

REFERENCE OF TENDER	DESCRIPTION OF TENDER	TIME PERIOD OF TENDER	DEPARTMENT/DIVISION/UNIT REQUESTING TENDER	FEES	CLOSING DATE NOT LATER THAN 2.00PM	FOCAL PERSON
KK/120/2024/LAB	TO SUPPLY AND DELIVER COVID-19 ART KITS FOR POINT OF CARE TESTING SECTION DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF ONE(1) YEAR USAGE	1 YEAR	DEPARTMENT OF LABORATORY SERVICES	\$30.00	18 TH JUNE 2024	<p>Susylawati binti Haji Magon Point of Care Testing Section Department of Laboratory Services Ministry of Health Negara Brunei Darussalam Contact No: 2242424 ext 6354/6358 email: susylawati.magon@moh.gov.bn</p>

NOMBOR TAWARAN : KK/120/2024/LAB

**KEMENTERIAN KESIHATAN
NEGARA BRUNEI DARUSSALAM**

**TO SUPPLY AND DELIVER COVID-19 ART KITS FOR POINT OF CARE
TESTING SECTION , DEPARTMENT OF LABORATORY SERVICES,
MINISTRY OF HEALTH FOR A PERIOD OF ONE(1) YEAR USAGE**

YURAN TAWARAN: \$30.00

NOMBOR RESIT :

TARIKH TUTUP : HARI SELASA, 18HB JUN 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/120/2024/LAB

INVITATION TO TENDER

**TO SUPPLY AND DELIVER COVID-19 ART KITS FOR POINT OF CARE TESTING SECTION,
DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF ONE
(1) YEAR USAGE**

DELIVERY TIME	4-8 WEEKS AND NO LONGER THAN 12 WEEKS
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NO.	ITEM DESCRIPTIONS AND SPECIFICATIONS	PACKAGING SIZE	TOTAL ESTIMATE USAGE/YEAR
1	<p>COVID-19 ART KITS</p> <p>Pack of 25 units (per test kits) or equivalent of the following:</p> <ol style="list-style-type: none">1. Test cassette2. Pre-filled tube containing reagent/extraction buffer solution with nozzle/cap of the extraction tube.3. Single-use sterile swab for sample collection of nasal or anterior nasal only4. Waste disposal plastic bag (zip lock)	25 TESTS KITS/BOX OR EQUIVALENT	300,000 TEST KITS

NO.	SPECIFICATIONS AND REQUIREMENTS
1	All reagent test kits / consumables supplied throughout this tender <u>shall</u> 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	TECHNICAL SPECIFICATIONS: <u>COVID-19 ANTIGEN RAPID TEST KITS</u>
3.1	Tender shall include supply and delivery of Covid-19 antigen rapid test kits and technical support when required by Point-of-Care Testing Section, Department of Laboratory Services. The offered test kits must be listed in the COVID-19 Rapid Test Kits (ART) Authorised for Used in Brunei Darussalam . Evidence of documentation shall be provided with tender document
3.2	International markings: products must be CE marked and approved with FDA Emergency Use Authorisation. Documentation of conformity to the above criteria shall be provided with tender document
3.3	Vendor, on behalf of user must request for shelf-life extension of ART kits from manufacturer when required.
3.4	Vendor must submit one (1) box of 25 test kits (or 20 test kits according to manufacturer's packaging) to be offered for SAMPLER with tender document The offered COVID-19 Rapid Antigen Test kits should content the following items: Covid-19 Antigen Test cassette (20 or 25 units) Reagent/extraction buffer solution in pre-filled tubes with nozzle/cap (20 or 25 sets) Waste disposal plastic bag (zip-lock) (20 or 25 units) Instruction for use (both in English and Malay languages) (1 copy in each box)
3.5	The principle of the assay of the test kit is a qualitative membrane based chromatographic immunoassay for the qualitative detection of nucleocapsid antigen from SARS-CoV-2 in human nasal swab.
3.6	The lateral flow method must be specific to SARS CoV-2 nucleocapsid antigens
3.7	The kit must be in a cassette format intended to be used at POCT setting and self-testing .
3.8	Methodology of the test kit should comply with ISO 13485 certification, (globally recognized system for the design, development, and manufacture of medical devices) Evidence of documentation shall be provided with tender document
3.9	Performance Characteristics (Nasal): <ul style="list-style-type: none"> • Clinical sensitivity – shall reach a minimum of 97% • Clinical specificity – shall reach a minimum of 97%

NO.	SPECIFICATIONS AND REQUIREMENTS
	<ul style="list-style-type: none"> • Analytical specificity – Assays detects all strains SARSCoV-2 viral strains and does not cross-react with common interfering substances or other human coronaviruses such as SARS-CoV-1 or any other common human diseases, especially those presenting with similar signs and symptoms of Covid-19 (e.g. Influenzae A, B, RSV, malaria and dengue) • Limit of Detection – Less than 1×10^2TCID50/mL <p>Independent study laboratory report on the performance of the test kit must be submitted with the tender document.</p>
3.10	<p>The test kits must NOT be affected by the Sars-CoV-2 variant of interest such as:</p> <ul style="list-style-type: none"> • Alpha variant (United Kingdom) • Gamma variant (South Africa) • Delta variant (India) • Epsilon variant (USA) • Omicron variant (South Africa) <p>Evidence or report on the effect of Covid-19 variants listed above shall be submitted with the tender document</p>
3.11	<p>Specimen volume and type:</p> <ul style="list-style-type: none"> • Single-use swab – 1 unit • Nasal/anterior nasal nares ONLY • Swab can be used for children 2 years above.
3.12	<p>Test Results:</p> <ul style="list-style-type: none"> • Qualitative • Time to resulting is at 10 or 15 minutes and not exceeding 30 minutes
3.13	<p>End-point Stability: Fixed reading time as per stated in the manufacturer’s instruction for use.</p>
3.14	<p>Quality Control: Shall have two types of Quality Controls:</p> <ul style="list-style-type: none"> • <u>Internal Quality Control</u> (for sample flow/migration) within the individual testing device. • <u>External Positive and Negative Control swabs</u> <ul style="list-style-type: none"> ○ 5 sets of external positive and negative control swabs shall be supplied for each batch (delivery or lot number). ○ Documentation pertinent to the control swabs such as instruction for use, MSDS and Certificate of Analysis shall be provided with tender document.
3.15	<p>Successful vendor must submit the following documents upon each delivery of the test kits:</p> <ul style="list-style-type: none"> • Certificate of Analysis (for each lot or batch number of the supplied test kits). • Instruction for use (both in English and Malay languages). • Material Safety Data Sheet of the cassette and nasal swab. • Demonstration video of step-by-step procedure of self-testing performing the test which includes nasal sampling, testing, result interpretation and disposal of waste)
3.16	<p>Environmental Requirements: Transport and storage requirements: Test kits:</p> <ul style="list-style-type: none"> • Temperature – 2- 40°C • Humidity – 75 – 80% <p>Specimen collection media:</p> <ul style="list-style-type: none"> • Temperature – 2 - 30°C
3.17	<p>The successful vendor is to perform the method verification procedure for the kits to be offered prior to be used by the users at no additional cost. Report of method verification is to be submitted to Point-of-Care Testing Section for authorization of use. Requirement of method of verification must be consulted with Point of Care Testing Section prior to performing the method verification of the test kits.</p>

NO.	SPECIFICATIONS AND REQUIREMENTS
3.18	<p>The successful vendor is to provide the following on-site training at no additional cost and to submit the evidence of training conducted (Certificate of Training) to the POCT Section:</p> <ul style="list-style-type: none"> • New user training • Refresher training if required
3.19	<p>The successful vendor must replace any faulty test kits such as insufficient materials supplied, spoilt test kits or collection swabs or other materials supplied, tampered test when identified during the period of tender.</p> <p>The successful vendor is to provide support in troubleshooting if there are any incidents or issued reported that are related to the use and quality of the supplied test kits.</p>
3.20	<p>Staggered delivery will be applied upon request by the Point-of Care Testing Section for the period of 1 year.</p> <p>The successful vendor must provide proper storage area in accordance with the environmental requirement of the test kits for test kits that have yet to be delivered to Point of Care Testing Section</p>
3.21	<p>All test kits supplied throughout this tender must have a minimum expiry date of ONE (1) YEAR on staggered delivery. Should the reagent be urgently needed, provision of a reagent test kit or consumable with expiry date of less than ONE (1) YEAR should be first agreed by the POCT Section before delivery is made.</p>
4	<p>TECHNICAL SPECIFICATIONS: <u>SARS-COV-2 EXTERNAL QUALITY CONTROL PROGRAM</u></p>
4.1	<ul style="list-style-type: none"> • shall be simulated nasal specimens containing noninfectious SARS-COV-2 antigen. • storage and stability – 2-8°Celsius
4.3	<p>Successful vendor shall assist in enrolling/registering the External</p> <ol style="list-style-type: none"> 1. Quality Control Program on behalf of Point of Care Testing Section, Department of Laboratory Services
4.4	<p>Able to submit and receive results and reports respectively via online (website)</p>
5	<p>MISCELLANEOUS</p>
5.1	<p>Product inserts and MSDS shall be provided to the User</p>
5.2	<p>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:</p> <ol style="list-style-type: none"> 1. Tampered or damaged box 2. Leakage upon delivery 3. Items stored pre-delivery not in accordance to manufacturer's instruction 4. Expiry date not meeting requirement
5.3	<p>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:</p> <ol style="list-style-type: none"> 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
5.4	<p>Vendor shall submit samples of the offered items directly to the Users no later than 7 days after the Closing Date of this advertisement or as required by the Users.</p>

NO.	SPECIFICATIONS AND REQUIREMENTS
6	FINANCIAL AGREEMENT
6.1	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.
6.2	Buffer stock of the test kit including reagents, consumables and accessories shall be available at the local representative as contingency.
6.3	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.
6.4	EXIT CLAUSE:
	<p>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:</p> <ol style="list-style-type: none"> 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. <p>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 (<i>Lembaga Tawaran Kecil</i>).</p>
7	DELIVERY PERIOD: Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order
8	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

DELIVERY PERIOD AFTER PO ISSUED	4-8 weeks and no longer than 12 weeks	
Lab/Section/Unit	POINT OF CARE TESTING SECTION	
Lab/Section/Unit Ref No.:	DLS/PU/POC/2024/05-01	
Person to Contact	Name: SUSYLAWATI BINTI HAJI MAGON	
	E-mail: susylawati.magon@moh.gov.bn	
	Tel. No.: 2242424 ext. 6354	Fax No. : 2220869
FOR ADMINISTRATION USE ONLY		
PPM/PROC Ref No.	PPM/PROC/2024/>50k/014(POC)	
Advertisement Ref. No.		Date :

SECTION 3

TENDER FORMS

TENDER REFERENCE NO: **KK/120/2024/LAB**

INVITATION TO TENDER

TO SUPPLY AND DELIVER COVID-19 ART KITS FOR POINT OF CARE TESTING SECTION, DEPARTMENT OF LABORATORY SERVICES, MINISTRY OF HEALTH FOR A PERIOD OF ONE (1) YEAR USAGE

DELIVERY PERIOD	
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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	COVID-19 ART KITS Pack of 25 units (per test kits) or equivalent of the following: 1. Test cassette 2. Pre-filled tube containing reagent/extraction buffer solution with nozzle/cap of the extraction tube. 3. Single-use sterile swab for sample collection of nasal or anterior nasal only 4. Waste disposal plastic bag (ziplock)	25 TESTS KITS/BOX OR EQUIVALENT	300,000 TEST KITS						

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
1	All reagent test kits / consumables supplied throughout this tender <u>shall</u> 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	TECHNICAL SPECIFICATIONS: COVID-19 ANTIGEN RAPID TEST KITS	
3.1	Tender shall include supply and delivery of Covid-19 antigen rapid test kits and technical support when required by Point-of-Care Testing Section, Department of Laboratory Services. The offered test kits must be listed in the COVID-19 Rapid Test Kits (ART) Authorised for Used in Brunei Darussalam . Evidence of documentation shall be provided with tender document	
3.2	International markings: products must be CE marked and approved with FDA Emergency Use Authorisation. Documentation of conformity to the above criteria shall be provided with tender document	
3.3	Vendor, on behalf of user must request for shelf-life extension of ART kits from manufacturer when required.	
3.4	Vendor must submit one (1) box of 25 test kits (or 20 test kits according to manufacturer's packaging) to be offered for SAMPLER with tender document The offered COVID-19 Rapid Antigen Test kits should content the following items: – Covid-19 Antigen Test cassette (20 or 25 units) – Reagent/extraction buffer solution in pre-filled tubes with nozzle/cap (20 or 25 sets) – Waste disposal plastic bag (zip-lock) (20 or 25 units)	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	– Instruction for use (both in English and Malay languages) (1 copy in each box)	
3.5	The principle of the assay of the test kit is a qualitative membrane based chromatographic immunoassay for the qualitative detection of nucleocapsid antigen from SARS-CoV-2 in human nasal swab.	
3.6	The lateral flow method must be specific to SARS CoV-2 nucleocapsid antigens	
3.7	The kit must be in a cassette format intended to be used at POCT setting and self-testing .	
3.8	Methodology of the test kit should comply with ISO 13485 certification, (globally recognized system for the design, development, and manufacture of medical devices) Evidence of documentation shall be provided with tender document	
3.9	<p>Performance Characteristics (Nasal):</p> <ul style="list-style-type: none"> • Clinical sensitivity – shall reach a minimum of 97% • Clinical specificity – shall reach a minimum of 97% • Analytical specificity – Assays detects all strains SARSCoV-2 viral strains and does not cross-react with common interfering substances or other human coronaviruses such as SARS-CoV-1 or any other common human diseases, especially those presenting with similar signs and symptoms of Covid-19 (e.g. Influenzae A, B, RSV, malaria and dengue) • Limit of Detection – Less than 1×10^2TCID50/mL <p>Independent study laboratory report on the performance of the test kit must be submitted with the tender document.</p>	
3.10	<p>The test kits must NOT be affected by the Sars-CoV-2 variant of interest such as:</p> <ul style="list-style-type: none"> • Alpha variant (United Kingdom) • Gamma variant (South Africa) • Delta variant (India) • Epsilon variant (USA) • Omicron variant (South Africa) 	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
	Evidence or report on the effect of Covid-19 variants listed above shall be submitted with the tender document	
3.11	Specimen volume and type: <ul style="list-style-type: none"> • Single-use swab – 1 unit • Nasal/anterior nasal nares ONLY Swab can be used for children 2 years above.	
3.12	Test Results: <ul style="list-style-type: none"> • Qualitative • Time to resulting is at 10 or 15 minutes and not exceeding 30 minutes 	
3.13	End-point Stability: Fixed reading time as per stated in the manufacturer's instruction for use.	
3.14	Quality Control: Shall have two types of Quality Controls: <ul style="list-style-type: none"> • <u>Internal Quality Control</u> (for sample flow/migration) within the individual testing device. • <u>External Positive and Negative Control swabs</u> <ul style="list-style-type: none"> ○ 5 sets of external positive and negative control swabs shall be supplied for each batch (delivery or lot number). ○ Documentation pertinent to the control swabs such as instruction for use, MSDS and Certificate of Analysis shall be provided with tender document. 	
3.15	Successful vendor must submit the following documents upon each delivery of the test kits: <ul style="list-style-type: none"> • Certificate of Analysis (for each lot or batch number of the supplied test kits). • Instruction for use (both in English and Malay languages). • Material Safety Data Sheet of the cassette and nasal swab. • Demonstration video of step-by-step procedure of self-testing performing the test which includes nasal sampling, testing, result interpretation and disposal of waste) 	
3.16	Environmental Requirements: Transport and storage requirements: <ol style="list-style-type: none"> 1. Test kits: <ul style="list-style-type: none"> • Temperature – 2- 40°C • Humidity – 75 – 80% 2. Specimen collection media: <ul style="list-style-type: none"> • Temperature – 2 - 30°C 	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
3.17	The successful vendor is to perform the method verification procedure for the kits to be offered prior to be used by the users at no additional cost. Report of method verification is to be submitted to Point-of-Care Testing Section for authorization of use. Requirement of method of verification must be consulted with Point of Care Testing Section prior to performing the method verification of the test kits.	
3.18	The successful vendor is to provide the following on-site training at no additional cost and to submit the evidence of training conducted (Certificate of Training) to the POCT Section: <ul style="list-style-type: none"> • New user training • Refresher training if required 	
3.19	The successful vendor must replace any faulty test kits such as insufficient materials supplied, spoilt test kits or collection swabs or other materials supplied, tampered test when identified during the period of tender. The successful vendor is to provide support in troubleshooting if there are any incidents or issued reported that are related to the use and quality of the supplied test kits.	
3.20	Staggered delivery will be applied upon request by the Point-of Care Testing Section for the period of 1 year. The successful vendor must provide proper storage area in accordance with the environmental requirement of the test kits for test kits that have yet to be delivered to Point of Care Testing Section	
3.21	All test kits supplied throughout this tender must have a minimum expiry date of ONE (1) YEAR on staggered delivery . Should the reagent be urgently needed, provision of a reagent test kit or consumable with expiry date of less than ONE (1) YEAR should be first agreed by the POCT Section before delivery is made.	
4	TECHNICAL SPECIFICATIONS: <u>SARS-COV-2 EXTERNAL QUALITY CONTROL PROGRAM</u>	
4.1	<ul style="list-style-type: none"> • shall be simulated nasal specimens containing noninfectious SARS-COV-2 antigen. • storage and stability – 2-8°Celsius 	
4.3	Successful vendor shall assist in enrolling/registering the External <ul style="list-style-type: none"> • Quality Control Program on behalf of Point of Care Testing Section, Department of Laboratory Services 	

NO.	SPECIFICATIONS AND REQUIREMENTS	VENDOR'S OFFER (PLEASE STATE)
4.4	Able to submit and receive results and reports respectively via online (website)	
5	MISCELLANEOUS	
5.1	Product inserts and MSDS shall be provided to the User	
5.2	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: <ol style="list-style-type: none"> 1. Tampered or damaged box 2. Leakage upon delivery 3. Items stored pre-delivery not in accordance to manufacturer's instruction 4. Expiry date not meeting requirement 	
5.3	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: <ol style="list-style-type: none"> 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 	
5.4	Vendor shall submit samples of the offered items directly to the Users no later than 7 days after the Closing Date of this advertisement or as required by the Users.	
6	FINANCIAL AGREEMENT	
6.1	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.	
6.2	Buffer stock of the test kit including reagents, consumables and accessories shall be available at the local representative as contingency.	
6.3	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)
6.4	EXIT CLAUSE:	
	<p>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:</p> <ol style="list-style-type: none"> 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. <p>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 (<i>Lembaga Tawaran Kecil</i>).</p>	
7	DELIVERY PERIOD: Preferably 4 – 8 weeks and no later than 12 weeks after issue of Purchase Order	(Yes / No) (If No, please specify)
8	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).	