**P R O F O R M A**

**Request for Market Information (“RFI”) for
Supply of** **Laboratory Automation System (LAS)**

**to The Chinese Medicine Hospital of Hong Kong (“CMHHK”)**

**(CMHPO Ref.: HHB/H/24/17/3/3/3)**

To : Project Director (CMHPO)

 (Attn. Ms Stella Cheung)

[by fax: 2127 4795 or email: syhcheung@healthbureau.gov.hk]

Your ref: ( ) in L/M to HHB/H/24/17/3/3/3

In response to the RFI of the CMHHK, my/our company, with contact details provided in Part 1 below, would like to provide the information and relevant supporting documents in Parts 2 to 9 of this Proforma.

**Part 1 – Supplier’s Contact Details**

From:

(Name of the Supplier): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in)

Name and Post of Contact person: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in)

Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Telephone no.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in) (please fill in)

**-----------------------------------------------------------------------------------------------------------------**

*This document does not constitute any offer or invitation / solicitation of any offer in connection with the exercise described herein. Neither this document nor any activities in connection therewith shall create any legal obligations or liabilities in any way on the part of the Health Bureau (HHB) or the Government of Hong Kong Special Administrative Region. Neither this document nor anything contained herein shall form the basis of any contract or commitment whatsoever. In responding to the RFI, a respondent shall be deemed to have agreed to all the terms of this Request for Market Information.*

**Purpose and Background Information of the RFI**

1. Purpose

Chinese Medicine Hospital Project Office (“**CMHPO**”) of the Health Bureau (“**HHB**”) of the Government intends to invite a tender for the supply and installation of Laboratory Automation System (LAS)(hereinafter refers as the “**System**”) to The Chinese Medicine Hospital of Hong Kong (“**opCMHHK**”) located at 1 Pak Shing Kok in Tseung Kwan O, New Territories, Hong Kong. The CMHPO therefore wishes to collect market information on the System.

1. Background of the CMHHK Project

The Chief Executive announced in the 2014 Policy Address that the Government had decided to reserve a site in Tseung Kwan O for setting up a CMHHK. The 2017 Policy Address stated that the Government decided to finance the construction of the CMHHK and identify by way of tender a suitable non-profit-making organisation (“NPMO”) to operate the CMHHK. CMHHK will be owned by the Government and the selected NPMO will operate the CMHHK. The CMHHK would be positioned as a flagship Chinese Medicine (“CM”) institution leading the development of CM services and Chinese medicines in Hong Kong. It will be a change driver, promoting service development, education and training, innovation and research, and facilitating collaboration with both local and international parties.

The CMHHK with provision of 400 beds will provide a comprehensive range of CM services. Service types include pure CM services, services with CM playing the predominant role in collaboration with Western Medicine (“WM”) and Integrated Chinese-Western Medicine (“ICWM”) services. The scope of service to be provided in the CMHHK covers inpatient, day-patient, outpatient and community outreach services.

To take forward the planning and development of the project on CMHHK, a designated office i.e. CMHPO, was established under the Health Bureau (the former Food and Health Bureau) on 2 May 2018. Hong Kong Baptist University (HKBU) was selected as the Contractor for the CMHHK operation. HKBU, as the Contractor, has incorporated a company limited by guarantee, namely HKBU Chinese Medicine Hospital Company Limited as the Operator to manage, operate and maintain the CMHHK. The CMHHK project has proceeded to the commissioning stage in 2021. It is targeted to commence hospital services by phases from 2025.

More information on the services provision and design of the CMHHK can be found in the following link:

<https://www.healthbureau.gov.hk/en/press_and_publications/otherinfo/200900_cmhp/index.html>

**Note to Suppliers**

1. If your company have more than one Laboratory Automation System that may meet the requirements of the System stated in this Proforma, **please complete and return, together with relevant supporting documents, one set of Proforma for each different Laboratory Automation System**.

**Part 2 – General Information of the System**

|  |  |
| --- | --- |
| 1. Place of origin
 |  |
| 1. Name of manufacturer
 |  |
| 1. Address of the manufacturer’s factory or plant (“Manufacturing Plant”)
 |  |
| 1. Product name of the System
 |  |
| 1. Model number/ name/ version number of the System
 |  |
| 1. Authorised agent or distributor of the manufacturer in Hong Kong
 |  |
| 1. Packing (if applicable)
 |  |
| 1. Delivery method and route (where the place of origin is outside Hong Kong)
 |  |
| 1. Warranty period of the System

(*Please refer to section F in Part 3 for details of the warranty service requirements*) | \_\_\_\_\_\_\_\_\_\_\_\_ months from Acceptance of the System(*Should not be less than 12 months*) |
| 1. Expected serviceable life (*Please specify any components of the System that cannot meet the serviceable life*)
 | The System shall have a serviceable life of \_\_\_\_\_\_\_ years from its date of acceptance except the following components: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(*Please also provide the expected life of these excluded components*) |
| 1. \*Total weight of the proposed System
 | \_\_\_\_\_\_\_\_\_\_\_\_kg |
| 1. \*Floor loading requirement for the proposed System
 | \_\_\_\_\_\_\_\_\_\_\_ kPa  |

\* *The maximum floor loading capacity where the System is to be installed is* ***5 kPa****. Please ensure that your proposed System can comply with this requirement.*

**Part 3 – Indicative Technical Requirements**

*Notes to Suppliers for Completion of Part 3*

1. *Unless specified otherwise, the “****System****” in this Part 3* ***refers to section AI.1 below****.*
2. *The indicative technical requirements are for the purpose of collecting market information only. They are subject to changes and do not represent the final technical requirements of the intended tender.*
3. *Please indicate, as a point by point compliance statement, whether your proposed System “****Comply****” or “****Not Comply****” with an indicative technical requirement stated in Column II by ticking (🗸) in the appropriate box under* ***Column III*** *and* ***Column IV*** *respectively.*
4. ***Where applicable****, please quote the value of your proposed System in either Column III (if “****Comply****”) or Column IV (if “****Not Comply****”) respectively against corresponding indicative technical requirement (use additional sheet(s) if space is insufficient*
5. *Please provide supporting documents (such as catalogues, user manual and/or operation manual, DICOM conformance statement, etc.) to illustrate the features of your proposed computed tomography system against the corresponding indicative technical requirements.*

| **Column****I** | **Column** **II** | **Column** **III** | **Column****IV** |
| --- | --- | --- | --- |
| **Section** | **Technical Specification** | **Tick (🗸) the Appropriate Box***(For aspects “Not Comply”, please also provide alternative proposal, if any)* |
| **Comply** | **Not Comply** |
| **A** | **Technical Requirements** |
| **I** | **General Features** |
|  | The Laboratory Automation System (“**LAS”)** shall occupy space as designated by the Department of Pathology, **CMHHK.** Tenderers confirm in writing in their tender submission that the delivery, conditions of installation site including space and associated facilities are suitable for the proposed system. The proposed **LAS** which requires more physical space shall NOT be considered. |  |  |
|  | Tenderers shall be required and responsible for connecting the **LAS** to the infrastructure and building services as shown in the Composite Drawings (**Appendix 1**). Any revision or addition work on the infrastructure services provided shall be responsible by the Tenderers subjected to such work to be approved. |  |  |
|  | Tenderers shall provide, at the time of tender submission, a detailed floor plan with schematic diagrams on the specific arrangement of different components of the **LAS,** including related ancillary units such as uninterrupted power supply, waste tank, water system and compressor whenever appropriate, to **CMHHK.** |  |  |
|  | All components of the **LAS** as required in the specifications shall be offered as a whole. Partial offer shall NOT be accepted. |  |  |
|  | All components of the proposed **LAS** including instruments and reagents shall conform to NCCLS / industry automation standards and comply with FDA’s Good Manufacturing Practices (GMP) or its equivalents; and be licensed by the FDA of USA, CE-mark or by other licensing authority determined as appropriate by **CMHHK**. |  |  |
|  | Full details on the make, model and specification of all the offered units of the **LAS** shall be provided in details. |  |  |
|  | All units of the **LAS** must be operable 24 hours a day, 7 days a week, and ready for analysis of both routine and urgent samples. |  |  |
|  | Tenderer shall guarantee the serviceable life span of the **LAS** for a period of not less than 10 years from the date of acceptance of the System. |  |  |
|  | Tenderer shall undertake to maintain a stable supply of quality reagents and consumables to **CMHHK** for a period of not less than 10 years; and during the entire serviceable life of the **LAS**. |  |  |
|  | The **LAS** is required to perform all but not limited to the tests in random order listed in the **Appendix II**. Tenderers shall provide a detail list of tests that can be performed on the **LAS** along with their tender submission. |  |  |
|  | Analytical methodologies shall be of international standards, e.g. methods recommended by the International Federation of Clinical Chemistry (IFCC) and acceptable to the laboratory’s accreditation body, the Hong Kong Accreditation Service (HKAS). Tenderers shall provide a full list of test methodologies and their traceability to the reference methods in their tender submission. |  |  |
|  | Quality control performance (both internal and external) shall be in concordant with international standards with reference to analytical performance specifications set by the Royal College of Pathologists of Australasia – the Australasian Association of Clinical Biochemists Quality Assurance Program (RCPA-AACB QAP)and analytical goals based on intra-individual biological variation. **CMHHK** reserves the final right to define the acceptance criteria. |  |  |
|  | Assays of analyzer units shall be well correlated. The inter-instrument variation shall comply with international standards of allowable error with reference to analytical performance specifications set by the Royal College of Pathologists of Australasia – the Australasian Association of Clinical Biochemists Quality Assurance Program (RCPA-AACB QAP). |  |  |
|  |  |  |  |
| **II** | **Laboratory Automation System (LAS)** |
|  | **General Requirements** |
|  | The Analytical System shall be consisted of an ISE unit, a clinical chemistry analytical unit and an immunoassay analytical unit integrated with a built-in sample transportation mechanism. |  |  |
|  | The Analytical System shall be capable of performing all the tests in random order (both in terms of sample type and test type) as required. |  |  |
|  | Tenderer shall provide two identical Analytical Systems for mutual back-up purpose. |  |  |
|  | The ISE analytical unit shall be an independent analzyer unit without compromising the total throughput during a mix of photometric and electrolyte measurements. |  |  |
|  | The Analytical System shall be provided with single sample entry and exit point for loading and unloading of samples. |  |  |
|  |  |  |  |
|  | **Analytical System General Specificaton** |
|  | The Analytical System shall allow user define and program automatic startup and shutdown maintenance functions. |  |  |
|  | The Analytical System shall allow user to define the automatic startup time. |  |  |
|  | The Analytical System shall comprise the following components: |  |  |
|  | System Controller unit |  |  |
|  | Sample transportation unit |  |  |
|  | ISE analytical unit |  |  |
|  | Clinical chemistry analytical unit |  |  |
|  | Immunochemistry analytical unit |  |  |
|  | Data Management Unit |  |  |
|  | Combination of analytical units connected to the Analytical System can be reconfigured at any time after installation for optimizing test throughput. |  |  |
|  | The Analytical System shall be configurable to connect with immunoassay analytical unit without external track system. |  |  |
|  | The analytical units of the Analytical System should be physically connected for high efficiency testing. |  |  |
|  | The Analytical System shall be built on a modular designed for expandability by installing additional unit to the original Analytical System by on-site reconfiguration. Configuration of Analytical Systems should be modifiable and without any need of changing the existing controlling software. |  |  |
|  | The operation of the Analytical System shall remain unchanged after reconfiguration. |  |  |
|  | The Analytical System shall allow automatic test application download via electronic service unit to eliminate manual data entry, ensures all test parameters are up to date according to supplier's recommendation. |  |  |
|  | The Analytical System shall provide real time reagent availability level monitoring. Warning alarm shall be generated according to user defined level for user attention. |  |  |
|  | The Analytical System shall allow user to mask individual analytical unit for maintenance or service action while the other analytical units are operating. |  |  |
|  | The Analytical System shall allow user define and program automatic startup and shutdown maintenance functions. |  |  |
|  | The Analytical System shall allow user to define the automatic startup time. |  |  |
|  | The Analytical System shall allow urgent sample processing with priority. |  |  |
|  | The Analytical System shall allow user to change the status of samples which are already in the system from routine to STAT so that the system can process it with priority. |  |  |
|  | The system shall operate in discrete, random access modes with STAT function. Routine sample can be interrupted any time to allow the system to handle STAT samples. |  |  |
|  | The Analytical System shall automatically recommend calibration under necessary conditions such as: reagent pack change, reagent lot change, time exceed operators’ pre-defined intervals and user defined QC violation rules. |  |  |
|  | The Analytical System shall automatically mask a test channel according to QC results and user defined QC violation error criteria. |  |  |
|  | The Analytical System shall has real time QC monitoring function. QC violation error criteria for each test shall be user-definable. |  |  |
|  | The Analytical System shall be capable to archive detail analytical information such as reagent lot used and calibration curve used for all test results in an electronic format which can be exported to an external medium for result traceability documentation and audit purpose. |  |  |
|  |  |  |  |
|  | **System Controller Unit** |  |  |
|  | The System Controller Unit shall compose: |  |  |
|  | Analyzer Controller Unit |  |  |
|  | Electronic Service Unit |  |  |
|  | The Analyzers Controller Unit shall be able to perform the following functions: |  |  |
|  | To monitor the operation conditions of all components of Analytical system and display status on a single screen |  |  |
|  | To display error message in real time and alert the operators by visual and audible signals |  |  |
|  | To keep the routing history of every sample that is on the Analytical system |  |  |
|  | To track and report the location of every sample on the Analytical system |  |  |
|  | To report the last known position of a sample by rack/holder/tray number when that is not currently on the Analytical system |  |  |
|  | To perform multi tasks at once on a graphical user interface operating system |  |  |
|  | To store at least 12,000 sample data with lab no, test results and other details. |  |  |
|  | The System Controller Unit shall be interfaced bi-directionally with the LIS via the Data Management Unit. |  |  |
|  | Electronic Service Unit shall allow on-line connection with the system for monitoring and maintenance of the Analytical System remotely by supplier. |  |  |
|  | The Electronic Service Unit shall act as an on-line electronic library system which allow operators to directly access customized updates of application and product information (e.g. packing inserts and value sheet) for reagents, calibrators and controls. |  |  |
|  |  |  |  |
|  | **Sample Transportation Unit Specification** |  |  |
|  | The Sample Transportation Unit shall consist of sample loading, unloading, buffering area and sample transportation line. |  |  |
|  | Sample racks shall be color-coded for differentiation and identification of sample type, e.g. routine and STAT samples, calibrators, quality controls etc. |  |  |
|  | The Sample Transportation Unit shall be able to convey samples to different analytical unit for processing intelligently according to testing priority, workload distribution to maximize throughput and efficiency of the system. |  |  |
|  | The Sample Transportation Unit shall accommodate not less than 850 within the system. |  |  |
|  | All the urgent/STAT samples shall be processed by the system within 1 minute. |  |  |
|  | Sample trays shall hold not less than 15 racks with a total of 75 samples for carrying samples into and out of the input and output buffer of the system. |  |  |
|  | The sample barcode reader shall identify the following types: |  |  |
|  | code 128 |  |  |
|  | codabar (NW7) |  |  |
|  | Interleaved Two of Five |  |  |
|  | code 39 |  |  |
|  | Sample ID can be used up to 22 alphanumeric with check digits. |  |  |
|  | The Sample transportation unit shall be able to handle and process sample containers including, but not limited to : |  |  |
|  | Primary tubes: 5 to 10 ml (sizes of 16x100 mm, 16x75 mm, 13x100 mm, 13x75 mm) |  |  |
|  | Sample cups: 2.5 ml with dead volume not more than 100 ul. The sample cups should not be proprietary but also available as a generic product obtainable elsewhere. |  |  |
|  | Micro-sample cups: 0.5 ml with dead volume not more than 50 ul. |  |  |
|  | Sample cup on tube: sample cups on top of 16x75 mm or 16x100 mm. |  |  |
|  | Variety of non-standard false bottom tubes can be defined. |  |  |
|  | The Sample transportation unit shall provide separate sample inlet for urgent sample loading without interruption to transportation of other routine samples. |  |  |
|  | Sample identifications shall be done using barcode labels on the sample containers for processing and analysis according to the information from the LIS. |  |  |
|  | Sample transportation unit shall have a throughput of not less than 1000 samples per hour. |  |  |
|  | The Sample Transportation Unit shall capable to act as a samples buffer for holding samples which are waiting for processing, rerun or reflex tests. |  |  |
|  | The Sample Transportation Unit shall transfer the processed samples automatically and directly to the output buffer. |  |  |
|  | Barcode readers shall be installed along the sample transportation lane for sample delivery tracking to the destination within the system. |  |  |
|  | The Sample Transportation Unit shall should allow random access of sample racks, so that each rack can be freely moved out from any position of the rack queue for analysis. |  |  |
|  | The Sample Transportation Unit shall be covered, so as to provide a dust-free environment within the transportation path. |  |  |
|  | The Sample Transportation Unit shall employ two independent transportation lines for sample transportation to analytical unit, buffer, loading and unloading area to avoid bottle neck of sample traffic within the analytical system. |  |  |
|  | Samples shall be transported in racks to the analytical unit. |  |  |
|  |  |  |  |
|  | **ISE analytical unit Specification** |  |  |
|  | The ISE analytical unit shall be an independent analzyer from clinical chemistry analyzer to allow maintenance be done independently. |  |  |
|  | Sample clot, sample liquid level and sample foam detection mechanism shall be incorporated for sample pipetting. |  |  |
|  | The ISE sample probe shall have a cleaning mechanism by ultrasound to avoid sample carryover. |  |  |
|  | When clot is detected, the sample probe shall be cleaned by ultrasound to avoid sample probe clogging. |  |  |
|  | Sample volume required for ISE measurement shall equal or less than 15 uL. |  |  |
|  | The electrodes shall be housed and replaced individually in the ISE unit. |  |  |
|  | The ISE analytical unit shall have a 2D electrode barcode reader to register new electrodes on-board. |  |  |
|  | The ISE analytical unit shall have a throughput not less than 300 ISE measurements per hour. One ISE measurement is defined as simultaneous quantification of sodium, potassium and chloride in serum / plasma sample. |  |  |
|  | The measuring ranges (according to CLSI EP17-A2 Guideline) shall be: |  |  |
|  | Na (serum/plasma): 80-180 mmol/L |  |  |
|  | K (serum/plasma): 1.5-10.0 mmol/L |  |  |
|  | Cl (serum/plasma): 60-140 mmol/L |  |  |
|  | Na (urine): 20-350 mmol/L |  |  |
|  | K (urine): 3-100 mmol/L |  |  |
|  | Cl (urine): 20-350 mmol/L |  |  |
|  | The ISE analytical unit shall allow random analysis of plasma/serum and urine without the need of re-calibration before processing different sample type. |  |  |
|  | The ISE analytical unit shall measure sodium, potassium and chloride on a single sample of human plasma, serum and urine. |  |  |
|  | The ISE analytical unit shall use indirect potentiometry and use flow through electrodes for measurement. |  |  |
|  |  |  |  |
|  | **Clinical Chemistry Analytical Unit Specification** |  |  |
|  | The photometric test throughput of the clinical chemistry analytical unit shall be equal or greater than 1,000 tests per hour. |  |  |
|  | The Analytical System shall support program up to 680 photometric applications, 3 ISE, 3 serum indices and 8 calculated tests. |  |  |
|  | The Analytical System shall allow at least 10 User-programmable (Open Channel) channels for 3rd party reagents on the high and clinical chemistry analytical unit. |  |  |
|  | The Analytical System shall capable to flag analytical result for potential interference according to serum indices of each samples and the interference limit of each assays parameters. |  |  |
|  | The clinical chemistry analytical unit shall be floor-standing type. |  |  |
|  | The reagents shall be RFID labeled for identification by the system. |  |  |
|  | The clinical chemistry analytical unit shall allow automatic reagent loading without manual decappaing during standby and/or operation mode to ensure no interruption of routine workflow. |  |  |
|  | The reagent manager shall be able to detect and pierce the caps of reagent pack automatically without any manual intervention. |  |  |
|  | The system shall calculates the average consumption of the last 9 weeks for a specific weekday and generate a consumption-based load list of reagent to calculate the required reagent thresholds. |  |  |
|  | The Clinical Chemistry Analytical Subunit shall have a reagent manager device to provide not less than 5 reagent buffer positions which allow automatic reagent loading. |  |  |
|  | The total reagent on-board capacity shall be not less than 60 positions per clinical chemistry analytical unit. |  |  |
|  | The reagent compartment shall be cooled at 5 to 15 °C. |  |  |
|  | The onboard stability of all listed clinical chemistry testing based on appendix 2 should be not less than 28 days. |  |  |
|  | Reagent packs shall be unloaded by the analytical unit automatically without manual intervention. |  |  |
|  | Automatic reagent pack changeover shall be possible. |  |  |
|  | The clinical chemistry analytical unit shall allow user to mask specific reagent pack which on boarded in the reagent compartment. |  |  |
|  | The clinical chemistry analytical unit shall have reagent aspiration check mechanism to avoid insufficient volume aspiration. Alarm has to be generated in case of insufficient reagent. |  |  |
|  | The analytical unit shall be capable to perform automatic dilution according to user setting. |  |  |
|  | The clinical chemistry analytical unit shall be capable to rerun samples with out of measuring range results with automatic dilution. |  |  |
|  | Sample clot, sample liquid level and sample foam detection mechanism shall be incorporated for sample pipetting. |  |  |
|  | A electrostatic noise preventive mechanism shall be available to ensure the sample aspiration accuracy. |  |  |
|  | Sample volume required for each chemistry assay should be from 1.0 to 25 uL, in 0.1 uL intervals. |  |  |
|  | Reaction cuvettes shall be made of durable materials with onboard stability not less than 1 month. |  |  |
|  | The clinical chemistry analytical unit shall equip with ultrasonic mixer for carryover free mixing of reaction mixture, as well as reduction of air bubbles and water consumption for washing. |  |  |
|  | The reaction temperature shall be maintained at 37 +/- 0.1°C by circulating water bath. |  |  |
|  | Reaction time for all chemistry assays shall be from 3 - 10 minutes. |  |  |
|  | Reagent volume shall be from 5 ul to 120 ul, in 1 ul intervals. |  |  |
|  | The clinical chemistry analytical unit shall have a throughput not less than 1000 photometric tests per hour. |  |  |
|  | The clinical chemistry analytical unit shall equip with 2 sample probes dedicated for serum/plasma and whole blood sample. |  |  |
|  | The clinical chemistry analytical unit shall have a cleaning mechanism by ultrasound for sample probes to avoid sample carryover. |  |  |
|  | When clot is detected, the sample probe shall be cleaned by ultrasound to avoid sample probe clogging. |  |  |
|  | The clinical chemistry analytical unit shall equip with automatic cell rinse unit for washing of semi-disposable reaction cuvettes. |  |  |
|  | The clinical chemistry analytical unit shall equip with probe rinsing station for sample and reagent probe washing after each pipetting. |  |  |
|  | All system washing solutions of the clinical chemistry analytical unit shall be RFID tagged. |  |  |
|  | The clinical chemistry analytical unit shall be fully automatic employing spectrophotometric techniques for measurement of analytes in human serum, plasma, CSF and urine. |  |  |
|  | The following measurement modes shall be supported: end point, reaction rate, 2-point rate, sample and/or reagent blanking, prozone checking and serum indices. |  |  |
|  | The clinical chemistry analytical unit shall support both monochromatic and bichromatic measurements. |  |  |
|  | The wavelengths available for photometric measuring system shall be in the range from 340 to 800 nm. |  |  |
|  | Water consumption shall be equal or less than 32 liters per hour under routine condition. |  |  |
|  | Independent water purification system shall be used for supply of pure water to the Analytical unit for analysis. |  |  |
|  | The clinical chemistry analytical unit shall have no manual daily mainteance to increase the system uptime. |  |  |
|  |  |  |  |
|  | **Immunoassay analytical unit Specification** |  |  |
|  | Quick start up mode is available for startup time no more than 12 minutes. |  |  |
|  | The total immunoassay throughput of all analytical system shall be equal or greater than 600 with providing no more than 2 analytical modules. |  |  |
|  | The Analytical System shall support program up to 200 immunoassay for immunoassay analytical unit. |  |  |
|  | The Analytical System shall allow fully automated measurements and calculations of various infectious diseases assays combinations and to perform decision algorithms for sample predilution or repeat measurements. Sample shall stay within the system during the automatic programmed testing algorithms. This features should appy to: Anti-HCV, HBsAg, Syphilis, HTLV-I/II, HBsAg quant, Toxo Avidity, CMV avidity, HIV Duo, HCV Duo, HBsAg AutoConfirm. |  |  |
|  | All immunoassay calibrators vials should be barcoded for system identification to achieve program-by-loading feature without any manual position assignment. |  |  |
|  | Calibration shall adopt 2-points calibration mode or better for all immunoassay test applications. |  |  |
|  | The Immunoassay Analytical unit shall be floor-standing type. |  |  |
|  | The reagents shall be RFID labeled for identification by the system. |  |  |
|  | The reagent should be ready to use upon delivery and require no operator preparation including mixing. |  |  |
|  | The reagent should require no operation preparation including pre-opening before loading to analyzer. |  |  |
|  | Automatic cap-opening and closing system shall be available to ensure the reagent bottles are left closed when not in use for evaporation protection. |  |  |
|  | The Immunoassay Analytical unit shall has a mixer for magnetic micro particle beads reagent mixing to ensure homogenous reagent for measurement. |  |  |
|  | Re-loading of tips, cuvettes, system reagents and unloading of solid waste shall be possible during operation with no interruption. |  |  |
|  | The Analytical unit shall have a reagent manager device to provide not less than 5 reagent positions which allow simultaneous reagent loading during operation with no interruption. |  |  |
|  | The total reagent on-board capacity shall be not less than 48 positions per Immunoassay Analytical unit. |  |  |
|  | Automatic reagent pack changeover shall be possible. |  |  |
|  | The Immunoasasy Analytical unit shall have a CCD camera and pressure sensor for bubble detection. |  |  |
|  | The Immunoassay Analytical unit shall has liquid level detection sensor for reagent bubble and volume detection to avoid insufficient reagent aspiration. Alarm has to be generated in case of insufficient reagent. |  |  |
|  | The reagent compartment shall be maintained at 5-10 °C in order to keep the stability of the reagents. |  |  |
|  | Disposable reaction cuvettes shall be used to eliminate carry-over in reaction vessels. |  |  |
|  | The Immunoassay Analytical unit shall equip with non-invasive vortex mixers for mixing of reaction mixture. |  |  |
|  | The reaction temperature shall be maintained at 37 +/- 0.3°C by metallic heat block. |  |  |
|  | Assay time including wash steps and incubation for all immunoassays with pretreatment shall be equal or less than 30 minutes. |  |  |
|  | Assay time including wash steps and incubation for all immunoassays without pretreatment shall be equal or less than 20 minutes. |  |  |
|  | Assay time including wash steps and incubation for all STAT immunoassays shall be equal or less than 10 minutes. |  |  |
|  | All STAT immunoassays shall use the same reagent pack as immunoassays without pretreatment. |  |  |
|  | Total reaction volume shall be less than or equal to 120 uL. |  |  |
|  | For sandwich immunoassay, one step approach should be used to ensure fewer assay steps are involved which improve assay precision. |  |  |
|  | The Immunoassay Analytical unit shall have a throughput not less than 300 immunoassay tests per hour. |  |  |
|  | The Immunoassay Analytical unit shall capable to perform automatic dilution according to user setting. |  |  |
|  | The Immunoassay Analytical unit shall capable to rerun samples with out of measuring range results with automatic dilution. |  |  |
|  | Clot and liquid level detection mechanism shall be incorporated for sample pipetting. |  |  |
|  | Disposable pipette tips shall be used for sample pipetting to eliminate sample to sample carry-over. |  |  |
|  | Sample volume required for all immunoassay should be equal or less than 60 uL. |  |  |
|  | The Immunoassay Analytical unit shall be fully automatic employing electrochemiluminescence technology for measurement of analytes in at least human serum, plasma, urine and saliva but not limited to these sample type only. |  |  |
|  | The Immunoassay Analytical unit shall use electrochemiluminescence technology for qualitative and quantitative measurement. |  |  |
|  | Water consumption shall be equal or less than 30 liters per hour under routine condition. |  |  |
|  | Independent water purification system shall be used for supply of pure water to the Analytical unit for analysis. |  |  |
|  | Daily maintenance time shall be 5 minutes or less. |  |  |
|  | The Immunoassay Analytical unit shall have 2 measuring cells. |  |  |
|  | The reagent onboard stability for Immunoassay Analytical Subunit shall be up to at least 110 days. |  |  |
|  | The calibration stability for Immunoassay Analytical Subunit shall be up to 84 days. |  |  |
|  |  |  |  |
|  | **Data Management Unit** |  |  |
|  | General Requirements: |  |  |
|  | The System Controller Unit (SCU) shall provide bi-directional interfaces to the analyzers, Automated Sample Processing System and Hospital's LIS for test result manipulation, QC data handling and data management of the LAS. Protocols for interfacing shall be provided. |  |  |
|  | It shall allow multiple levels of security for data access. Access to the functions of the SCU shall be restricted to authorized personnel with passwords only. Stratified log-in security levels shall be user-defined. |  |  |
|  | It shall provide multi-tasking with mulit-user environment for simultaneous operation. |  |  |
|  | When LIS is down, it can provide full back up in test registration, test data management and result reporting. When LIS resumes operation, data for processed samples can be up-loaded from the LAS to LIS. |  |  |
|  | Support the workflow |  |  |
|  | The system can handle multiple alternate sample workflows. |  |  |
|  | It shall be show to the users the different target where the samples have been sorted. |  |  |
|  | The user can define the sample workflow as a decision tree with following target types: |  |  |
|  | Instrument |  |  |
|  | Instrument buffer |  |  |
|  | Manual archive |  |  |
|  | Virtual target |  |  |
|  | Manual aliquot |  |  |
|  | Support Laboratory Information System (LIS) |  |  |
|  | Tenderer shall be responsible for implementing network connection to CMHHK LIS by providing enough medical network data ports (dual and normal) and necessary software and hardware including but not limited to terminal servers and oblige to the rules and regulations of the Hospital LIS. Tenderer shall be responsible for all the cost for medical network data ports construction, network connection and terminal servers provision.  |  |  |
|  | It shall provide a standard interface for connevtivity to one or multiple host systems. Connection can be serial, TCP/IP, Web service, Miscellaneous or file based.  |  |  |
|  | It shall support HL7 (v2.3, v2.4) and ASTM(E1381-91, E1394-91) communication protocols. |  |  |
|  | It shall be able to receive data from the host system, including: patient, order, sample test request, comments. |  |  |
|  | It shall be able to apply rules when the order is received, to add tests or test profiles. Rule setting shall be user friendly and does not require programming language. |  |  |
|  | It shall be received rerun requests from the host. |  |  |
|  | It shall connect instruments, with serial port or network connection, according to the instrument protocol specifications. It shall be able to connect instruments in query or in download mode, according to the instrtument protocol. |  |  |
|  | Regardless of where problems may arise, the Tenderer shall provide all the necessary assistance, consultancy, time and resources as requested by the CMHHK to ensure the successful completion of the LIS / LAS interface.  |  |  |
|  | Result review and Management |  |  |
|  | The system can assign alarms to the incoming results by checking following ranges. |  |  |
|  | Normal range used for patient reference values. |  |  |
|  | Validation range for blocking results in technical validation. |  |  |
|  | Critical range for raising alarm flags. |  |  |
|  | The delta-check is defined by a percentage, an absolute value and the time to consider the validity of the previous result. |  |  |
|  | The system can use the status of the quality controls to block results. |  |  |
|  | The system provides a rule engine to execute algorithms for technical or medical validation purpose. |  |  |
|  | The rule engine can trigger following several actions |  |  |
|  | add or remove a test or a test profile; |  |  |
|  | block a test result for validation; |  |  |
|  | add or remove comments; |  |  |
|  | change the sample workflow; |  |  |
|  | trigger rerun with dilution; |  |  |
|  | When LIS is down, with operator initiation, there shall be automatic generation of result report. |  |  |
|  | Patient cumulative results and reports can be generated as when required. |  |  |
|  | It shall be able to manually or automatically validate result. |  |  |
|  | It shall be support requesting re-runs of tests with manual and instrument dilutions. |  |  |
|  | Results can be entered manually or received from instruments. |  |  |
|  | Manage orders / samples |  |  |
|  | The system shall be able to tailor made a order list screen to show the order/patient demographic of the order accroding to the customer's requirement.  |  |  |
|  | The system provides an order entry function to enter manually patient, samples and related test requests. |  |  |
|  | The system allows the modification and deletion of an order/sample and its tests, for authorized users. |  |  |
|  | It can accept test request downloaded directly from LIS. |  |  |
|  | Quality Control Functions |  |  |
|  | Study period to store the quality control (QC) result in the QC evaluation period. |  |  |
|  | The QC system shall be able to calculate the QC running mean and running SD value during the evaluation peroid and apply the value easily to the production period. |  |  |
|  | Different QC period can be created within the same QC lot so that each QC period can have its own QC Target and QC SD.  |  |  |
|  | Individual QC result can be rejected so that the rejected result will not be used to count the QC cumulative mean, SD and %CV. |  |  |
|  | The QC system shall be able to track at the module level of instrument. |  |  |
|  | The QC system shall be able to see QC on the same patient review screen. |  |  |
|  | At least 20 QC material can be configured to each individual tests. |  |  |
|  | Individual QC raw data with analysis date and time can be traced and pritned out as when required. |  |  |
|  | Automatic application of Westgard Rules or its equivalents shall be applied for monitoring QC raw data. |  |  |
|  | There shall be automatic acceptance of QC data based on preset criteria. |  |  |
|  | Levy Jennings charts on screen and printout shall be available. |  |  |
|  | Manual editing/addition/reject of raw data shall be allowed.  |  |  |
|  | Free text and predefined remarks can be entered for individual QC result and this can be viewed on screen as well as pritned out together with raw data, analysis date and time. |  |  |
|  | Summarized weekly and monthly QC reports including cumulative mean, SD and %CV can be accessed and printed out. |  |  |
|  | QC data can be downloaded in Microsoft Excel format for further manipulation. |  |  |
|  | Patient Moving mean chart from selected test by each analyser. |  |  |
|  | Support bracket QC function. |  |  |
|  | Screen to show the sample list of each QC bracket. |  |  |
|  | Screen to show the affected patient samples that violate the QC rule. |  |  |
|  | Batch Patient samples rerun when the closing bracket of a bracket QC violate the QC predefined rule.  |  |  |
|  | User should have the right to release the patient results manually when the closing bracket QC value not exist or out of range. |  |  |
|  | It shall be able to support BioRAD utility Bi-directional connection or equivalent. |  |  |
|  | Sample Tracking Function |  |  |
|  | It shall provide a real time monitoring of the sample location and allow the user to track the status and position of any sample after beign registered. |  |  |
|  | Various searching criteria shall be available, e.g. by sample number, patient ID, etc, to enable sample tracking. |  |  |
|  | Easy to read graphical interface shall be available. |  |  |
|  | Such searching information shall be available for specimen retrieval purpose within a week. |  |  |
|  | Monitor laboratory production |  |  |
|  | The (System Control Unit) SCU shall have the capability of utilizing bi-directional interface with LIS |  |  |
|  | The SCU shall be able to display the real-time performance dashboard, in order to show the average TAT in colorful graphics. |  |  |
|  | The SCU shall be able to show the real-time TAT for each sample, monitor and update the sample status constantly, so as to notify the laboratory personnel instantly by generating visual alerts for immediate actions. |  |  |
|  | The SCU shall be able to support the tablet devices for checking TAT Monitoring status |  |  |
|  | The SCU shall allow the user to track the status and location/position of any sample in analytical system and sample processing management |  |  |
|  | The SCU shall be able to display error messages in real-time and alert the operator. List of errors can be displayed and printed out. |  |  |
|  | Backup/standby controller |  |  |
|  | Both "Clean backup" and "synchronized backup" server shall be availiable so that when hardware or software fault detected, the clean backup or synchorized backup can be take over the original server. |  |  |
|  | Scheduled Synchronization feature of the database shall be available  |  |  |
|  | Software shall have backup / shadow abilities so that the recovery time is less than 1 hours. |  |  |
|  | The restoration process shall have the capability to restore the system to a different time point before the failure, providing flexibility in the recovery process |  |  |
|  | The switchover to backup controller shall be simple as “plug and play” and be handled by laboratory worker without sophisticated training on information technology, so as to minimize the interruption of service. |  |  |
|  | The switchover shall be completed by user within half an hour. |  |  |
|  | The switchover to backup controller shall lead to no data loss with regard to patient records." |  |  |
|  | Other Requirements |  |  |
|  | The system shall have the archive capability, assign and store the carrier / tray ID and sample position within the carrier / tray for every sample. |  |  |
|  | The system shall be 100% web-based user interface which support common browsers like windows IE, Firefox, Google Chrome with configurable user interface |  |  |
|  | The system support different operating system like windows server, linux server.  |  |  |
|  | The SCU shall be equipped with the following configuration or better: a) 32GB RAM b) 6x 500GB Harddisk c)Redundant Power Supply d)Support RAID 1 or 5 |  |  |
|  | Server capacity shall be able to cope with 1000 specimens per hour for upload and download to LIS and analyzers simultaneously |  |  |
|  | The SCU shall be able to support the Virtual Machine ESXI |  |  |
|  | The SCU shall be able to install to the tablet devices  |  |  |
|  | The Middleware shall be able to upload the error log and database status through the internet for proactive maintenance service |  |  |
|  | The Middleware shall comply with ISO 13485 international standard  |  |  |
|  |  |  |  |
|  | **Electrical and Safety Requirements**  |
|  | The Analyzer shall be provided with an over-current protection cutout device. |  |  |
|  | The Analyzer shall remain operational and within specifications throughout the voltage range of 220V +/- 6%, 50 HZ +/-2%, 1-phase A.C. electrical supply.  |  |  |
|  | Single phase mains-operated equipment shall be fitted with a power plug suitable for the site condition. The plug shall comply with relevant standards e.g. BS1363 for 13A plugs.  |  |  |
|  | The Analyzer offered shall comply with the safety requirements of IEC61010-1 or equivalent.  |  |  |
|  | The Analyzer offered shall comply with the electromagnetic compatibility (EMC) requirements of IEC 61326-1 or equivalent.  |  |  |
|  | The Analyzer shall comply with the requirements of IEC61010-2-081 and IEC61010-2-101 or equivalent. |  |  |
|  | The requirements for the flexible power cords including mainly the marking requirements on the outer sheath, the requirements on colour identification, conductors and insulation shall comply with the relevant standards. For example, the thickness of the insulation shall not be less than the figures given in IEC60227 and IEC60245. |  |  |
|  | The accessible parts and accessories of the Analyzer shall be free of burrs, sharp edges, protrusions and other defects which may cause hazard to usersor the samples being processed.All motors, gears, chains, belts and flywheels of the equipment, if equipped, shall be enclosed in protective covers and shall not be accessible by users during normal operation of the equipment. |  |  |
|  | The Analyzer shall be in compliance with the relevant safety requirements of the latest edition of the “The Electrical Products (safety) Regulation” under Electrical Ordinance, Cap 406. |  |  |
|  | The Analyzer shall be effectively bonded to earth unless it is double insulated. |  |  |
|  | The Analyzer shall be fitted with suitable power supply cables which shall be in compliance with BS EN 50525-1:2011 or an equivalent international standard. |  |  |
|  | The system shall comply with the emission and immunity requirements described in standard IEC 61326-2-6 or equivalent standard. |  |  |
|  | The system offered shall be suitable for use throughout the environmental ranges unless otherwise specified: |  |  |
|  | Ambiet Temperature: 18 – 32°C |  |  |
|  | Relative humidity: 30-85% (non-condensing) |  |  |
|  | Total noise generation shall be less than 70 dB at full operation. |  |  |
|  | The maximal floor loading without deflection shall be less than 5 kPa. Floor flatness shall be tolerable to 5-degree slope (rise of 1” to 12”) |  |  |
|  |  |  |  |
|  | **Uninterruptible Power Supply (UPS)** |
|  | The UPS system shall provide at least visual indication for overload, over-temperature, critical breaker open, low battery voltage and input power failure. |  |  |
|  | The UPS shall be installed to protect the entire System and computers from power spike and to maintain power supply for at least 15 minutes during power breakdown. Please show the calculation of the choice.The UPS provided shall be of adequate power rating and online double-conversion type. |  |  |
|  | The UPS offered shall comply with the safety, performance and test requirements of IEC62040-1, IEC62040-2 and IEC62040-3 or equivalent.  |  |  |
|  | Throughout the serviceable life span of the LAS, the Tenderer shall furnish all maintenance services including scheduled preventive and corrective services by qualified maintenance engineer to maintain the UPS in working order. Shall any of the UPS fails to deliver its function, the Tenderer shall undertake complete repair of the UPS and minimize service interruption. For UPS beyond repair, the Tenderer shall provide full replacement of the UPS free of charge. |  |  |
|  | The Contrcator shall provide and install external service bypass switch(es) for the purpose of UPS maintenance.. |  |  |
|  | The UPS shall be provided by the successful Tenderer at no additional charges. |  |  |
|  |  |  |  |
|  | **Water Purification System** |  |  |
|  | Tenderer shall provide a water purification system in the Main Laboratory with backup capabilities at no extra cost to CMHHK to generate adequate volume of deionized water as required by the LAS. The water consumption requirements of the entire LAS should be provided in tender submission. |  |  |
|  | The purity of water produced by the water system shall be monitored by a metering system. The data from the metering system shall be real-time and printable when needed. Tenderer shall provide the monitoring device of the system at no additional cost. |  |  |
|  | There shall be visual and audible alarm signal for alerting the laboratory of any faults or malfunctions of water purification system |  |  |
|  |  |  |  |
|  | **Other Requirements** |
|  | The successful Tenderer shall be responsible for delivery of the equipment to the installation site of CMHHK. The exact delivery date shall be subject to the final confirmation from the Hospital and no temporary storage will be provided. |  |  |
|  | The Successful Tenderer shall be responsible for the installation of the analyzer with accessories (if any) by qualified engineer(s). Number of items shall be verified upon delivery. |  |  |
|  | The Successful Tenderer shall confirm that appropriate means of transportation can be arranged by themselves for the delivery of their equipment to the specific location of the CMHHK buildings within installation site and that they shall liaise and confirm with the Hospital to ensure the route of delivery to the installation site are feasible for the passage for their equipment. |  |  |
|  | The Successful Tenderer shall arrange insurance appropriately to cover damages to the equipment during the period of delivery, storage, installation, testing and commissioning. The Successful Tenderer shall provide their own temporary protection for their works before hand-over of the works to the Hospital. |  |  |
|  | The Successful Tenderer shall be responsible to clear away all packing materials, demolished and unused structural materials to a legal place after delivery/installation of the equipment at its own cost. |  |  |
|  | The Successful Tenderer should note that they will be held responsible for any damage to hospital property or that of the building contractor as may be caused during equipment transportation and installation. All due measures should be taken by the tenderers to protect such property. |  |  |
|  | The Successful Tenderer shall be responsible for the make good of ceiling, wall and floor in the installation site after completion of equipment installation. |  |  |
|  | When dirty work is carried out the entire area adjacent to the site shall be left clean and suitable for hospital work. Utility services in the building shall not be interrupted. |  |  |
|  | The Successful Tenderer shall provide all testing instruments and/or materials to conduct site acceptance test. The test shall be carried out by the Hospital Representative(s) and assistance or facilitation from Successful Tenderer may also be required. All testing instruments to be used for the acceptance test shall be calibrate and copies of calibration certificates shall be forwarded to the Hospital Representative(s) for records. |  |  |
|  | Enough working space shall be provided by the Successful Tenderer for the middleware and handling manual works for checking purpose with the requirement of user in order to provide extra working area at no extra cost. |  |  |
|  | The successful tenderer shall provide on-site free technical support and all the required reagents, and any necessary consumables for functional evaluation, validation, initial startup, correlation and customization of the system at no extra cost |  |  |
|  | Supply of reagents, spare parts and consumables: |  |  |
|  | Tenderers shall guarantee to maintain the stable supply of required reagents, calibrators, necessary consumables and other spare parts for at least 8 years and during the serviceable life span of the System after acceptance. |  |  |
|  | Unless specifically requested by end-user, each item of calibrator or quality control deliverd shall be of the same lot on each delivery upon availability. |  |  |
|  | User shall have the right to reserve for a particular lot of reagent, calibrator or control upon availability. Partial delivery and scheduled delivery for same lot order shall be available upon availability and within 3 months from date of order. |  |  |
|  | The shelf-life of calibrators, control materials and reagents shall not be less than 4 months upon delivery to CMHHK. |  |  |
|  | The reagents shall pass the manufacturer's specifications. All sub-optimal reagents shall be replaced at no extra cost. |  |  |
|  | The Tenderer shall accept the responsibility for the satisfactory quality, design and workmanship of all materials, whether they are manufactured by the Tenderer, or supplied to the Tenderer by other manufacturers. The Tenderer shall have full responsibility for the performance of all such materials in use. |  |  |
|  | The Tenderer shall provide the latest / new version of reagents of same methodology, calibrators, QCs and necessary consumables (as appropriate) so as to achieve higher quality of analytical performance. |  |  |
|  | In the event that new version of assay is released by the manufacturer, the successful Tenderer shall provide necessary manpower and specialist to CMHHK to conduct the full assay performance evaluation of the latest / new version of assay according to international standards, e.g. Clinical Laboratory Standard Institute (CLSI) and laboratory's accrediting bodies, e.g. Hong Kong Laboratory Accreditation Scheme (HOKLAS) and / or National Association of Testing Authorities, Australia. |  |  |
|  | Provision of Architectural, Building Services |  |  |
|  | Tenderers are advised to check and confirm building services provisions of the laboratory site, such as room space, ceiling headroom, ceiling and floor loading, main supply current rating, air-conditioning capacity and water supply, drainage system, etc. |  |  |
|  | The Tenderer shall provide design, plan and details in the tender submission including: |  |  |
|  | detailed floor plan of the proposed System showing detail physical dimensions, weights of individual unit, layout, electrical power, wiring, telephone line, piping, ducting, trunkings and conduits for computer network, location and sizes of electrical junction boxes, and space requirement for inspection and maintenance; |  |  |
|  | any special environmental requirements; |  |  |
|  | any special arrangement necessary for the delivery and installation of the proposed System; and |  |  |
|  | the floor loading of individual items according to submitted layout of the System, etc. |  |  |
|  | CMHHK reserves the right to reject any offer if there is difficulty in accommodating the offered System. |  |  |
|  | The site modification work requirements should be clearly depicted in appropriate drawings, which should be accompanied by detailed information with cross-reference, where applicable, to the drawings. |  |  |
|  | The site renovation / modification work details shall include but not limited to the dimensions, layout, openings, and other relevant information regarding concealed or under-floor ducting for electrical cables and other services. |  |  |
|  | The design, plan and details of the site renovation / modification shall be vetted and approved prior to the award of the contract. |  |  |
|  | The successful Tenderer shall observe all statutory requirements regarding safety and environmental issues. |  |  |
|  | The successful Tenderers shall ensure the site renovation / modifications are conducted by quality constructor. All works shall be done by certified or registered workers / contractors and in the manners as required by the corresponding regulation as relevant. |  |  |
|  | All materials supplied and used on the works shall be suitable for the purpose intended. They shall comply with the current Hong Kong Building, Factory, Fire and other applicable regulations and shall be demonstrably manufactured in accordance with approved internationally recognized standards. |  |  |
|  | The successful Tenderers shall accept responsibility for the satisfactory quality, design and workmanship of all materials, whether they have been manufactured by him, or have been supplied to him or by other manufacturers; the successful Tenderers shall also be responsible for the behavior of such materials in use. |  |  |
|  | The Contractor shall be responsible for provision of any building service installations necessary for the proper installation, operation and maintenance of the equipment supplied. The building service installations provided by the Contractor shall comply with requirements of the General Specification for Building Service Installations in Government Buildings of the HKSAR (and any corrigendum) issued by the Architectural Services Department. |  |  |
|  | The Contractor shall be responsible for provision of any builder’s works necessary for the proper installation, operation and maintenance of the equipment supplied. The builder’s works provided by the Contractor shall comply with requirements of the General Specification for Building (and any corrigendum) issued by the Architectural Services Department. |  |  |
|  | Unless otherwise specified in the Specification, all works, materials, and workmanship carried out and terminology used in this tender shall comply, where applicable, with the following specifications, standards and documents together with any supplements and amendments made thereto: |  |  |
|  | General Specification for Building Service Installations in Government Buildings of the HKSAR, Hong Kong, the latest edition (and any coorigendum) issued by the Architectural Services Department |  |  |
|  | General Specification for Buildings, the latest edition (and any coorigendum) issued by Architectural Services Department |  |  |
|  | The latest edition of the Wiring Regulations of the Institution of Engineering and Technology (IET) or equivalent |  |  |
|  | The Code of Practice for the Electricity (Wiring) Regulations published by Electrical and Mechanical Services Department |  |  |
|  | Construction Site Safety Manual issued by the Development Bureau, Hong Kong SAR Government |  |  |
|  | The successful Tenderers shall comply with the laws of Hong Kong; these shall include but not be limited to all the applicable ordinances and statutory regulations, in particular, the Electricity Ordinance, Chapter 406. |  |  |
|  | The successful Tenderer shall comply with all the applicable requirements imposed by the Local Authorities e.g. Fire Services Department, Labour Department, Environmental Protection Department, Water Supplies Department, etc. |  |  |
|  | The successful Tenderers shall be registered electrical contractor or sub-let the electrical works to a registered electrical contractor. All works on fixed electrical installations shall be carried out by registered electrical workers of the appropriate class. |  |  |
|  | The quality shall be evaluated and accepted after the completion of site renovation / modification by the Electrical and Mechanical Services Department (EMSD). |  |  |
|  | Workmanship and materials provided by the successful Tenderer for all alteration of the existing building and building services installations should be matched to the existing. |  |  |
|  | All works by the successful Tenderer should be compliance with the relevant General Specifications and Code of Practices of the latest edition issued by the relevant Government Department of the Hong Kong Special Administrative Region and authorities. |  |  |
|  | The successful Tenderer shall make good and repair all defects and damages due to the works/installations undertaken.  |  |  |
|  | No cost/recurrent cost and/or other direct or indirect work cost should be incurred to CMHHK as a result of the construction works. |  |  |
|  | The successful Tenderer shall undertake to perform site modification work, including relocation of existing instrument(s), if any; for installation and operation of the System at no addition cost. |  |  |
|  | The successful Tenderer shall ensure that the design, items, components, etc. of the equipment are integrated to give a pleasing aesthetic appearance to the overall System. |  |  |
|  | All fixings shall be concealed or discrete. Where visible they shall blend with the visual design. Where fixings shall be removable for maintenance purposes, the finish shall be sufficiently durable for the purpose. |  |  |
|  | The connections of System including but not limited to electricity, LAN cable, and water supply shall go through the ceiling and employ “dropper” or relevant facilities from ceiling as far as possible. |  |  |
|  | The successful Tenderer shall provide sufficient number of working benches and other necessary accessories to accommodate its control units, associated workstations and printers, for user operation and carry out maintenance to the System. These working benches shall be aesthetically and ergonomically designed to suit the local workforce, and match with other components of theSystem. |  |  |
|  | The successful Tenderer shall undertake to perform site modification work to meet the requirement that the layout of the System will provide adequate, clear and convenient working space and associated work areas for staff to monitor the smooth operation of the System and easy access for servicing and replacement of faulty components. |  |  |
|  | The design of the layout shall also make the most economical use of the area of the laboratory, leaving ample space for working tables and other equipment that are not connected to the System, with easy access for operation. |  |  |
|  | Installation and Commissioning implementation  |  |  |
|  | The successful Tenderer shall be responsible for the installation of the analyzers together with the connection of services from the supply points to the analyzers located in the Clinical Laboratory of CMHHK. |  |  |
|  | The successful Tenderer shall submit at the time of tender submission an implementation schedule showing the proposed dates of delivery, installation, testing, commissioning and trial run of the various components of the System. The successful Tenderer shall also provide a list of Tenderer-directly employed staff of service engineer, product specialist and information technology. |  |  |
|  | Within two weeks of acceptance of offer, the Tenderer shall submit a detailed plan for the entire work. The plan shall show, as a minimum requirement, the start and finish dates of the following activities for each piece of analyser of the System.  |  |  |
|  | Drawing and design  |  |  |
|  | Submission of drawings for approval  |  |  |
|  | Site renovation / modification  |  |  |
|  | Delivery and installation of equipment  |  |  |
|  | Optimization of different components of the System |  |  |
|  | Evaluation |  |  |
|  | LIS connectivity  |  |  |
|  | TAT simulation  |  |  |
|  | Acceptance testing and commissioning  |  |  |
|  | Operational and maintenance staff training  |  |  |
|  | Live run |  |  |
|  | The Tenderer shall provide at no additional cost, sufficient reagents, calibrators, quality control materials and consumables for a full evaluation of the System and two dedicated experienced technical specialists of the System for performing the initial setup and evaluation work. Upon request from CMHHK, additional experienced manpower shall be provided. CMHHK has the right to accept or change the personnel provided by the Tenderer for the evaluation. |  |  |
|  | The evaluation protocol shall include but not limit to the requirement of the following aspects and CMHHK reserves final right to design and decide the scope of evaluation and its criteria of acceptance in concordance with international accreditation standards, e.g. Clinical Laboratory Standard Institute (CLSI) and laboratory's accrediting bodies, e.g. Hong Kong Laboratory Accreditation Scheme (HOKLAS) : |  |  |
|  | Within- and between-day precision studies |  |  |
|  | Accuracy studies |  |  |
|  | Limit of blank, detection and quantitation |  |  |
|  | Linearity |  |  |
|  | Correlation with existing methods (Bland Altman Plot for method comparison) |  |  |
|  | Inter-instrument correlation |  |  |
|  | Carry-over studies |  |  |
|  | Interference studies |  |  |
|  | High dose hook effect, if applicable |  |  |
|  | Over range dilution recovery |  |  |
|  | Reference interval validation |  |  |
|  | Turn-around time studies including stress tests |  |  |
|  | The verification report shall include, but not limit to the following contents: |  |  |
|  | Name of person(s) carrying out the verification |  |  |
|  | Objective of the verification |  |  |
|  | Period of the verification and the analytes and applications covered |  |  |
|  | Name and model of the auto-analyzer and number of instrument units |  |  |
|  | For each analyte and application, details of each study performed including types and number of samples used, number of runs per sample, reagent lot and expiry date, etc. and the results |  |  |
|  | The statistical method used for data analysis for each study and the acceptance criteria (should be defined before the study) |  |  |
|  | Summary data with appropriate graphical presentation and analysis |  |  |
|  | Results and conclusions |  |  |
|  | Limitations and precautions, if any |  |  |
|  | Source of references |  |  |
|  | The successful Tenderer shall arrange sufficient manpower including IT hardware engineer(s), IT software engineer(s), LAS service engineer(s) and product / application specialist(s) during normal office hours for supporting and monitoring the performance of the System for a period of not less than two weeks or as agreed with the user during both trial run and live-run period which also including non-office hour telephone support to ensure smooth implementation of the System after acceptance of the System. |  |  |
|  | The successful Tenderer shall provide evaluation software for generating the evaluation report at no additional cost. |  |  |
|  | CMHHK would not be held liable for any damage to the analyzers during the period of delivery, installation, testing and commissioning. |  |  |
|  |  |  |  |
| **B** | **Training** |
|  | On-site maintenance and operational training shall be provided at no additional charges for maintenance and operation staff. |  |  |
|  | training shall be conducted in English or Cantonese by personnel fully conversant with the operation and design of the System; |  |  |
|  | course content and course duration shall be submitted for evaluation; |  |  |
|  | training shall include classroom lectures on theory and also practical onsite training with actual equipment including demonstrations and hands-on practice by the trainees under the supervision of the Contractor’s staff; |  |  |
|  | training materials shall be:- written in English;- include course notes, diagrams, flow charts, video or slide presentations, where appropriate;- available at the time of the training;- of good quality;- supplied in sufficient number of copies. (at least one copy to each trainee). |  |  |
|  | The supplier shall be responsible to provide session(s) of on-site maintenance training to representatives of CMHHK upon request. The course shall cover at least basic theory of operation, circuit description, trouble-shooting technique, preventive maintenance procedures , calibration and alignment, adjustment. |  |  |
|  | The successful Tenderer shall provide detailed operational training for all the staff of the Core Laboratory within first 9 (nine) months. The above training shall be conducted on-site in small groups by application specialist / engineer of the successful tenderer where appropriate. It’s objective is to ensure that the participants are fully trained and equipped with the necessary knowledge and skills to effectively operate all the equipment including peripherals. The training shall also cover: |  |  |
|  | routine operation |  |  |
|  | routine maintenance and |  |  |
|  | simple troubleshooting |  |  |
|  | The successful Tenderer shall provide advanced level training of the System for at least 6 staff members in 3 separate sessions within the first six months. The above training is to be conducted on-site by application specialist / IT specialist of the Tenderer where appropriate. The training shall be hardware and software orientated. It shall cover:  |  |  |
|  | periodic maintenance; |  |  |
|  | troubleshooting; |  |  |
|  | all programmable functions of the controller, middleware and all associated programs of the System; |  |  |
|  | operations in relation to LIS / LAS interface. |  |  |
|  | The time-table and commencement dates for the training shall be advised at least one month prior to the commencement of the course. Detailed syllabuses shall be submitted for approval, upon request. The practical part of the training shall coincide with the installation and commissioning of the Goods. |  |  |
|  | Training protocol of operator and content shall be provided upon the request of laboratory staff and certificate shall be provided after the training as the reqirement of laboratory accreditation. |  |  |
|  |  |  |  |
| **C** | **Documentation** |
|  | All photocopies of operation and maintenance manuals shall be properly binded, stamped and certified as true copies of the original by the manufacturer. |  |  |
|  | Should any original equipment manufacturer products be included, the documents as specified above shall also be provided |  |  |
|  | At the time of delivery of the equipment, two sets of the manufacturer’s original operation and maintenance manuals in English complete with full circuit diagrams levels shall be provided with the equipment ordered. The content of the operation and maintenance manuals shall also include, but not limited to, the following information: (a) description of the Analyzer;(b) list of installed equipment;(c) spare parts and special tools list;(d) manufacturers’ certificates;(e) safety precautions for operation and maintenance;(f) operation instructions;(g) maintenance instructions;(h) maintenance schedules; and(i) drawing lists and drawings. |  |  |
|  | The Contractor shall provide all necessary passcodes or passwords for enabling the Government’s representatives to carry out servicing and maintenance for the System. If service cards or dongles are required for enabling the Government’s representatives to carry out servicing and maintenance, two (2) sets of such service cards or dongles shall be provided to the Government within one month after the commencement of the warranty period. |  |  |
|  | Technical aspects of each test shall be described with respect to: |  |  |
|  | Principle of tests |  |  |
|  | Specimen types |  |  |
|  | Reagents |  |  |
|  | Test procedures and parameters |  |  |
|  | Reference range |  |  |
|  | Traceability of calibration |  |  |
|  | Sample volume |  |  |
|  | Linearity limits |  |  |
|  | Lowest detectable limit |  |  |
|  | Within-batch precision |  |  |
|  | Between-batch precision |  |  |
|  | Interference |  |  |
|  | Source of referenc |  |  |
|  | The Successful Tenderer shall provide the relevant Material Safety Data Sheet (MSDS) for all reagents used in the System. |  |  |
|  | The Successful Tenderer shall provide Standard Operating Procedures (SOPs) in electronic format such as CDROM, in addition to hard copies for easy customization |  |  |
|  |  |  |  |
| **D** | **Acceptance Tests** |
| 1 | Safety Test For the purpose of this contract the Goods shall be subject to a safety test after delivery and installation. Such test is to be carried out by the Contracor with the witness of representative of CMHHK. The safety test will normally be conducted within 6 to 8 weeks after delivery and installation of the Goods. The date of completion shall be based upon the satisfactory result of such safety test. |  |  |
| 2 | Functional TestFor the purpose of this Contract the Goods shall be subject to a functional test for its conformance with the operational and reliability requirements to the satisfaction of the user. In the event that the equipment fails to conform to the above stated requirements, the successful tenderer is required to carry out appropriate remedial measures and/or any rectification works, including replacement of the entire equipment, where deemed necessary. The date of acceptance of the Goods shall be determined by the Hospital based upon the satisfactory completion of such functional test. |  |  |
| 3 | On-site Functional Test |  |  |
| 3.1 | The successful Tenderer shall provide on-site free technical support by the qualified product specialist(s) and all the required reagents of various test profiles and any necessary consumables for functional test, evaluation, initial startup, correlation and customization of the system without additional cost.  |  |  |
| 3.2 | Calibration methodology and intervals shall comply with the established accreditation scheme (e.g. HKAS). |  |  |
| 3.3 | The functional test shall comply with the requirement for Hong Kong Laboratory Accreditation Scheme (HOKLAS) for Analyzer (Supplementary Criteria No.28 and No. 38) and follow the Clinical and Laboratory Standards Institute (CLSI) guidelines on Validation of Automated Systems for Immuno-hematological Testing before Implementation (I/LA33-A). |  |  |
|  | Other requirements |  |  |
|  | The Contractor shall submit the acceptance test schedule, procedures, forms and testing method to the representatives of CMHHK for prior approval before the tests. |  |  |
|  | The Contractor shall provide all testing instruments to conduct site acceptance tests. All testing instruments to be used for the acceptance test shall be calibrated and copies of calibration certificates or other supporting documents shall be forwarded to the representatives of CMHHK for records. |  |  |
|  |  |  |  |
| **E** | **Indicative Warranty Service** |
|  | The potential supplier shall guarantee the equipment or any part thereof for a period of at least 12 months commencing from the date of acceptance of the equipment. The potential supplier shall also replace faulty parts and provide both schedule and breakdown maintenance service by qualified maintenance personnel. In case of replacement of parts, they will be free of charge. |  |  |
|  | The potential supplier shall provide preventive maintenance service (as recommended by the manufacturer) to the equipment during the guarantee period and the scope of preventive maintenance shall be compatible and customizable based on the specific condition and performance of the analytical units in CMHHK. The date and time for carrying out such service shall be ssomprpmised with the user in CMHHK.. Also, the potential supplier shall carry out electrical safety test on the equipment annually during the guarantee period. The electrical safety standard shall be IEC 60601-1 / IEC 61010-1 / IEC 62353 or equivalent. The potential supplier is required to submit consolidated corrective and preventive maintenance summary to the user department in hospital. |  |  |
|  | During the warranty period, all services, which include replacement of spare parts and faulty parts, scheduled preventive and corrective services carried out by qualified maintenance engineer, shall be provided free of charge. |  |  |
|  | During the warranty period, the potential supplier shall provide a round-the-clock phone contact for urgent service call with response time not more than 30 minutes\*. Unlimited on-site corrective maintenance services shall be carried out by manufacturer service engineers within 4 hours for emergency service and no longer than 24 hours for other calls. \* 09:00 – 17:00 from Monday to Friday excluding the public holidays under normal circumstance. If > 50% capacity of analyzer modules for 24hr urgent tests are down, Saturday urgent service is need at no extra cost. At any time throughout the warranty period, the Tenderer shall maintain at least one functional and well conditioned chemistry analyzer unit and immunoassay analyzer unit. If these foresaid criteria are not fulfilled, the response time of answering service calls and the on-site corrective maintenance services depicted in this clause shall apply to 24 hours a day and 7 days a week. |  |  |
|  | The potential supplier shall ensure the down-time of any equipment of the LAS will not be more than three consecutive calendar days excluding public holiday and Sunday at any time of the warranty period. Sufficient quantity of essential parts of the System shall be stocked in the local office of the Tenderer. Long shipment time of replacement part(s) is not accepted as the reason for prolonged down-time of the system. |  |  |
|  | The preventive maintenance work shall be carried out as follows with no additional charge:Normal working hours (09:00 – 18:00 hours Monday to Friday, excluding public holidays and 09:00 - 13:00 Saturday, excluding Public Holiday) |  |  |
|  | The potential supplier shall provide replacement of the modules / analytical units or any component of the System at no extra cost, if the cumulative downtime of the component is more than 400 hours per year during the warranty period upon successful installation and acceptance of the System. "Downtime" will be calculated from the time a down system call is raised to the time of completion of repair and issue of a service report to CMHHK, counting normal working hours as 09:00 - 18:00 from Monday to Friday, excluding public holidays. "Downtime" is the time when the system is down and not available for use. It shall not include the time for any scheduled maintenance, system upgrade, and the time when the system is down due to user misuse and negligence. |  |  |
|  | The potential supplier shall be responsible to make good to the satisfaction of CMHHK Operator, any defects on the equipment due to improper workmanship, faulty design or component failure which may arise within the warranty period of the equipment. |  |  |
|  | Upon notification by the CMHHK Operator of a defect in the operation of the equipment of part thereof, the potential supplier shall perform the corrective maintenance within 48 hours upon request from the CMHHK Operator. This service shall include all necessary repairs, adjustment and replacement of parts to restore the equipment to its normal operational conditions in a time of no more than 3 working days. If such work being maintenance are not completed at the end of particular normal working period, subject to the CMHHK Operator’s agreement, the maintenance work will either be completed on next working day, or arrangement will be made for the supplier to carry on working until the particular maintenance task is completed. |  |  |
|  | Upon completion of the corrective maintenance works, the potential Tenderer shall submit a report on the equipment breakdown investigation result and corrective action taken. |  |  |
|  | The successful Tenderer shall guarantee to provide, at no additional cost, not less than 10 years of necessary software upgrades to all parts of the System for operation enhancement or necessary modification due to LIS upgrading. |  |  |
|  | The successful Tenderer shall provide the support service plan to the operation of the System throughout the life span of the LAS. |  |  |
|  |  |  |  |
| **F** | **Indicative Maintenance Service** |
|  | The potential supplier shall quote the charge for annual maintenance services after the warranty period within the serviceable life of the proposed Goods. If the system on offer contains OEM products, the tenderers shall give a breakdown of the maintenance charges in respect of the main equipment and OEM products wherever applicable. The overall annual maintenance charges for comprehensive maintenance shall not be more than 10% of the equipment list price or tender amount, averaged over 10 years life span. |  |  |
|  | The potential supplier shall submit a price list of all spare parts of the Goods chargeable to the CMHHK Operator. For spare parts not covered by the submitted prices, the potential supplier must submit a quotation to the CMHHK Operator for consideration every time when spares are required. |  |  |
|  | The potential supplier shall deploy properly trained service personnel to carry out the maintenance services and shall ensure that all necessary precautions for their safety are taken. |  |  |
|  | The potential supplier shall provide free of additional charge corrective maintenance service for providing immediate repair service for the goods and related equipment in normal working hours. |  |  |
|  | The maintenance services shall be carried out in accordance with the maintenance procedures as described in the relevant equipment services manuals. |  |  |
|  | Upon notification by the CMHHK Operator of a defect (departure from performance specifications) in the operation of the equipment of part thereof, the potential supplier shall perform the corrective maintenance within 48 hours upon request from the CMHHK Operator. This service shall include all necessary repairs, adjustment and replacement of parts to restore the equipment to its normal operational conditions in a time of no more than 3 working days. If such work is not completed at the end of particular normal working period, subject to the user’s agreement, the maintenance work will either be completed on next working day, or arrangement will be made for the supplier to carry on working until the particular maintenance task is completed.  |  |  |
|  | Upon completion of the corrective maintenance works, the supplier shall submit a report on the equipment breakdown investigation result and corrective action taken. |  |  |
|  |  |  |  |
| **G** | **Reagents, Consumables and Spare Parts Requirment** |
|  | The Supplier shall guarantee the availability of maintenance spare parts for the anticipated life of the System.  Sufficient spare parts shall be held by the successful supplier to cater for the maintenance during the warranty period. |  |  |
|  | The Suppliers, in their tender submission, shall provide a comprehensive list of recommended spare parts with unit prices valid for at least one (1) year after expiry of warranty. |  |  |
|  | The Supplier shall guarantee to maintain the stable supply of required reagents, calibrators, necessary consumables and other spare parts for at least 10 years and during the serviceable life span of the System after acceptance. |  |  |
|  | Reagents and consumables of up to 3 months utilization shall be delivered to CMHHK approximately 4 weeks upon order confirmation so that service shall not be interrupted due to shipment delay or whatever reason. Urgent order shall be available at no extra cost. |  |  |
|  | Unless specifically requested by end-user, each item of calibrator or quality control deliverd shall be of the same lot on each delivery upon availability. |  |  |
|  | User shall have the right to reserve for a particular lot of reagent, calibrator or control upon availability. Partial delivery and scheduled delivery for same lot order shall be available upon availability and within 3 months from date of order. |  |  |
|  | The Supplier shall guarantee that the normal delivery time of consumables, spare parts and reagents from Hong Kong warehouse to CMHHK is not more than 3 working days. |  |  |
|  | The shelf-life of calibrators, control materials and reagents shall not be less than 4 months upon delivery to CMHHK. |  |  |
|  | The reagents shall pass the manufacturer's specifications. All sub-optimal reagents shall be replaced at no extra cost. |  |  |
|  | The Supplier shall accept the responsibility for the satisfactory quality, design and workmanship of all materials, whether they are manufactured by the Supplier, or supplied to the Supplier by other manufacturers. The Supplier shall have full responsibility for the performance of all such materials in use. |  |  |
|  | The Supplier shall provide the latest / new version of reagents of same methodology, calibrators, QCs and necessary consumables (as appropriate) so as to achieve higher quality of analytical performance. |  |  |
|  | In the event that new version of assay is released by the manufacturer, the successful Tenderer shall provide necessary manpower and specialist to CMHHK to conduct the full assay performance evaluation of the latest / new version of assay according to international standards, e.g. Clinical Laboratory Standard Institute (CLSI) and laboratory's accrediting bodies, e.g. Hong Kong Laboratory Accreditation Scheme (HOKLAS) and / or National Association of Testing Authorities, Australia. |  |  |

**Part 4 – Implementation Plan**

*(Note to Suppliers: Please provide the estimated time periods required (in terms of month(s)) for the completion of the following tasks, counting from the date of issue an order (“Order Date”). The System should be* ***Ready for Use after passing the Acceptance Tests unless as specified in (j).****)*

|  |  |
| --- | --- |
| **Tasks of the Implementation Plan** | **Estimated Time Period for** **Performing the Tasks**(in terms of accumulated months)(The Order Date is set as Month **0**) |
| **Start** (Month) | **End** (Month) |
|  | Order Date *(i.e. the date of order placed by the Government, if any)*  | **0** | **0** |
|  | Submission of Site Preparation Information (if applicable) |  |  |
|  | Design of the System (if applicable) |  |  |
|  | Delivery of the System  |  |  |
|  | Installation of the System |  |  |
|  | Implementation Services (*Please refer to* ***Section 12.14, 12.15 and 12.20 in Part 3*** *for details*) |  |  |
|  | Delivery of Documentation (*Please refer to* ***section C in Part 3*** *for details*) |  |  |
|  | Training (*Please refer to* ***section B in Part 3*** *for Details*) |  |  |
|  | Acceptance Tests |  |  |
|  | Any other tasks considered necessary by your company *(Please provide details, use separate sheet if space is insufficient)*: |  |  |
|  | System Ready for Use *(i.e. the date when the System has passed all acceptance tests and accepted by the Government)*  |  |  |

**Part 5 – Information on Compliance with International, National and other Recognised Standards** **or Certifications (if applicable)**

(*Note to Suppliers: Please indicate in the box below whether the proposed Laboratory Automation System can meet with the standards stated in Column I* ***by inserting a tick in an appropriate box under Column III****. If your proposed Laboratory Automation System does not meet the standards stated in Column I, please indicate the equivalent standards met by your proposed Laboratory Automation System in Column IV. In any case,* ***please attach copies of relevant valid certificates to prove compliance with such standards****.*)

|  |  |  |  |
| --- | --- | --- | --- |
| **Column I** | **Column II** | **Column III** | **Column IV** |
| International, National and other Recognised Standards or Certifications | Requirements  | Comply with the Standard in Column I? | Comply with the following equivalent standard (*If “****No****” in Column III*) |
| Yes | No |
| IEC61010-1 or equivalent | As per the requirements stated in clause 9.4 |  |  |  |
| IEC 61326-1 or equivalent. | As per the requirements stated in clause 9.5 |  |  |  |
| IEC61010-2-081 and IEC61010-2-101 or equivalent | As per the requirements stated in clause 9.6 |  |  |  |
| IEC 61326-2-6 or equivalent standard. | As per the requirements stated in clause 9.12 |  |  |  |
| IEC62040-1, IEC62040-2 and IEC62040-3 or equivalent. | As per the requirements stated in clause 10.3 |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Compliance with other international, national and recognised standard(s) or certification(s) in addition to the above (*please specify*) |
|  |  |  |  |  |

**Part 6 – Information on Licencing, Marketing Authorization and MDACS Listing (if applicable)**

(*Note to Suppliers: Please advise whether your company and the proposed System have the following licence, marketing authorization and Medical Device Administrative Control System (“MDACS”) listing. If affirmative, please provide copies of relevant licences, confirmation and certificates for our reference.)*

| Question | Licensing/Certification/Listing Information of the System |  *(Please tick in the appropriate box)* |
| --- | --- | --- |
| #Yes | No |
| 1 | Does your company have valid licence(s) to sell, deal with, possess and use irradiating apparatus in Hong Kong issued under the Radiation Ordinance (Chapter 303 of the Laws of Hong Kong) (“IA Licence”)? |  |  |
| 2 | Has the proposed System been listed in a valid IA Licence? |  |  |
| 3 | Dose the proposed System have marketing authorization of Food and Drug Administration (FDA) of the United States? |  |  |
| 4 | If the proposed System has marketing authorization of FDA, please specify below the type of marketing authorization (i.e. approval, clearance or exemption). \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 5 | Does the proposed System have marketing authorization of the European Union (EU) for affixing of CE marking on the product? |  |  |
| 6 | If the proposed System has marketing authorization of EU, please state the type of supporting document (\*delete which is not applicable).* + - * 1. \*Declaration of conformity by the manufacturer; or
				2. \*Certificate of conformity issued by a notified body.
 |  |  |
| 7 | Does the proposed System have marketing authorization in country/region other than United States and EU? Please specify below if your answer is “Yes”.Country / Region : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 8 | Has your proposed System been listed in the MDACS of the Department of Health?  |  |  |
| 9 | What class of medical device is your proposed System (if applicable)?1. EU : Class \_\_\_\_\_\_
2. United States : Class \_\_\_\_\_\_
3. Other country/region (please specify below):
* Country/Region \_\_\_\_\_\_\_\_\_
* Class \_\_\_\_\_\_\_\_\_
 |  |  |

#Please provide a copy of the licence/confirmation/certificate for reference.

**Part 7 – Indicative Price Information**

(*Note* *to Suppliers: The price information provided in this Part 7 is for Government’s consideration only and shall not constitute any commitment on the part of the Government or your company. Nevertheless, please provide the information as accurate as possible.*)

**(a) Indicative Price Information for the System**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Description** | **Estimated****Quantity** | **Unit Price** | **Estimated Goods Price** |
| **One-time Unit Price(HK$)** | **Estimated Goods Price for the Item specified opposite****(HK$)** |
|  |  | **(a)** | **(b)** | **(c) = (a) x (b)** |
| 1 | Supply, delivery, installation, testing and commissioning of the System and related accessories, as more particularly specified in **section A1.1 in Part 3**, including the provision of a minimum 12-months warranty period. | 1 set |  | ***(Please also provide breakdown cost for key components of the System, if any)*** |
| 2 | Provision of implementation services as detailed in **Section 12.14, 12.15 and 12.20 in Part 3** | 1 lot |  |  |
| 3 | Provision of training services as detailed in **section B in Part 3**  | 2 courses |  |  |
| 4 | Documentation as detailed in **section C in Part 3** | 1 lot |  |  |
| 5 | Other (please specify) | (please specify) |  |  |
| **Total One-time Charge**(i.e. Sum of Estimated Goods Prices of Item 1- 5) |  |

**Part 8 – Indicative Maintenance Charges and Spare Parts Price**

(Notes to Suppliers for completion of Part 8)

1. *Pursant to item 1 of Part 7(a) above, the proposed System shall have a warranty period of not less than 12 months. The indicative warranty service requirements are stipulated in* ***section E in Part 3****, which are subject to changes at the sole discretion of the Government.*
2. *Indicative maintenance service requirements after the free warranty period are stipulated in* ***section F in Part 3****, which are subject to changes at the sole discretion of the Government*
3. *It is expected that the maintenance services shall be comprehensive, all inclusive and shall cover all parts, components, labour and software support services. If your company considers that any components of the System may not be covered by the maintenance services (****saving that the labour shall always be covered by the maintenance services****) and may need to be charged separately, please indicate replacement costs of these components and their replacement frequency.*
4. *The annual maintenance charge within the serviceable life of the proposed System* ***is adjustable in accordance with the consumer price index (B) upon the expiry of each 12-months period of maintenance service****.*
5. **Indicative Maintenance Prices of the Proposed System**

| **Year** | **Annual Maintenance Charge****(HK$ per annum)** |
| --- | --- |
| First 12-months period of maintenance service after the end of warranty period |  |

1. **Indicative Replacement Prices of System’s Components not covered by the Maintenance Services (if applicable) (***Leave the following table blank if not applicable***)**

(*Note to Suppliers:* ***The labor costs for replacement of these components shall always be covered by the maintenance charges for the provision of the maintenance services*** *regardless whether the prices for the supply of these components are covered by the maintenance services or not.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Name of Items | Indicative Replacement Price (HK$/no.) | Indicative Replacement Frequency (*e.g. once every 3 years*) |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

1. **Indicative overtime charges for provision of maintenance services after office hours (if applicable)**

(*Office hours mean 9 am to 6 pm from Monday to Friday excluding public holidays*)

|  |  |  |
| --- | --- | --- |
| (a) | Rates of overtime charges for maintenance service outside the office hours | HK$ per hour |
| (b) | Minimum service hour(s) per call |  service hour(s) per call |

1. **Indicative Prices for Replacement of Other Spare Parts (if applicable)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Item | Name of Items | Price (HK$/no.) | Indicative Replacement Frequency (*e.g. once every 3 years*) | Expected time for delivery (weeks) |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

1. **Indicative Price for Annual Support Services of Software (if applicable)**

(*Note to Suppliers:* Please provide below annual charge for support services of the System’s software during the serviceable life of the System for the CMHHK Operator’s consideration. *The support services should include but not limited to:*

1. *provision and renewal of software toolkits, access codes, passwords, software keys and hardware keys, etc. necessary for all kinds of adjustments, in-depth diagnosis and trouble shooting of the System; and*
2. *version upgrade of the software.)*

|  |  |
| --- | --- |
|  | (a) Free of charge during serviceable life  |
|  |  |
|  | (b) Yearly cost at $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Part 9 – Supplementary Information**

1. Number of proposed System Already Installed (leave blank if information is not available)

In Hong Kong : \_\_\_\_\_\_\_\_\_\_ sets

Globally : \_\_\_\_\_\_\_\_\_\_ sets

1. Year of Launch of the Proposed System (leave blank if information is not available)

My/our proposed System was first launched in the market in Year \_\_\_\_\_\_\_\_\_\_\_\_\_

1. Pre-Installation Requirements of the Proposed System (if any)

*(Pre-installation requirements may include any preparation work and provisions that are necessary for the installation of the System, such as the requirements of ceiling mount support, power supply requirements, etc.)*

**END**