the materials are fit for purpose. 2.2.6 Please provide at least 2 level of Quality Control at clinically relevant level for both of the serum and urine specimens. 2.2.7 Calibration traceability – The system should be calibrated against NIST Traceable Reference solutions and comply with Pharmacopeia guidelines. Please provide the documents that supports this statement. 2.2.8 The vendor shall perform the required annual method verifications of the lab, including, but not limited to, accuracy, precision, linearity, inter-instrument verification, limit of detection/blank/quantitation or as required. The vendor must bear all the cost pertaining to the annual method verification, including the purchase of verification kits like linearity,

NO.	SPECIFICATIONS AND REQUIREMENTS
	whenever deemed necessary. 2.2.9 QC New Lot Verification – For every new Lot of QC supplied to the laboratory, the vendor should initially provide 1 box, or enough to collect at least 20 QC points, for the user to first verify the acceptability of the new lot QC before sending the rest of the QCs (similar lot).
2.3	**Back-up Analyser:** 2.3.1 The system must be available daily with minimum daily start up time. It is preferred that the reagents can be loaded or replaced on the fly without disrupting routine sample loading or run. 2.3.2 Please provide the system specifications being offered including the hardware offered. 2.3.3 Please provide a list of laboratory users currently using the system in the region. 2.3.4 The methodology required will be Freezing Point Depression. 2.3.5 Please provide scientific studies detailing the interferences or limitations on the analysers, including the effect of hemolysis, icterus and lipemia on sample results. 2.3.6 The system reports Osmolality in mOsm/kg H_2O unit. 2.3.7 The system preferably capable of measuring between 0 to 2000 mOsm/kg. Please state the reportable measuring range of the system. 2.3.8 The specifications of QC Performance for the back-up analyser should be the same as the main analyser.
3.0	**TECHNICAL SPECIFICATIONS**
3.1	**Main System:** 3.1.1 It is envisaged that the system will be using a data manager that should be able to be linked to a LIS for data retrieval and monitoring. A bidirectional connection between analyser and LIS is required. 3.1.2 LIS connection must be included, either interfaced to our LIS or linked via middleware. This is inclusive of all required costs including for auto verification. 3.1.3 Provide contingency procedure in the event of a LIS breakdown or downtime. 3.1.4 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. 3.1.5 An on-board trouble-shooting guide should be available. 3.1.6 List details on daily and periodic maintenance including time required to perform the maintenance and to restart analysis 3.1.7 Describe how operator-changeable parameters are backed up. State if password protection of these parameters is included. 3.1.8 Patient data and quality control (QC) data back-up should be done at regular intervals. Minimum frequency of data back-up is 1 week. 3.1.9 A large storage or memory capacity to store calibration, quality control and patient results records.
3.2	**Sampling System:** 3.2.1 System is able to recognize the laboratory sample barcode format. Please include examples of acceptable barcode labels. 3.2.2 Able to sample primary sample tubes. Sampling system uses a level sensing mechanism. Indicate an alternative procedure for samples tubes without barcodes. 3.2.3 Indicate the minimum sample volume required for analysis. 3.2.4 For insufficient sample volume, indicate if there is any alternative procedure. 3.2.5 State the measurement time required for one sample. 3.2.6 Please provide a document that contains all the details of sample acceptability, including the type of specimen, stability of specimen, pre-handling process of specimen, any testing requirements, or any scientific studies that supports the information required above.

NO.	SPECIFICATIONS AND REQUIREMENTS
3.3	**Quality Management System:** 3.3.1 On board Quality Control (QC) software on the analyser is provided. 3.3.2 This includes a Levey Jennings (LJ) graph view. 3.3.3 Westgard warning rules and alerts are available on the analyser 3.3.4 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. 3.3.5 Quality Control (QC) data management system is provided. 3.3.6 The QC data is automatically transmitted from the analyser to the QC data management system. 3.3.7 The QC data management system that is available for peer groups, i.e., web-based peer group program like Advanced Peer QC is provided. 3.3.7 The QC data management provides the tools in monitoring the reliability, precision and performance of the laboratory testing. This includes peer to peer review and comparison of instrument performance. 3.3.8 The vendor should bear the cost of registration for any QC data management system, whether it is a web-based peer group program or in-house IQC management system. 3.3.9 The vendor should assist the users in any issues pertaining the QC data management system
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.
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. Please state the proposed plan in ensuring there is a continuous support to the laboratory in application and technical issues. 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 and bear the costs for the preventive maintenance (Weekly, Monthly, and Quarterly as needed) and breakdown maintenance of the analysers. Any breakdown should be quickly attended to within 2 hours.

NO.	SPECIFICATIONS AND REQUIREMENTS
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 perform full initial method validation and verification of a comprehensive methods performance for all of the tests listed above of both analysers including, but not limited to, precision, accuracy, linearity, sensitivity, specificity, carryover, limit of detection/blank/quantitation, reference range verification or as required by the User depending on the nature of testing. The vendor must bear all the cost pertaining to the annual method verification, including the cost of test, reagents, consumables and the purchase of verification kits like linearity, whenever deemed necessary. Report of the validation/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 arising issues. This includes any issues pertaining to the performance of the analyser, like IQC and EQA, and not limited to just analytical issues.
4.13	Backup is particularly important for all aspects of the system. The proposed analyser should be provided with backup instruments and should be able to perform the same test parameters as in the above list. It would be preferred that the analyser in the system would be provided at least in duplicate.
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.
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. 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	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

NO.	SPECIFICATIONS AND REQUIREMENTS
	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, for example, sample racks, waste bottles and sample tube adaptors are provided by the vendor. A trolley for the storage of reagents and consumables of both analysers are to be provided. This is sufficient for the storage of accessories and waste bottles of both analysers.
6.2	A computer for LIS interface and patient results back-up is to be supplied. The computer specifications should meet the minimum requirements set by EGNC. The memory capacity and speed should be sufficient in backing-up patient data and connecting to LIS.
6.3	A printer for the purpose of patient results printing is to be supplied. This includes the supply of ink cartridge toner.
6.4	Method validation will also be required when the instrument has been moved at a significant distance. Vendor is required to assist the laboratory in performing the method validation according to the laboratory's protocol.
7.0	**LITERATURE**
7.1	To supply one (1) softcopy 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
8.0	**TRAINING**
	TRAINING - <u>FOR 5 YEARS TERM CONTRACT</u>
8.1	Training shall be provided, at no additional cost, as follows:
8.2	On-site training for ALL staff members expected to handle the machine, or any related software pertaining to the analyser, such as the QC management software. Please ensure that adequate time is allocated such that training will take place in small groups to minimize staff shortage in the laboratory.
8.3	Certificate of competence is to be issued to all trainees after completion of training.
8.4	The successful tenderer needs to ensure the key users are updated on the current or relevant information related to the system used. They should provide **TWO** off-site trainings 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

NO.	SPECIFICATIONS AND REQUIREMENTS
	airport and place of training.
8.5	Successful tenderer shall invite speakers from overseas to give talks or presentations to our local users as part of user training.
8.6	To provide refresher course or training when deemed necessary during the period of 5-year contract.
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 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 Clinical Chemistry Reference Laboratory	
Lab/Section/Unit Ref No.:	DLS/PU/NCCRL/2024/5	
Person to Contact	Name : Siti Mahirah Awang Mahmud	
	E-mail : Mahirah.mahmud@moh.gov.bn	
	Tel. No. : 2242424 ext. 6321	Fax No: 2220869
FOR ADMINISTRATION USE ONLY		
PPM/PROC Ref.No.	PPM/PROC/2024/>50K/007(NCCRL)	
Advertisement Ref. No.		Date :

SECTION 3

FORMS TO BE USED

CONTENTS

SCHEDULE 1

TENDER FORM

To:

TENDER REFERENCE NO: KK/86/2024/LAB(TC)

INVITATION TO TENDER

TO SUPPLY AND DELIVER OSMOMETER REAGENTS AND CONSUMABLES 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 _____

1. SUPPLY OF REAGENTS

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

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

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	50 mOsm Calibration Standard	10 x 2ml / Box	9 Boxes						
2	850 mOsm Calibration Standard	10 x 2ml / Box	9 Boxes						
3	2000 mOsm Calibration Standard	10 x 2ml / Box	6 Boxes						
4	Automated Osmo Calibration Set	4 x 2ml / Box	4 Boxes						
5	3-Level Osmometer Control for Serum	9 x 3ml / Box	15 Boxes						
6	2-Level Osmometer Control for Urine	8 x 3 ml / Box	10 Boxes						
7	290 mOsm Reference Solution	10 x 2 ml / Box	4 Boxes						
8	Osmometer Maintenance Kit	Per Box	8 Boxes						

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$)**	**TOTAL COSTS (B$)**
9	Sample Tips, Chamber Cleaners and Plunger Wire	1 x 500 / Packs	8 Packs						
10	Inserts, Small Volume, Package Of 100	100 pieces / Pack	1 Pack						
TOTAL PRICE (B$)									

***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**	
	Supply, deliver, install and commission free of charge to the government two (2) units of Osmometer analysers to perform measurement of Osmolality. **1 of the unit will be the main analyser with LIS connectivity and the other unit will act as a back-up analyser.**	
2.0	**EQUIPMENT SPECIFICATION**	
2.1	**Main Analyser**: 2.1.1 A single sample entry point to the system is preferred. No sample preparation is required. 2.1.2 The single-entry point must have the capacity in handling primary tubes as is specified below. 2.1.3 The system must be able to load a minimum of 10 samples at one time and allow continuous sample loading. This should provide a reasonable free walk-away time. 2.1.4 The system must be available daily with minimum daily start up time. It is preferred that the reagents can be loaded or replaced on the fly without disrupting routine sample loading or run. 2.1.5 It is preferred that 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 5 years 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 Please provide the system specifications being offered including the hardware offered. 2.1.8 Please provide a list of laboratory users currently using the system in the region. 2.1.9 The methodology required will be Freezing Point Depression. 2.1.10 Please provide scientific studies detailing the interferences or limitations on the analysers, including the effect of hemolysis, icterus and lipemia on sample results.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	2.1.11 The system reports Osmolality in mOsm/kg H_2O unit. 2.1.12 The system preferably capable of measuring between 0 to 2000 mOsm/kg. Please state the reportable measuring range of the system.	
2.2	**Quality Performance:** 2.2.1 The system has a total analytical imprecision of less than 2 mOsm/kg SD from the mean. Provide a document stating this. 2.2.2 It is preferred that a quality control interval setting is available to alert the laboratory users. This should be set at a pre-determined interval. 2.2.3 It is preferred that the results are not released from the system when quality run exceeds the predetermined interval time. 2.2.4 No or minimum carry over between samples. State if there are any special precautions or wash cycles required. If so, state in full details and state its turnaround time (TAT). 2.2.5 Please provide the Certificate of Analysis that contains all the required information on the standards, confirming that all the materials are fit for purpose. 2.2.6 Please provide at least 2 level of Quality Control at clinically relevant level for both of the serum and urine specimens. 2.2.7 Calibration traceability – The system should be calibrated against NIST Traceable Reference solutions and comply with Pharmacopeia guidelines. Please provide the documents that supports this statement. 2.2.8 The vendor shall perform the required annual method verifications of the lab, including, but not limited to, accuracy, precision, linearity, inter-instrument verification, limit of detection/blank/quantitation or as required. The vendor must bear all the cost pertaining to the annual method verification, including the purchase of verification kits like linearity, whenever deemed necessary. 2.2.9 QC New Lot Verification – For every new Lot of QC supplied to the laboratory, the vendor should initially provide 1 box, or enough to collect at least 20 QC points, for the user to first verify the acceptability of the new lot QC before sending the rest of the QCs (similar lot).	
2.3	**Back-up Analyser:** 2.3.1 The system must be available daily with minimum daily start up time. It is preferred that the reagents can be loaded or replaced on the fly without disrupting routine sample loading or run. 2.3.2 Please provide the system specifications being offered including the	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	hardware offered. 2.3.3 Please provide a list of laboratory users currently using the system in the region. 2.3.4 The methodology required will be Freezing Point Depression. 2.3.5 Please provide scientific studies detailing the interferences or limitations on the analysers, including the effect of hemolysis, icterus and lipemia on sample results. 2.3.6 The system reports Osmolality in mOsm/kg H_2O unit. 2.3.7 The system preferably capable of measuring between 0 to 2000 mOsm/kg. Please state the reportable measuring range of the system. 2.3.8 The specifications of QC Performance for the back-up analyser should be the same as the main analyser.	
3.0	**TECHNICAL SPECIFICATIONS**	
3.1	**Main System:** 3.1.1 It is envisaged that the system will be using a data manager that should be able to be linked to a LIS for data retrieval and monitoring. A bidirectional connection between analyser and LIS is required. 3.1.2 LIS connection must be included, either interfaced to our LIS or linked via middleware. This is inclusive of all required costs including for auto verification. 3.1.3 Provide contingency procedure in the event of a LIS breakdown or downtime. 3.1.4 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. 3.1.5 An on-board trouble-shooting guide should be available. 3.1.6 List details on daily and periodic maintenance including time required to perform the maintenance and to restart analysis 3.1.7 Describe how operator-changeable parameters are backed up. State if password protection of these parameters is included. 3.1.8 Patient data and quality control (QC) data back-up should be done at regular intervals. Minimum frequency of data back-up is 1 week. 3.1.9 A large storage or memory capacity to store calibration, quality control and patient results records.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
3.2	**Sampling System:** 3.2.1 System is able to recognize the laboratory sample barcode format. Please include examples of acceptable barcode labels. 3.2.2 Able to sample primary sample tubes. Sampling system uses a level sensing mechanism. Indicate an alternative procedure for samples tubes without barcodes. 3.2.3 Indicate the minimum sample volume required for analysis. 3.2.4 For insufficient sample volume, indicate if there is any alternative procedure. 3.2.5 State the measurement time required for one sample. 3.2.6 Please provide a document that contains all the details of sample acceptability, including the type of specimen, stability of specimen, pre-handling process of specimen, any testing requirements, or any scientific studies that supports the information required above.	
3.3	**Quality Management System:** 3.3.1 On board Quality Control (QC) software on the analyser is provided. 3.3.2 This includes a Levey Jennings (LJ) graph view. 3.3.3 Westgard warning rules and alerts are available on the analyser 3.3.4 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. 3.3.5 Quality Control (QC) data management system is provided. 3.3.6 The QC data is automatically transmitted from the analyser to the QC data management system. 3.3.7 The QC data management system that is available for peer groups, i.e., web-based peer group program like Advanced Peer QC is provided. 3.3.7 The QC data management provides the tools in monitoring the reliability, precision and performance of the laboratory testing. This includes peer to peer review and comparison of instrument performance. 3.3.8 The vendor should bear the cost of registration for any QC data management system, whether it is a web-based peer group program or in-house IQC management system. 3.3.9 The vendor should assist the users in any issues pertaining the QC data management system	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
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.	
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. Please state the proposed plan in ensuring there is a continuous support to the laboratory in application and technical issues. 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 and bear the costs for the preventive maintenance (Weekly, Monthly, and Quarterly as needed) and breakdown maintenance of the analysers. Any breakdown should be quickly attended to	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	within 2 hours.	
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 perform full initial method validation and verification of a comprehensive methods performance for all of the tests listed above of both analysers including, but not limited to, precision, accuracy, linearity, sensitivity, specificity, carryover, limit of detection/blank/quantitation, reference range verification or as required by the User depending on the nature of testing. The vendor must bear all the cost pertaining to the annual method verification, including the cost of test, reagents, consumables and the purchase of verification kits like linearity, whenever deemed necessary. Report of the validation/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 arising issues. This includes any issues pertaining to the performance of the analyser, like IQC and EQA, and not limited to just analytical issues.	
4.13	Backup is particularly important for all aspects of the system. The proposed analyser should be provided with backup instruments and should be able to perform the same test parameters as in the above list. It would be preferred that the analyser in the system would be provided at least in duplicate.	
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	VENDOR'S OFFER (PLEASE STATE)
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. 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	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**	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
6.1	Accessories, for example, sample racks, waste bottles and sample tube adaptors are provided by the vendor. A trolley for the storage of reagents and consumables of both analysers are to be provided. This is sufficient for the storage of accessories and waste bottles of both analysers.	
6.2	A computer for LIS interface and patient results back-up is to be supplied. The computer specifications should meet the minimum requirements set by EGNC. The memory capacity and speed should be sufficient in backing-up patient data and connecting to LIS.	
6.3	A printer for the purpose of patient results printing is to be supplied. This includes the supply of ink cartridge toner.	
6.4	Method validation will also be required when the instrument has been moved at a significant distance. Vendor is required to assist the laboratory in performing the method validation according to the laboratory's protocol.	
7.0	**LITERATURE**	
7.1	To supply one (1) softcopy 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	
8.0	**TRAINING**	
	TRAINING - <u>FOR 5 YEARS TERM CONTRACT</u>	
8.1	Training shall be provided, at no additional cost, as follows:	
8.2	On-site training for ALL staff members expected to handle the machine, or any related software pertaining to the analyser, such as the QC management	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	software. Please ensure that adequate time is allocated such that training will take place in small groups to minimize staff shortage in the laboratory.	
8.3	Certificate of competence is to be issued to all trainees after completion of training.	
8.4	The successful tenderer needs to ensure the key users are updated on the current or relevant information related to the system used. They should provide **TWO** off-site trainings 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.	
8.5	Successful tenderer shall invite speakers from overseas to give talks or presentations to our local users as part of user training.	
8.6	To provide refresher course or training when deemed necessary during the period of 5-year contract.	
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.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
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 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
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:**	
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/86/2024/LAB(TC)

INVITATION TO TENDER

TO SUPPLY AND DELIVER OSMOMETER REAGENTS AND CONSUMABLES 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	50 mOsm Calibration Standard			
2	850 mOsm Calibration Standard			
3	2000 mOsm Calibration Standard			
4	Automated Osmo Calibration Set			
5	3-Level Osmometer Control for Serum			
6	2-Level Osmometer Control for Urine			
7	290 mOsm Reference Solution			
8	Osmometer Maintenance Kit			
9	Sample Tips, Chamber Cleaners and Plunger Wire			
10	Inserts, Small Volume, Package Of 100			

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 : _____