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/91/2024/LAB(TC)	TO SUPPLY AND DELIVER EXTERNAL QUALITY PROGRAMS FOR TRANSFUSION, SEROLOGY AND HAEMATOLOGY TESTS FOR BLOOD DONATION CENTRE, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF FIVE(5) YEARS (2025 - 2029)	5 YEARS	DEPARTMENT OF LABORATORY SERVICES	\$30.00	21 <sup>ST</sup> MAY 2024	Nur Afiqah binti Abdullah Blood Donation Centre Department of Laboratory Services Ministry Of Health Negara Brunei Darussalam email: afiqah.abdullah@moh.gov.bn

**NOMBOR TAWARAN: KK/91/2024/LAB(TC)** 

# KEMENTERIAN KESIHATAN NEGARA BRUNEI DARUSSALAM

TO SUPPLY AND DELIVER EXTERNAL QUALITY PROGRAMS FOR TRANSFUSION, SEROLOGY AND HAEMATOLOGY TESTS FOR BLOOD DONATION CENTRE, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF FIVE(5) YEARS (2025 - 2029)

YURAN TAWARAN: \$30.00

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

(NON CLUSTERING)

#### **SECTION 2**

## SPECIFICATIONS AND REQUIREMENTS

TENDER REFERENCE NO: KK/91/2024/LAB(TC)

#### **INVITATION TO TENDER**

TO SUPPLY AND DELIVER EXTERNAL QUALITY PROGRAMS FOR TRANSFUSION, SEROLOGY AND HAEMATOLOGY TESTS FOR BLOOD DONATION CENTRE, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR PERIOF OF FIVE (5) YEARS (2025 – 2029)

NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE / YEAR
1	EQA Program samples for Transfusion Tests. This program shall include the following:		
1A	EQA Program sample for General Compatibility	Any	1 program per year
1B	EQA Program sample for Basic Compatibility	Any	3 programs per year
1C	EQA Program sample for Antibody Titre	Any	1 program per year
1D	EQA Program sample for Blood Grouping and Antibody Screen Only	Any	1 program per year
1E	EQA Program sample for Phenotyping Module	Any	2 programs per year
2	EQA Program samples for Serology Tests. This program shall include the following:		
2A	EQA Program sample for Hepatitis B Surface Antigen	Any	2 programs per year
2B	EQA Program sample for Hepatitis C Virus Antibody	Any	2 programs per year
2C	EQA Program sample for Human Immunodeficiency Virus Antigen & Antibody	Any	2 programs per year
2D	EQA Program sample for Syphilis TP Antibody Test	Any	2 programs per year
3	EQA Program samples for Haematology Tests		
ЗА	EQA Program sample for Haemoglobin Level Test	Any	4 programs per year

Items 1, 2 & 3 shall be offered as a group/cluster separately. However, cost per unit for each program shall be quoted individually as per table above.

NO.	SPECIFICATIONS AND REQUIREMENTS			
1	Vendor shall make enrolment with the appropriate EQA program service for each respective laboratory section(user)			
2	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).			
3	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.			
4	Vendor shall provide or update the laboratory of details or information on the test menu covered by the selected EQA program module.			
5	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.			
6	Vendor shall subscribe each EQA program for a period of <b>FIVE YEARS</b> for each respective laboratory. The EQA subscriptions should cover for the year of 2025 – 2029. Please state the EQA service provider pre-scheduled cycle.			
7	A replacement, with no additional cost, should be provided to the laboratory in the event that EQA materials are received in unsatisfactory conditions. This includes and not limited to damaged material, broken bottles, and, unsatisfactory shipping and transportation conditions and temperature.			
8	A replacement, with no additional cost, should be provided to the laboratory in the event that the quality of EQA materials are affecting the performance of the laboratory's EQA programs.			
9	<ul> <li>The EQA programs to be offered shall: <ul> <li>a. Substantially fulfil the relevant requirement of ISO 17043 and/or approved by recognized international regulatory body</li> <li>b. Extensive test menu as listed in Appendix A: Individual EQA Programmes Specification.</li> <li>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 of such EQA Report as evidence. Please provide individual EQA report for each test menu if the EQA program is offering each test separately.</li> <li>d. Participation by sufficient number of peer groups. Vendor is to submit number of peer groups, with evidence, for user's method in each program.</li> <li>e. Educational program shall be available in the system. Vendor is to state the educational program on offer.</li> </ul> </li> </ul>			
	Module configuration and program structure shall be acceptable by the user.  Peer group is defined as a group of laboratories performing the test analysis with the same methodology and instrument.			
10	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.			
11	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 fulfilling the requirements of ISO 15189			

12	EQA programs with participants from advanced countries such as Australia, UK and USA will be an added advantage.
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	<ul> <li>EQA materials shall be:</li> <li>a. Delivered to each respective laboratory no later than two (2) weeks before the deadline or due date of the EQA result submission.</li> <li>b. Transported in compliance with Universal Post Union (UPU) regulations</li> <li>c. Packed and transported within the requirements of EQA materials</li> <li>d. Transported in such conditions that the quality and integrity of the EQA materials are maintained</li> <li>e. Packed adequately to avoid damage during transportation</li> <li>f. Labelled appropriately with the dispatch date clearly indicated</li> <li>g. Labelled clearly. This includes information of species of origin of the base material and Material Safety Data Sheet (MSDS)</li> <li>h. Stable throughout the transportation</li> <li>i. Stable during storage without affecting the stability and integrity of the analytes in the EQA materials</li> <li>j. Homogeneous once the EQA materials are reconstituted</li> <li>k. Available in sufficient volume for analysis</li> <li>l. Performing in similar manner as patient samples during test analysis</li> <li>m. In similar specimen types as patient samples e.g. whole blood, serum and urine</li> <li>n. Covering concentrations across the analytical measuring range of each analyte. This</li> </ul>
16	includes clinical decision making concentrations of each analyte.  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
17	<ul> <li>h. Other relevant details</li> <li>Wherever applicable, EQA reports for tests must include the following: <ul> <li>a. The reports are in a user-friendly format</li> <li>b. One-page report per parameter or analyte allowing easy interpretation of the analytical performance</li> <li>c. 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 or other visual graphs.</li> <li>d. At-a-glance summary page for all parameters or analytes in the programme</li> <li>e. Comparison of the laboratory result against statistically robust consensus means</li> </ul> </li> <li>Wherever provided and available, the EQA reports test also include the following <ul> <li>a. Statistical analysis by all methods. This includes a running mean or results for the last 10 samples.</li> <li>b. Visual charts illustrating laboratory performance trends, biases and precisions</li> <li>c. Charts of Target Scores illustrating the performance of the recent 20 samples, inclusive of the samples in previous cycle</li> </ul> </li> <li>Wherever applicable, acceptability of parameter or analyte performance uses the following fit-for-purpose performance indicators: <ul> <li>i. Standard Deviation Index (SDI)</li> <li>ii. Percentage of Deviation</li> <li>iii. Target Score</li> </ul> </li> <li>d. Each parameter or analyte report shall include any of the following: <ul> <li>i. Levey-Jennings Charts</li> </ul> </li> </ul>

	" 0/ Davistica Objects
	iii. % Deviation Charts iv. % Deviation by concentration charts
	v. Other visual graphs of equivalent and relevant
	e. Available and accessible online within 72 hours of deadline of EQA program result
	submission f. Accessible via Cloud Based Data System
	g. 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
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 1 instrument.
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.
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	TRAINING Training shall be provided, at no additional cost, as follows:
28.1	On-site training for ALL staff members expected to handle the machine. Please ensure that adequate time is allocated such that training will take place in small groups to minimize staff shortage in the laboratory.
28.2	Certificate of competence is to be issued to all trainees after completion of training.
28.3	The successful tenderer needs to ensure the key users are updated on any relevant information related to the laboratory testing. They shall provide TWO off-site training for two (2) key users. All expenses for attending the training shall be borne by the vendor; full registration, air ticket, daily allowance, accommodation, transport to and from the airport and place of training. Training may be in the form of operator's training, workshop, congress, international conference including 3 <sup>rd</sup> -party conference, or other forms of training that is deemed appropriate and relevant.
28.4	Inviting speakers from overseas to give talks or presentations to the users on topics related to the laboratory testing as part of users' continuous education. Certificate of attendance is to be issued to all trainees after completion of training.

29	FINANCIAL AGREEMENT		
29.1	Supply of the EQA programs is based on the number of programs required in the Purchase Order according to an agreed schedule period.		
29.2	Should there be any discontinuity of EQA program due to any unforeseeable circumstances; the vendor must be able to provide an alternative so that the EQA programs are still available for the laboratory.		
29.3	<ul> <li>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: <ol> <li>When the testing is no longer required or relevant i.e. test is obsolete, to the laboratory or the Department.</li> <li>When the item(s) set out in this tender is/are no longer required by the laboratory or the Department.</li> <li>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).</li> </ol> </li> </ul>		
30	DELIVERY PERIOD: According to the EQA provider schedule.		
31	PRICE VALIDITY: The quotation shall remain valid for TWELVE (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).		

 $<sup>^{\</sup>ast}$  6 months validity required for <\$50K or 12 months for >\$50K

DELIVERY PERIOD AFTER PO ISSUED	Accordin	ng to the EQA provider so	chedule	
Lab/Section/Unit	BLOOD I	DONATION CENTRE		
Lab/Section/Unit Ref No.:	DLS/PU/	BDC/2024/001		
	Name	: NUR AFIQAH BINTI AB	DULLAH	
Person to Contact	E-mail	E-mail: AFIQAH.ABDULLAH@MOH.GOV.BN		
	Tel. No.	: 6738840680	Fax No. : -	
FOR ADMINISTRATION USE ONLY				
PPM/PROC Ref. No.	PPM/PR	OC/2024/>50K/010(BDC)		
Advertisement Ref. No.			Date :	

# **APPENDIX A**

## INDIVIDUAL EQA PROGRAMMES SPECIFICATIONS

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	
1	EQA Program samples for Transfusion Tests shall include the following programs:			
1A	EQA Program sample for General Compatibility	<ul> <li>Program must include:         <ul> <li>ABO grouping</li> <li>Rh grouping</li> <li>Antibody Screen</li> <li>Antibody Identification</li> <li>Red Blood Cell Antigen Phenotyping</li> <li>Crossmatch/Compatibility testing</li> <li>Direct Antiglobulin Test (DAT)</li> <li>Elution</li> </ul> </li> <li>Minimum of 6 surveys per year</li> <li>Sample type: EDTA Whole blood and Red Blood Cell Suspension</li> <li>Preferably not less than 10 peer group</li> <li>Program must include Clerical Error assessment</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey</li> <li>Each sample purchased should be at least 4 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any	
1B	EQA Program sample for Basic Compatibility	<ul> <li>Program must include:         <ul> <li>ABO grouping</li> <li>Rh grouping</li> <li>Antibody Screen</li> <li>Direct Antiglobulin Test (DAT)</li> <li>Crossmatch/ Compatibility testing</li> </ul> </li> <li>Minimum of 4 surveys per year</li> <li>Sample type: EDTA Whole blood and Red Blood Cell Suspension</li> <li>Preferably not less than 10 peer group</li> <li>Program must include Clerical Error assessment</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey</li> <li>Each sample purchased should be at least 4 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any	
1C	EQA Program sample for Antibody Titre	<ul> <li>Program must include:         <ul> <li>Antibody titre</li> </ul> </li> <li>Minimum of 4 surveys per year</li> <li>Sample type: plasma</li> <li>Preferably not less than 10 peer group</li> <li>Program must include Clerical Error assessment</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey</li> <li>Each sample purchased should be at least 4 ml for I nitial run and repeat (in case there is invalid batch run).</li> </ul>	Any	

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE
1D	EQA Program sample for Blood Grouping and Antibody Screen Only	<ul> <li>Program must include:         <ul> <li>ABO grouping</li> <li>Rh grouping</li> <li>Antibody Screen</li> </ul> </li> <li>Minimum of 6 surveys per year with minimum of 2 samples per survey</li> <li>Sample type: EDTA Whole blood</li> <li>Preferably not less than 10 peer group</li> <li>Current method: Bio-Rad DiaClon ABO/D + Reverse Grouping and ID-DiaCell I-II-III Asia</li> <li>Program must include Clerical Error assessment</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey</li> <li>Each sample purchased should be at least 4 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any
1E	EQA Program sample for Phenotyping Module	<ul> <li>Program must include the following test: Phenotyping (at least these Rhesus antigens should be tested: C, E, c, e and K)</li> <li>Sample Type: EDTA Whole Blood Sample should be Suitable to be performed on Bio-Rad IH 1000 platform with no manual mixing or reconstitution of sample</li> <li>Not Less than 10 peer groups</li> <li>Minimum of 6 surveys per year</li> <li>Please provide list of red cell antigen phenotyping that are included and available to be tested</li> <li>Each sample purchased should be at least 4 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any
2	EQA Program samp	eles for Serology Tests shall include the following prog	grams:
2A	EQA Program sample for Hepatitis B Surface Antigen	<ul> <li>Program must include:         <ul> <li>HBsAg screening test</li> </ul> </li> <li>Minimum of 6 surveys per year with minimum of 2 samples per survey</li> <li>Sample type: Serum</li> <li>Current Method: DiaSorin Liaison XL murex HBsAg Quant</li> <li>Preferably not less than 10 peer group</li> <li>Program must include Clerical Error assessment</li> <li>Online result entry must include entry of quantitative values, reagent lot and reagent expiry date</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey</li> <li>Each sample purchased should be at least 1.5 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE
2B	EQA Program sample for Hepatitis C Virus Antibody	<ul> <li>Program must include:         <ul> <li>AHCV Screening Test</li> </ul> </li> <li>Minimum of 6 surveys per year with minimum of 2 samples per survey</li> <li>Sample type: Serum</li> <li>Current Method: DiaSorin Liaison XL murex HCV Ab</li> <li>Preferable, not less than 10 peer group</li> <li>Program must include Clerical Error assessment</li> <li>Online result entry must include entry of quantitative values, reagent lot and reagent expiry date</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey.</li> <li>Each sample purchased should be at least 0.5 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any
2C	EQA Program sample for Human Immunodeficiency Virus Antigen & Antibody	<ul> <li>Program must include:         <ol> <li>HIV antigen/antibody combo screening</li> </ol> </li> <li>Minimum of 6 surveys per year with minimum of 2 samples per survey</li> <li>Sample type: Serum</li> <li>Current Method: DiaSorin Liaison XL murex Ab/Ag</li> <li>Preferably, not less than 10 peer group</li> <li>Program must include Clerical Error assessment Online result entry must include entry of quantitative values, reagent lot and reagent expiry date</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey.</li> <li>Each sample purchased should be at least 1.0 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any
2D	EQA Program sample for Syphilis TP Antibody Test	<ul> <li>Program must include: <ul> <li>Syphilis Total antibody screening assay</li> </ul> </li> <li>Minimum of 4 surveys per year with minimum of 2 samples per year</li> <li>Sample type: Serum</li> <li>Current Method: DiaSorin Liaison Treponema</li> <li>Not less than 10 peer group</li> <li>Program must include Clerical Error assessment Online result entry must include entry of quantitative values, reagent lot and reagent expiry date</li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey.</li> <li>Each sample purchased should be at least 0.5 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any

NO.	ITEM NAME	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	
3	EQA Program samples for Haematology Tests			
3A	EQA Program sample for Haemoglobin Level Test	<ul> <li>Program must include: <ol> <li>HB (Haemoglobin level)</li> <li>Full Blood Count</li> </ol> </li> <li>Minimum of 12 surveys per year with minimum of 2 samples per year</li> <li>Each program can be used on a minimum of three (3) instruments.</li> <li>Please state number of peer group for these analyzers: <ol> <li>Hemocue 201+</li> <li>Hemocue 301</li> <li>Hemocue 301</li> <li>Sysmex XN1000</li> </ol> </li> <li>Program report must show peer group histogram or equivalent showing the performance of participants in each survey.</li> <li>Report to indicate whether the result is acceptable or not or allowable limit of performance.</li> <li>Graph for past and present result.</li> <li>Each sample purchased should be at least 1.5 ml for initial run and repeat (in case there is invalid batch run).</li> </ul>	Any	

# **SECTION 3**

# **FORMS TO BE USED**

## **CONTENTS**

- **SCHEDULE 1 TENDER FORM**
- **SCHEDULE 2 INFORMATION SUMMARY**
- **SCHEDULE 3 SUB-CONTRACTS**
- **SCHEDULE 4 COMPANY BACKGROUND**
- **SCHEDULE 5 REFERENCES**
- SCHEDULE 6 SUBMISSION OF SAMPLE
- **SCHEDULE 7 LETTER OF DECLARATION**

## **SCHEDULE 1**

## **TENDER FORM**

To:

#### TENDER REFERENCE NO: KK/91/2024/LAB(TC)

#### **INVITATION TO TENDER**

TO SUPPLY AND DELIVER EXTERNAL QUALITY PROGRAMS FOR TRANSFUSION, SEROLOGY AND HAEMATOLOGY TESTS FOR BLOOD DONATION CENTRE, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR PERIOF OF FIVE (5) YEARS (2025 – 2029)

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	1 EQA Program samples for Transfusion Tests. This program shall include the following:								

	USER'S REQ	UIREMENTS		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\$)
1A	EQA Program sample for General Compatibility	Any	1 program per year						
1B	EQA Program sample for Basic Compatibility	Any	3 programs per year						
1C	EQA Program sample for Antibody Titre	Any	1 program per year						
1D	EQA Program sample for Blood Grouping and Antibody Screen Only	Any	1 program per year						
1E	EQA Program sample for Phenotyping Module	Any	2 programs per year						
2	EQA Program samples for S	Serology Tests.	This progran	n shall include the fo	ollowing:				
2A	EQA Program sample for Hepatitis B Surface Antigen	Any	2 programs per year						
2B	EQA Program sample for Hepatitis C Virus Antibody	Any	2 programs per year						
2C	EQA Program sample for Human Immunodeficiency Virus Antigen & Antibody	Any	2 programs per year						
2D	EQA Program sample for Syphilis TP Antibody Test	Any	2 programs per year						
3	EQA Program samples for F	laematology Te	sts						

	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\$)
ЗА	EQA Program sample for Haemoglobin Level Test	Any	4 programs per year						
TOTAL PRICE (B\$)									

Items 1, 2 & 3 shall be offered as a group/cluster separately. However, cost per unit for each program shall be quoted individually as per table above.

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
1	Vendor shall make enrolment with the appropriate EQA program service for each respective laboratory section(user)	
2	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).	
3	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.	
4	Vendor shall provide or update the laboratory of details or information on the test menu covered by the selected EQA program module.	
5	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.	
6	Vendor shall subscribe each EQA program for a period of <b>FIVE YEARS</b> for each respective laboratory. The EQA subscriptions should cover for the year of 2025 – 2029. Please state the EQA service provider pre-scheduled cycle.	
7	A replacement, with no additional cost, should be provided to the laboratory in the event that EQA materials are received in unsatisfactory conditions. This includes and not limited to damaged material, broken bottles, and, unsatisfactory shipping and transportation conditions and temperature.	
8	A replacement, with no additional cost, should be provided to the laboratory in the event that the quality of EQA materials are affecting the performance of the laboratory's EQA programs.	
9	<ul> <li>The EQA programs to be offered shall:</li> <li>a. Substantially fulfil the relevant requirement of ISO 17043 and/or approved by recognized international regulatory body</li> <li>b. Extensive test menu as listed in Appendix A: Individual EQA Programmes Specification.</li> <li>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 of such EQA Report as evidence. Please provide individual EQA report for each test menu if the EQA program is offering each test separately.</li> </ul>	

	<ul> <li>d. Participation by sufficient number of peer groups. Vendor is to submit number of peer groups, with evidence, for user's method in each program.</li> <li>e. Educational program shall be available in the system. Vendor is to state the educational program on offer.</li> <li>Module configuration and program structure shall be acceptable by the user.</li> </ul>	
	Peer group is defined as a group of laboratories performing the test analysis with the same methodology and instrument.	
10	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.	
11	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 fulfilling the requirements of ISO 15189	
12	EQA programs with participants from advanced countries such as Australia, UK and USA will be an added advantage.	
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	<ul> <li>EQA materials shall be:</li> <li>a. Delivered to each respective laboratory no later than two (2) weeks before the deadline or due date of the EQA result submission.</li> <li>b. Transported in compliance with Universal Post Union (UPU) regulations</li> <li>c. Packed and transported within the requirements of EQA materials</li> </ul>	

		<del>-</del>	
1	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	
	I.	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.	
		ctions for use for each EQA material shall be provided. The instruction shall	
	include		
		Nature of the EQA material	
		Treatment of the EQA material	
16		Safety precautions	
		Due date of result submission	
	e.	Reconstitution and preparation procedure Expiry date	
	1.	Stability of each analyte	
	g.	Other relevant details	
		ever applicable, EQA reports for tests must include the following:	
		The reports are in a user-friendly format	
		One-page report per parameter or analyte allowing easy interpretation of	
		the analytical performance	
	C.		
17	0.	group, methodology peer group and all methods group. The comparison is	
		illustrated in a histogram format or other visual graphs.	
	d.		
	e.		
		means	
<u> </u>	l		

	Wherever provided and excitable, the FOA reports test also include the following	
	Wherever provided and available, the EQA reports test also include the following	
	a. Statistical analysis by all methods. This includes a running mean or results	
	for the last 10 samples.	
	b. Visual charts illustrating laboratory performance trends, biases and	
	precisions	
	c. Charts of Target Scores illustrating the performance of the recent 20	
	samples, inclusive of the samples in previous cycle	
	Wherever applicable, 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	
	d. Each parameter or analyte report shall include any of the following:	
	i. Levey-Jennings Charts	
	ii. Histograms	
	iii. % Deviation Charts	
	iv. % Deviation by concentration charts	
	v. Other visual graphs of equivalent and relevant	
	e. Available and accessible online within 72 hours of deadline of EQA	
	program result submission	
	f. Accessible via Cloud Based Data System	
	g. Current and previous reports are available for download on the EQA	
	service provider site.	
	Solvide 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	
	•	
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	
19	1 instrument.	
	Vendor shall provide necessary advice and consultation promptly when the	
	laboratory requires assistance. When vendor is unable to provide the required	
20	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.	
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	TRAINING Training shall be provided, at no additional cost, as follows:	
28.1	On-site training for ALL staff members expected to handle the machine. Please ensure that adequate time is allocated such that training will take place in small groups to minimize staff shortage in the laboratory.	
28.2	Certificate of competence is to be issued to all trainees after completion of training.	
28.3	The successful tenderer needs to ensure the key users are updated on any relevant information related to the laboratory testing. They shall provide TWO off-site training for two (2) key users. All expenses for attending the training shall be borne by the vendor; full registration, air ticket, daily allowance, accommodation, transport to and from the airport and place of training. Training may be in the form of operator's training, workshop, congress, international conference including 3 <sup>rd</sup> -party conference, or other forms of training that is deemed appropriate and relevant.	
28.4	Inviting speakers from overseas to give talks or presentations to the users on topics related to the laboratory testing as part of users' continuous education. Certificate of attendance is to be issued to all trainees after completion of training.	

29	FINANCIAL AGREEMENT	
29.1	Supply of the EQA programs is based on the number of programs required in the Purchase Order according to an agreed schedule period.	
29.2	Should there be any discontinuity of EQA program due to any unforeseeable circumstances; the vendor must be able to provide an alternative so that the EQA programs are still available for the laboratory.	
29.3	<ul> <li>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: <ol> <li>When the testing is no longer required or relevant i.e. test is obsolete, to the laboratory or the Department.</li> <li>When the item(s) set out in this tender is/are no longer required by the laboratory or the Department.</li> <li>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).</li> </ol> </li> </ul>	
30	DELIVERY PERIOD: According to the EQA provider schedule.	(Yes / No) (If No, please specify)
31	PRICE VALIDITY: The quotation shall remain valid for TWELVE (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).	

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

- 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 <u>TWELVE (12)</u> 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 thisday of	, 20
	Tenderer's official stamp:
[Signature of authorised officer of Tenderer]	renderer e emelar etamp.
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

		Alliance Relationship between Contractor and Sub-contractor(s)		
Company Name	Responsibility Description	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/91/2024/LAB(TC)

#### **INVITATION TO TENDER**

TO SUPPLY AND DELIVER EXTERNAL QUALITY PROGRAMS FOR TRANSFUSION, SEROLOGY AND HAEMATOLOGY TESTS FOR BLOOD DONATION CENTRE, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR PERIOF OF FIVE (5) YEARS (2025 – 2029)

#### **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 samples for Transfusion Tests. This program shall include the following:			
1A	EQA Program sample for General Compatibility			
1B	EQA Program sample for Basic Compatibility			
1C	EQA Program sample for Antibody Titre			
1D	EQA Program sample for Blood Grouping and Antibody Screen Only			
1E	EQA Program sample for Phenotyping Module			
2	EQA Program samples for Serology Tests. This program shall include the following:			
2A	EQA Program sample for Hepatitis B Surface Antigen			
2B	EQA Program sample for Hepatitis C Virus Antibody			
2C	EQA Program sample for Human Immunodeficiency Virus Antigen & Antibody			
2D	EQA Program sample for Syphilis TP Antibody Test			
3	EQA Program samples for Haematology Tests			
ЗА	EQA Program sample for Haemoglobin Level Test			

We understand as s considered.	tated in the Instructions to Tenderers th	at Tenders without samples shall not be
- 0	zed officer of Tenderer]	Tenderer's official stamp:
Name:		
Designation:		
Date:		
_	FOR OFFICE USE	
Date of receipt	:	
Receiving Officer	<b>:</b>	