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/65/2022/LAB(TC)	TO SUPPLY AND DELIVER EXTERNAL QUALITY ASSURANCE (EQA) MATERIALS FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DISTRICT LABORATORIES AND POINT OF CARE TESTING (POCT) SECTION, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF THREE (3) YEARS USAGE, PART I	3 YEARS	DEPARTMENT OF LABORATORY SERVICES	$30.00	23RD APRIL 2024	Nur Ahlina binti Abdul Ghani National Clinical Chemistry Reference Laboratory Department of Laboratory Services Ministry of Health Negara Brunei Darussalam Contact No.: 2242424 ext. 6047 e-mail: ahlina.ghani@moh.gov.bn

NOMBOR TAWARAN: KK/65/2024/LAB(TC)

KEMENTERIAN KESIHATAN
NEGARA BRUNEI DARUSSALAM

TO SUPPLY AND DELIVER EXTERNAL QUALITY ASSURANCE (EQA) MATERIALS FOR NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DISTRICT LABORATORIES AND POINT OF CARE TESTING (POCT) SECTION, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF THREE (3) YEARS USAGE, PART I

YURAN TAWARAN : $30.00

NOMBOR RESIT :

TARIKH TUTUP : HARI SELASA, 23HB APRIL 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/65/2024/LAB(TC)

INVITATION TO TENDER
TO SUPPLY AND **DELIVER EXTERNAL QUALITY ASSURANCE (EQA) MATERIALS** FOR **NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DISTRICT LABORATORIES AND POINT OF CARE TESTING (POCT) SECTION**, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF **THREE (3)** YEARS USAGE, **PART I**

DELIVERY PERIOD	**4-8 WEEKS AND NO LONGER THAN 12 WEEKS**

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
1	EQA Program for Blood Gases	**12 x 1.8mL**	26 Programs
2	EQA Program for Clinical Chemistry	**12 x 5mL**	2 Programs
3	EQA Program for Alcohol/Ammonia	**12 x 2mL**	1 Program
4	EQA Program for CSF Chemistry	**12 x 3mL**	1 Program
5	EQA Program for Immunoassay	**12 x 5mL**	1 Program
6	EQA Program for Immunoassay Specialty	**12 x 2mL**	1 Program
7	EQA Program for Therapeutic Drugs Monitoring	**12 x 5mL**	1 Program
8	EQA Program for Immunosuppressant Drugs	**12 x 2mL**	1 Program
9	EQA Program for Glycated Haemoglobin (HbA1c)	**12 x 0.5mL**	1 Program
10	EQA Program for Cardiac Marker	**12 x 3mL**	2 Programs
11	EQA Program for Lipid	**24 x 3mL**	1 Program
12	EQA Program for Specific Proteins	**24 x 3mL**	1 Program
13	EQA Program for Serum Hemolytic, Icteric and Lipemic (HIL) Indices	**18 x 1mL**	2 Programs
14	EQA Program for Paediatric Bilirubin	**12 x 3mL**	2 Programs

NO.	SPECIFICATIONS AND REQUIREMENTS
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.
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.
3	Vendor shall make enrolment with the appropriate EQA program service for each respective laboratory section(user)
4	Vendor shall make payment to the EQA program service provider for any enrolment to the specific program module as defined by each respective laboratory section (user).
5	Vendor shall ensure the EQA materials reach each respective laboratory within acceptable period of time. The materials should be delivered with enough time allowance for test analysis and results submission to the EQA program service provider.
6	Vendor shall provide or update the laboratory of details or information on the test menu covered by the selected EQA program module.
7	Vendor shall assist in results submission when there is a downtime that prevents the user from submitting the results to the EQA program service provider.
8	The EQA programs to be offered shall: a) Substantially fulfil the relevant requirement of ISO 17043 and/or approved by recognized international regulatory body b) Extensive test menu (Please refer to **Appendix A**) c) Survey / Generic reports come back within the acceptable turn-around time. **Please state the turn-around time of the EQA Report. Vendor is to submit an example as evidence.** d) Participation by sufficient number of peer groups. **Vendor is to submit number of peer groups for each laboratory in each program**. (Please refer to **Appendix A**). e) Educational program shall be available in the system. **Vendor is to state the educational program on offer.** Module configuration and program structure shall be acceptable by the user
9	The EQA Program Service Provider's Facility must be accredited by the National Association of Testing Authorities (NATA) and complies with the requirements of ISO/IEC 17043. Vendor is to submit the EQA Provider & Site Number.
10	The EQA materials provided must be accredited. Data processing program used must produce EQA reports and ranking which are suitable to the respective laboratory. The reports and ranking shall meet and satisfy the aim and goals of External Quality Assurance. External Quality Assurance (EQA) program is a management system used to monitor the performance of the laboratory testing services. The goals of EQA participation are: a) Ensuring patient results are reported with accuracy b) Comparing the performance of the laboratory against other laboratories within the region and advanced countries c) Comparing the performance of the laboratory against other laboratories within the same peer group i.e. laboratories with the same methodology and instrument d) Fulfilling the requirements of ISO 15189

NO.	SPECIFICATIONS AND REQUIREMENTS
11	The vendor shall include evidence of peer group and number of participations in their tender offer submission. The evidence shall include a copy of interim report for each analyte in each program. EQA programs with participants from advanced countries such as Australia, UK and USA will be an added advantage. Peer group is defined as a group of laboratories performing the test analysis with the same methodology and instrument.
12	Each parameter or analyte within the EQA programmes shall have a minimum of 15 participants within the laboratory's peer group.
13	The EQA Program Provider shall provide EQA Enrolment Certificate as evidence of enrolment into the program. A certificate shall be provided for each EQA program subscription.
14	EQA materials shall be: a) Delivered to each respective laboratory no later than **Two (2)** weeks before the deadline or due date of the EQA result submission. b) Transported in compliance with Universal Post Union (UPU) regulations c) Packed and transported within the requirements of EQA materials d) Transported in such conditions that the quality and integrity of the EQA materials are maintained e) Packed adequately to avoid damage during transportation f) Labelled appropriately with the dispatch date clearly indicated g) Labelled clearly. This includes information of species of origin of the base material and Material Safety Data Sheet (MSDS) h) Stable throughout the transportation i) Stable during storage without affecting the stability and integrity of the analytes in the EQA materials j) Homogeneous once the EQA materials are reconstituted k) Available in sufficient volume for analysis l) Performing in similar manner as patient samples during test analysis m) In similar specimen types as patient samples e.g. whole blood, serum and urine n) Covering concentrations across the analytical measuring range of each analyte. This includes clinical decision-making concentrations of each analyte.
15	Instructions for use for each EQA material shall be provided. The instruction shall include: a) Nature of the EQA material b) Treatment of the EQA material c) Safety precautions d) Due date of result submission e) Reconstitution and preparation procedure f) Expiry date g) Stability of each analyte h) Other relevant details

NO.	SPECIFICATIONS AND REQUIREMENTS
16	EQA reports for Quantitative test shall include the following: a) The reports are in a user-friendly format b) One-page report per parameter or analyte allowing easy interpretation of the analytical performance c) Statistical analysis by all methods. This includes a running mean for the last 10 samples d) Comparison of the laboratory performance against the instrument peer group, methodology peer group and all methods group. The comparison is illustrated in a histogram format e) Visual charts illustrating laboratory performance trends, biases and precisions f) Charts of Target Scores illustrating the performance of the recent 20 samples, inclusive of the samples in previous cycle g) At-a-glance summary page for all parameters or analytes in the programme h) Comparison of the laboratory result against statistically robust consensus means i) Acceptability of parameter or analyte performance uses the following fit-for-purpose performance indicators: i. Standard Deviation Index (SDI) ii. Percentage of Deviation iii. Target Score j) Each parameter or analyte report shall include: i. Levey-Jennings Charts ii. Histograms iii. % Deviation Charts iv. % Deviation by concentration charts k) Available and accessible online within 72 hours of deadline of EQA program result submission l) Accessible via Cloud Based Data System m) Emailed directly to participants in PDF format n) Current and previous reports are available for download on the EQA service provider site. In the event that EQA reports are no longer available on the EQA service provider site, the EQA service provider shall supply the laboratory with the requested EQA reports
17	At the end of each cycle, End-of-cycle report shall be available for each parameter or analyte. The report shall include: a) Inter-laboratory report b) Multi-instrument comparison report for up to 5 instruments c) Summary of the laboratory performance for the whole cycle
18	At the end of each cycle, a yearly performance certificate shall be provided by the EQA service provider for each EQA program subscribed
19	Each EQA program purchased can be enrolled/subscribed for a **minimum of two (2) instruments.**
20	Vendor shall provide necessary advice and consultation promptly when the laboratory requires assistance. When vendor is unable to provide the required assistance to the laboratory, specifically in troubleshooting, the vendor is to communicate immediately with the EQA provider or provide the contact details of the representative of the EQA provider to the relevant laboratory personnel.
21	Vendor shall provide continuous education or in-house training with topics relevant to EQA program and its interpretations and troubleshooting. This covers all disciplines subscribed by the laboratory.
22	Changes to the EQA service provider's administration, management or policy shall be made known to all participating laboratories promptly in written form via email.
23	Vendor shall include a list of technical support personnel, their qualifications and years of experience in EQA program support in the tender offer submission.

NO.	SPECIFICATIONS AND REQUIREMENTS
24	EQA program price shall be an all-inclusive price. The price submitted shall include door-to-door transportation and any other required fees where possible.
25	Each EQA material shall be delivered to its respective laboratory during office hours, between 8.30 am and 4.30 pm. The shipping and delivery status of each EQA material shall be regularly updated to its respective laboratory. The laboratories/sections are as follows: a) Clinical Chemistry Laboratory, RIPAS Hospital b) Clinical Chemistry/PMMPMHAMB Laboratory, PMMPMHAMB Hospital c) PIHM Laboratory, PIHM Hospital d) Point of Care Testing (POCT), RIPAS Hospital
26	Vendor shall ensure the selected courier service will transport and deliver the EQA materials to the laboratory in compliance with international guideline and regulation of biohazard specimen transportation.
27	Vendor shall devise customs clearance procedure when required
28	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
29	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 1 calculated from delivery date 4. Leakage upon delivery
30	A replacement should be provided to the laboratory in the event that the quality of EQA materials is affecting the performance of the laboratory's EQA programs.
31	A replacement should be provided to the laboratory for troubleshooting when required by the laboratory.
32	**FINANCIAL AGREEMENT**
32.1	Supply of the test kit including reagents, consumables and/or accessories is based on the number of kits required in the Purchase Order according to an agreed schedule period as stated in para 2.
32.2	Should there be any discontinuity of reagents / consumables due to non-compliance in the manufacturing of reagents; the vendor must be able to provide an alternative so that the test requests / services are still available for the customers.
32.3	**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 the 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*).
33	**DELIVERY PERIOD:** Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order

NO.	SPECIFICATIONS AND REQUIREMENTS
34	**PRICE VALIDITY:** The quotation shall remain valid for **12 MONTHS** from the final date for the submission of the quotation and no supplier may withdraw his/her quotation within that period. The Government reserves the right to extend this period if deemed necessary provided that such extension to the quotation validity period shall have written consent of the supplier(s).

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

To be filled in by Vendors:

NO.	ITEM NAME	INSTRUMENT	VENDOR'S OFFER					
			EQA PROGRAM NAME	ANALYTES AVAILABLE	SAMPLE FREQUENCY	SAMPLE TYPE	NO. OF PEERS (PLEASE SUBMIT EVIDENCE)	Able to Register a Minimum of 2 Instruments (Yes or No)
1.	EQA Program for Blood Gas	Radiometer ABL90 FLEX PLUS						
		Abbott I-STAT1						
2.	EQA Program for Clinical Chemistry	Abbott Alinity c-Series						
		Abbott Architect ci4100						
3.	EQA Program for Ammonia	Abbott Alinity c-Series						
4.	EQA Program for CSF Chemistry	Abbott Alinity c-Series						
5.	EQA Program for Immunoassay	Abbott Alinity i-Series						
6.	EQA Program for Immunoassay Specialty	Abbott Alinity i-Series						
7.	EQA Program for Therapeutic Drugs Monitoring	Abbott Alinity c-Series						
8.	EQA Program for Immunosuppressant Drugs	Abbott Alinity i-Series						
9.	EQA Program for Glycated Haemoglobin (HbA1c)	Bio-RAD D-100						
10.	EQA Program for Cardiac Marker	Abbott Alinity ci-Series						

NO.	ITEM NAME	INSTRUMENT	VENDOR'S OFFER					
			EQA PROGRAM NAME	ANALYTES AVAILABLE	SAMPLE FREQUENCY	SAMPLE TYPE	NO. OF PEERS (PLEASE SUBMIT EVIDENCE)	Able to Register a Minimum of 2 Instruments (Yes or No)
		Abbott Architect ci4100						
11.	EQA Program for Lipid	Abbott Alinity c-Series						
12.	EQA Program for Specific Proteins	Abbott Alinity c-Series						
13.	EQA Program for Serum Hemolytic, Icteric and Lipemic (HIL) Indices	Abbott Alinity ci-Series						
		Abbott Architect ci4100						
14.	EQA Program for Paediatric Bilirubin	Abbott Alinity c-Series						
		Abbott Architect ci4100						

DELIVERY PERIOD AFTER PO ISSUED	**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/2024/03	
Person to Contact	Name : Nur Ahlina Abdul Ghani	
	E-mail : Ahlina.ghani@moh.gov.bn	
	Tel. No. : 2242424 ext. 6321	Fax No. : 2220869
FOR ADMINISTRATION USE ONLY		
PPM/PROC Ref.No.	PPM/PROC/2024/>50K/005(NCCRL)	
Advertisement Ref. No.		Date :

APPENDIX A

INDIVIDUAL EQA PROGRAMMES SPECIFICATIONS

TENDER REF. NO.:	**KK/65/2024//LAB(TC)**
TENDER NAME:	TO SUPPLY AND **DELIVER EXTERNAL QUALITY ASSURANCE (EQA) MATERIALS** FOR **NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DISTRICT LABORATORIES AND POINT OF CARE TESTING (POCT) SECTION**, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF **THREE (3)** YEARS USAGE, **PART I**.

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE
1.	EQA Program for Blood Gases	• Program must include Chemistry tests as follows: pH, pCO2, pO2, Bicarbonate, total CO2, Ionised Calcium, Chloride, Glucose, Lactate, Potassium, Sodium • **Sample type**: Liquid ready-to-use. Aqueous material. • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instruments** (Laboratory Sites): Radiometer ABL90 Flex Plus (National Clinical Chemistry Reference Laboratory, RIPAS Hospital and POCT sites across all districts)	**12 x 1.8mL**
2.	EQA Program for Clinical Chemistry	• Program must include Chemistry test as follows: Albumin, Bicarbonate, Total Bilirubin, Conjugated bilirubin, Calcium, Chloride, Creatinine, Glucose, Lactate, Lithium, Magnesium, Osmolality, Phosphate, Potassium, Total Protein, Sodium, Urate, Urea, ALT, Alkaline Phosphatase, Amylase, AST, Cholinesterase, Creatinine Kinase, GGT, Lactate Dehydrogenase, Iron, Transferrin, Total Cholesterol, HDL Cholesterol, Triglyceride • **Sample type**: Lyophilised • **Sample Frequency**: Bi-weekly • Minimum of 24 samples per annual cycle • **Peer group** number is not less than 20 participants • **Instruments** (Laboratory Sites): i. Abbott Alinity c-Series (Clinical Chemistry Laboratory, RIPAS Hospital) ii. Advanced 3320 Osmometer (Clinical Chemistry Laboratory, RIPAS Hospital) Note: for Osmolality only iii. Advanced A2O Osmometer (Clinical Chemistry Laboratory, RIPAS Hospital) Note: for Osmolality only **iv.** Abbott Architect ci4100 (PIHM Laboratory)	**12 x 5mL**

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE
3.	EQA Program for Alcohol/Ammonia	• Program must include Chemistry test as follows: Ammonia • **Sample type**: Liquid ready to use • 12 samples per annual cycle • **Peer group** number is not less than 15 participants • **Instruments** (Laboratory Sites): i. Abbott Alinity c-Series (Clinical Chemistry Laboratory, RIPAS Hospital)	**12 x 2mL**
4.	EQA Program for CSF Chemistry	• Program must include Chemistry tests as follows: Albumin, Chloride, Glucose, Total Protein • **Sample type**: Liquid ready to use • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): i. Abbott Alinity c-Series (Clinical Chemistry Laboratory, RIPAS Hospital)	**12 x 3mL**
5.	EQA Program for Immunoassay	• Program must include immunoassay tests as follows: AFP, CA125, CA153, CA199, CEA, Cortisol, C-peptide, DHEA-S, Ferritin, Folate, Free T3, Free T4, FSH, HCG, Insulin, LH, Estradiol, Parathyroid Hormone, Progesterone, Prolaction, PSA, Psa,Free, SHBG, Testosterone, TSH, Vitamin B12, Paracetamol. • **Sample type**: Lyophilised serum • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instruments** (Laboratory Sites): i. Abbott Alinity i-Series (Clinical Chemistry Laboratory, RIPAS Hospital)	**12 x 5mL**
6.	EQA Program for Immunoassay Specialty	• Program must include immunoassay tests as follows: Procalcitonin • **Sample type**: Lyophilised serum • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instruments** (Laboratory Sites): i. Abbott Alinity i-Series (Clinical Chemistry Laboratory, RIPAS Hospital)	**12 x 2mL**
7.	EQA Program for Therapeutic Drugs Monitoring	• Program must include Chemistry tests as follows: Amikacin, Carbamazepine, Digoxin, Gentamicin, Methotrexate, Paracetamol, Phenobarbital, Phenytoin Salicylic acid, Theophylline, Valproic Acid, Vancomycin • 24 samples per annual cycle • **Sample type**: Liquid ready to use • Peer group number is not less than 15 participants • **Instruments** (Laboratory Sites): i. Abbott Alinity c-Series (Clinical Chemistry	**12 x 5mL**

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE
8.	EQA Program for Immunosuppressant Drugs	• Program must include tests as follows: Cyclosporine and Tacrolimus • **Sample type**: Lyophilised, whole blood • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): i. Abbott Alinity i-Series (Clinical Chemistry Laboratory, RIPAS Hospital) LC-MS reference values should be provided for result comparison	**12 x 2mL**
9.	EQA Program for Glycated Haemoglobin (HbA1c)	• Program must include tests as follow: HbA1c • **Sample type**: Lyophilised, 100% whole blood • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): Bio-RAD D-100 (Clinical Chemistry Laboratory, RIPAS Hospital)	**12 x 0.5mL**
10.	EQA Program for Cardiac Marker	• Program must include tests as follows: CK-MB Mass, Digoxin, hsCRP, NT-proBNP and hs-Troponin I • **Sample type**: Lyophilised • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): i. Abbott Alinity ci-Series (Clinical Chemistry Laboratory, RIPAS Hospital) ii. Abbott Architect ci4100 (PIHM Laboratory)	**12 x 3mL**
11.	EQA Program for Lipid	• Program must include tests as follows: Cholesterol, Triglycerides, HDL-Cholesterol and LDL-Cholesterol • **Sample type**: Lyophilised • 24 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): i. Abbott Alinity c-Series (Clinical Chemistry Laboratory, RIPAS Hospital)	**24 x 3mL**
12.	EQA Program for Specific Proteins	• Program must include tests as follows: AFP, C3, Albumin, C4, CRP, Alpha-1-antitrypsin, Ferritin, Haptoglobin, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Rheumatoid Factor, Beta-2-microglobulin (ß2M), Transferrin and Ceruloplasmin. • **Sample type**: Liquid • 24 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): i. Abbott Alinity ci-Series (Clinical Chemistry Laboratory, RIPAS Hospital)	**24 x 3mL**

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE
13.	EQA Program for Serum Hemolytic, Icteric and Lipemic (HIL) Indices	• **Program is an Indices Assessment** (Quantitative and Semi-Quantitative) i.e. Haemolysis, Icteric and Lipemic • **Parameter Assessment** (Quantitative) includes as follows: ALP, ALT, AST, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Cholesterol, CK, Creatinine, GGT, Glucose, HDL, Iron, Lactate, LDH, Magnesium, Phosphate, Potassium, Total Protein, Sodium, Triglycerides, Urea and Uric Acid. • **Sample type**: Lyophilised • **Sample Frequency**: Bi-monthly • 18 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): i. Abbott Alinity ci-Series (Clinical Chemistry Laboratory, RIPAS Hospital) ii. Abbott Architect ci4100 (PIHM Laboratory)	**18 x 1mL**
14.	EQA Program for Paediatric Bilirubin	• Program must include tests as follows: Direct Bilirubin and Total Bilirubin • **Sample type**: Lyophilised sample • 12 samples per annual cycle • Peer group number is not less than 15 participants • **Instrument** (Laboratory Site): i. Abbott Alinity ci-Series (Clinical Chemistry Laboratory, RIPAS Hospital) ii. Abbott Architect ci4100 (PIHM Laboratory)	**12 x 3mL**

SECTION 3

FORMS TO BE USED

CONTENTS

SCHEDULE 1

TENDER FORM

To:

TENDER REFERENCE NO: KK/65/2024/LAB(TC)

INVITATION TO TENDER
TO SUPPLY AND **DELIVER EXTERNAL QUALITY ASSURANCE (EQA) MATERIALS** FOR **NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DISTRICT LABORATORIES AND POINT OF CARE TESTING (POCT) SECTION**, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF **THREE (3)** YEARS USAGE, **PART I**

TENDER OF (*name of tenderer*) _____

Company/Business Registration No _____

Tender Closing Date _____

DELIVERY PERIOD	

	USER'S REQUIREMENTS			**VENDOR'S OFFER**					
NO.	**ITEM DESCRIPTIONS AND SPECIFICATIONS**	**PACKAGING SIZE**	**TOTAL ESTIMATE USAGE / YEAR**	**ITEM DESCRIPTIONS AND SPECIFICATIONS**	**PART/ CATALOGUE NUMBER AND BRAND**	**PACKAGING SIZE**	**TOTAL QUANTITY OFFERED / YEAR**	***COST PER UNIT (B$)**	**TOTAL COSTS (B$)**
1	EQA Program for Blood Gases	**12 x 1.8mL**	26 Programs						
2	EQA Program for Clinical Chemistry	**12 x 5mL**	2 Programs						

	USER'S REQUIREMENTS			VENDOR'S OFFER					
NO.	**ITEM DESCRIPTIONS AND SPECIFICATIONS**	**PACKAGING SIZE**	**TOTAL ESTIMATE USAGE / YEAR**	**ITEM DESCRIPTIONS AND SPECIFICATIONS**	**PART/ CATALOGUE NUMBER AND BRAND**	**PACKAGING SIZE**	**TOTAL QUANTITY OFFERED / YEAR**	***COST PER UNIT (B$)**	**TOTAL COSTS (B$)**
3	EQA Program for Alcohol/Ammonia	**12 x 2mL**	1 Program						
4	EQA Program for CSF Chemistry	**12 x 3mL**	1 Program						
5	EQA Program for Immunoassay	**12 x 5mL**	1 Program						
6	EQA Program for Immunoassay Specialty	**12 x 2mL**	1 Program						
7	EQA Program for Therapeutic Drugs Monitoring	**12 x 5mL**	1 Program						
8	EQA Program for Immunosuppressant Drugs	**12 x 2mL**	1 Program						
9	EQA Program for Glycated Haemoglobin (HbA1c)	**12 x 0.5mL**	1 Program						
10	EQA Program for Cardiac Marker	**12 x 3mL**	2 Programs						
11	EQA Program for Lipid	**24 x 3mL**	1 Program						
12	EQA Program for Specific Proteins	**24 x 3mL**	1 Program						
13	EQA Program for Serum Hemolytic, Icteric and Lipemic (HIL) Indices	**18 x 1mL**	2 Programs						
14	EQA Program for Paediatric Bilirubin	**12 x 3mL**	2 Programs						

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
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.	
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.	
3	Vendor shall make enrolment with the appropriate EQA program service for each respective laboratory section(user)	
4	Vendor shall make payment to the EQA program service provider for any enrolment to the specific program module as defined by each respective laboratory section (user).	
5	Vendor shall ensure the EQA materials reach each respective laboratory within acceptable period of time. The materials should be delivered with enough time allowance for test analysis and results submission to the EQA program service provider.	
6	Vendor shall provide or update the laboratory of details or information on the test menu covered by the selected EQA program module.	
7	Vendor shall assist in results submission when there is a downtime that prevents the user from submitting the results to the EQA program service provider.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
8	The EQA programs to be offered shall: a) Substantially fulfil the relevant requirement of ISO 17043 and/or approved by recognized international regulatory body b) Extensive test menu (Please refer to **Appendix A**) c) Survey / Generic reports come back within the acceptable turn-around time. **Please state the turn-around time of the EQA Report. Vendor is to submit an example as evidence.** d) Participation by sufficient number of peer groups. **Vendor is to submit number of peer groups for each laboratory in each program**. (Please refer to **Appendix A**). **e)** Educational program shall be available in the system. **Vendor is to state the educational program on offer.** Module configuration and program structure shall be acceptable by the user	
9	The EQA Program Service Provider's Facility must be accredited by the National Association of Testing Authorities (NATA) and complies with the requirements of ISO/IEC 17043. Vendor is to submit the EQA Provider & Site Number.	
10	The EQA materials provided must be accredited. Data processing program used must produce EQA reports and ranking which are suitable to the respective laboratory. The reports and ranking shall meet and satisfy the aim and goals of External Quality Assurance. External Quality Assurance (EQA) program is a management system used to monitor the performance of the laboratory testing services. The goals of EQA participation are: a) Ensuring patient results are reported with accuracy b) Comparing the performance of the laboratory against other laboratories within the region and advanced countries c) Comparing the performance of the laboratory against other laboratories within the same peer group i.e. laboratories with the same methodology and instrument d) Fulfilling the requirements of ISO 15189	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
11	The vendor shall include evidence of peer group and number of participations in their tender offer submission. The evidence shall include a copy of interim report for each analyte in each program. EQA programs with participants from advanced countries such as Australia, UK and USA will be an added advantage. Peer group is defined as a group of laboratories performing the test analysis with the same methodology and instrument.	
12	Each parameter or analyte within the EQA programmes shall have a minimum of 15 participants within the laboratory's peer group.	
13	The EQA Program Provider shall provide EQA Enrolment Certificate as evidence of enrolment into the program. A certificate shall be provided for each EQA program subscription.	
14	EQA materials shall be: a) Delivered to each respective laboratory no later than **Two (2)** weeks before the deadline or due date of the EQA result submission. b) Transported in compliance with Universal Post Union (UPU) regulations c) Packed and transported within the requirements of EQA materials d) Transported in such conditions that the quality and integrity of the EQA materials are maintained e) Packed adequately to avoid damage during transportation f) Labelled appropriately with the dispatch date clearly indicated g) Labelled clearly. This includes information of species of origin of the base material and Material Safety Data Sheet (MSDS) h) Stable throughout the transportation i) Stable during storage without affecting the stability and integrity of the analytes in the EQA materials j) Homogeneous once the EQA materials are reconstituted k) Available in sufficient volume for analysis l) Performing in similar manner as patient samples during test analysis m) In similar specimen types as patient samples e.g. whole blood, serum and urine n) Covering concentrations across the analytical measuring range of each analyte. This includes clinical decision-making concentrations of each analyte.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
15	Instructions for use for each EQA material shall be provided. The instruction shall include: a) Nature of the EQA material b) Treatment of the EQA material c) Safety precautions d) Due date of result submission e) Reconstitution and preparation procedure f) Expiry date g) Stability of each analyte h) Other relevant details	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
16	EQA reports for Quantitative test shall include the following: a) The reports are in a user-friendly format b) One-page report per parameter or analyte allowing easy interpretation of the analytical performance c) Statistical analysis by all methods. This includes a running mean for the last 10 samples d) Comparison of the laboratory performance against the instrument peer group, methodology peer group and all methods group. The comparison is illustrated in a histogram format e) Visual charts illustrating laboratory performance trends, biases and precisions f) Charts of Target Scores illustrating the performance of the recent 20 samples, inclusive of the samples in previous cycle g) At-a-glance summary page for all parameters or analytes in the programme h) Comparison of the laboratory result against statistically robust consensus means i) Acceptability of parameter or analyte performance uses the following fit-for-purpose performance indicators: i. Standard Deviation Index (SDI) ii. Percentage of Deviation iii. Target Score j) Each parameter or analyte report shall include: i. Levey-Jennings Charts ii. Histograms iii. % Deviation Charts iv. % Deviation by concentration charts k) Available and accessible online within 72 hours of deadline of EQA program result submission l) Accessible via Cloud Based Data System m) Emailed directly to participants in PDF format n) Current and previous reports are available for download on the EQA service provider site. In the event that EQA reports are no longer available on the EQA service provider site, the EQA service provider shall supply the laboratory with the requested EQA reports	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
17	At the end of each cycle, End-of-cycle report shall be available for each parameter or analyte. The report shall include: a) Inter-laboratory report b) Multi-instrument comparison report for up to 5 instruments c) Summary of the laboratory performance for the whole cycle	
18	At the end of each cycle, a yearly performance certificate shall be provided by the EQA service provider for each EQA program subscribed	
19	Each EQA program purchased can be enrolled/subscribed for a **minimum of two (2) instruments.**	
20	Vendor shall provide necessary advice and consultation promptly when the laboratory requires assistance. When vendor is unable to provide the required assistance to the laboratory, specifically in troubleshooting, the vendor is to communicate immediately with the EQA provider or provide the contact details of the representative of the EQA provider to the relevant laboratory personnel.	
21	Vendor shall provide continuous education or in-house training with topics relevant to EQA program and its interpretations and troubleshooting. This covers all disciplines subscribed by the laboratory.	
22	Changes to the EQA service provider's administration, management or policy shall be made known to all participating laboratories promptly in written form via email.	
23	Vendor shall include a list of technical support personnel, their qualifications and years of experience in EQA program support in the tender offer submission.	
24	EQA program price shall be an all-inclusive price. The price submitted shall include door-to-door transportation and any other required fees where possible.	
25	Each EQA material shall be delivered to its respective laboratory during office hours, between 8.30 am and 4.30 pm. The shipping and delivery status of each EQA material shall be regularly updated to its respective laboratory. The laboratories/sections are as follows: a) Clinical Chemistry Laboratory, RIPAS Hospital b) Clinical Chemistry/PMMPMHAMB Laboratory, PMMPMHAMB Hospital c) PIHM Laboratory, PIHM Hospital d) Point of Care Testing (POCT), RIPAS Hospital	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
26	Vendor shall ensure the selected courier service will transport and deliver the EQA materials to the laboratory in compliance with international guideline and regulation of biohazard specimen transportation.	
27	Vendor shall devise customs clearance procedure when required	
28	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	
29	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 1 calculated from delivery date 4. Leakage upon delivery	
30	A replacement should be provided to the laboratory in the event that the quality of EQA materials is affecting the performance of the laboratory's EQA programs.	
31	A replacement should be provided to the laboratory for troubleshooting when required by the laboratory.	
32	**FINANCIAL AGREEMENT**	
32.1	Supply of the test kit including reagents, consumables and/or accessories is based on the number of kits required in the Purchase Order according to an agreed schedule period as stated in para 2.	
32.2	Should there be any discontinuity of reagents / consumables due to non-compliance in the manufacturing of reagents; the vendor must be able to provide an alternative so that the test requests / services are still available for the customers.	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
32.3	**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 the 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*).	
33	**DELIVERY PERIOD:** Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order	**(Yes / No)** **(If No, please specify)**
34	**PRICE VALIDITY:** The quotation shall remain valid for **12 MONTHS** from the final date for the submission of the quotation and no supplier may withdraw his/her quotation within that period. The Government reserves the right to extend this period if deemed necessary provided that such extension to the quotation validity period shall have written consent of the supplier(s).	

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

To be filled in by Vendors:

NO.	ITEM NAME	INSTRUMENT	VENDOR'S OFFER					
			EQA PROGRAM NAME	ANALYTES AVAILABLE	SAMPLE FREQUENCY	SAMPLE TYPE	NO. OF PEERS (PLEASE SUBMIT EVIDENCE)	Able to Register a Minimum of 2 Instruments (Yes or No)
1.	EQA Program for Blood Gas	Radiometer ABL90 FLEX PLUS						
		Abbott I-STAT1						
2.	EQA Program for Clinical Chemistry	Abbott Alinity c-Series						
		Abbott Architect ci4100						
3.	EQA Program for Ammonia	Abbott Alinity c-Series						
4.	EQA Program for CSF Chemistry	Abbott Alinity c-Series						
5.	EQA Program for Immunoassay	Abbott Alinity i-Series						
6.	EQA Program for Immunoassay Specialty	Abbott Alinity i-Series						
7.	EQA Program for Therapeutic Drugs Monitoring	Abbott Alinity c-Series						
8.	EQA Program for Immunosuppressant Drugs	Abbott Alinity i-Series						

NO.	ITEM NAME	INSTRUMENT	VENDOR'S OFFER					
			EQA PROGRAM NAME	ANALYTES AVAILABLE	SAMPLE FREQUENCY	SAMPLE TYPE	NO. OF PEERS (PLEASE SUBMIT EVIDENCE)	Able to Register a Minimum of 2 Instruments (Yes or No)
9.	EQA Program for Glycated Haemoglobin (HbA1c)	Bio-RAD D-100						
10.	EQA Program for Cardiac Marker	Abbott Alinity ci-Series						
		Abbott Architect ci4100						
11.	EQA Program for Lipid	Abbott Alinity c-Series						
12.	EQA Program for Specific Proteins	Abbott Alinity c-Series						
13.	EQA Program for Serum Hemolytic, Icteric and Lipemic (HIL) Indices	Abbott Alinity ci-Series						
		Abbott Architect ci4100						
14.	EQA Program for Paediatric Bilirubin	Abbott Alinity c-Series						
		Abbott Architect ci4100						

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/65/2024/LAB(TC)

INVITATION TO TENDER
TO SUPPLY AND **DELIVER EXTERNAL QUALITY ASSURANCE (EQA) MATERIALS** FOR **NATIONAL CLINICAL CHEMISTRY REFERENCE LABORATORY, DISTRICT LABORATORIES AND POINT OF CARE TESTING (POCT) SECTION**, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF **THREE (3)** YEARS USAGE, **PART I**

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	EQA Program for Blood Gases			
2	EQA Program for Clinical Chemistry			
3	EQA Program for Alcohol/Ammonia			
4	EQA Program for CSF Chemistry			
5	EQA Program for Immunoassay			
6	EQA Program for Immunoassay Specialty			
7	EQA Program for Therapeutic Drugs Monitoring			
8	EQA Program for Immunosuppressant Drugs			
9	EQA Program for Glycated Haemoglobin (HbA1c)			
10	EQA Program for Cardiac Marker			
11	EQA Program for Lipid			
12	EQA Program for Specific Proteins			
13	EQA Program for Serum Hemolytic, Icteric and Lipemic (HIL) Indices			
14	EQA Program for Paediatric Bilirubin			

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 : _____