

PREQUALIFICATION DOCUMENTS

**(ANTI-HCV PCR TESTING KITS/DEVICES FOR HEPATITIS &
INFECTION CONTROL PROGRAM)**

**(MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN
PRINCIPALS)**



(FINANCIAL YEAR 2020-2021)

**Directorate General Health Services Punjab
24-Cooper Road Lahore.**

**Primary & Secondary Healthcare Department
Government of the Punjab**

INVITATION FOR PREQUALIFICATION (2020-21)
MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS OF ANTI-HCV
PCR TESTING KITS/DEVICES

1. Government of the Punjab is committed to procure quality Anti-HCV PCR Testing Kits/Devices for Prevention & Control of Hepatitis in Punjab working under the administrative control of Primary and Secondary Healthcare Department. To materialize this commitment Director General Health Services Punjab invites application for prequalification of Anti-HCV PCR Testing Kits/Devices for Financial Year 2020-21 from Local Manufactures, Sole Agents of Foreign Principals having established credentials in terms of technical, financial & managerial capabilities.
2. A complete set of Prequalification Documents can be downloaded from the following websites [\[www.ppra.punjab.gov.pk\]](http://www.ppra.punjab.gov.pk), [\[www.pshealth.punjab.gov.pk\]](http://www.pshealth.punjab.gov.pk) [\[www.dghs.punjab.gov.pk\]](http://www.dghs.punjab.gov.pk).
3. The last date and time for hard copy of application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road, Lahore on **31.12.2020** uptill **11:00 AM** which shall be opened on the same date at **11:30 AM**.
4. The firms shall pay a non-refundable Prequalification Fee as mentioned in Pre-qualification documents at The Accounts Branch, Directorate General Health Services Punjab, 24-Cooper Road, Lahore.
5. The Request for Proposals (RFP) will be called only from the Prequalified Firms by the concerned procuring agencies.
6. In case the date of opening or last date of submission is declared as a public holiday or non-working day due to any reason, the next official working day shall be deemed to be the date of submission and opening of printed applications accordingly. The time and venue shall remain the same.

Note: The process shall be governed by the Punjab Procurement Rules, 2014.

PROGRAM MANAGER (PHCP)
DIRECTORATE GENERAL HEALTH SERVICES
PUNJAB

Table of Contents

Section I: Instructions to Applicants (ITA)	5
A. General.....	5
1. Scope of Application.....	5
2. Fraud and Corruption	5
3. Eligible Applicants.....	6
B. Contents of the Prequalification Document.....	6
4. Sections of Prequalification Document	6
5. Clarification of Prequalification Document	6
6. Amendment of Prequalification Document	6
C. Preparation of Applications.....	7
7. Cost of Applications.....	7
8. Language of Application	7
9. Documents Comprising the Application.....	7
10. Application Submission Form	7
11. Documents Establishing the Eligibility of the Applicant.....	7
12. Documents Establishing the Qualifications of the Applicant	7
13. Signing of the Application and Number of Copies.....	7
D. Submission of Applications	8
14. Sealing and Identification of Applications.....	8
15. Deadline for Submission of Applications.....	8
16. Late Applications	8
17. Opening of Applications	8
E. Procedures for Evaluation of Applications	8
18. Confidentiality	8
19. Clarification of Applications	8
20. Responsiveness of Applications	9
21. Domestic Bidder Price Preference.....	9
F. Evaluation of Applications and Prequalification of Applicants.....	9
22. Evaluation of Applications.....	9

23. Right to Accept or Reject Applications.....	9
24. Prequalification of Applicants.....	9
25. Notification of Prequalification	9
26. Validity of Prequalification	9
Section II: Prequalification Criteria	11-13
Section III:	21-23
A: List of Kits/Medical Devices	21
B: Application Submission Form.....	22
C: Application Affidavit.....	23

Section I: Instructions to Applicants (ITA)

A. General

1. Scope of Application

- 1.1 In connection with the Invitation for Prequalification “as per PPR 2014” the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, issues this Prequalification Document (PQD) to applicants interested to prequalify Manufacturing Units & Sole Agents of Foreign Principals for Non-Drugs/Kits/Medical Devices against the list of items/sections contained in the Prequalification Documents. This prequalification will be concluded for DGHS. Prequalification will be carried for the items which comes under the definition of drugs under Drugs Act 1976/DRAP Act 2012/Punjab Drugs Rules 2007/ Punjab Drugs Amendment Act 2017 for Drug Items & Medical Devices Rules 2018. Procuring agency may physically verify firm’s claim regarding submitted documents.

2. Fraud and Corruption

- 2.1 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab requires that applicant observe the highest standard of ethics during the submission of application for prequalification and further documents required for prequalification.
- (a) In pursuance to this, the following terms are defined:
- (i) “corrupt practice” is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;
 - (ii) “fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;
 - (iii) “collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;
 - (iv) “coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;
 - (v) “obstructive practice” is deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

- (b) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will reject a proposal for prequalification if it determines that the applicant has directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the prequalification in question;
- (c) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will declare ineligible, either indefinitely or for a stated period of time, if it, at any time, determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for prequalification.
- (d) The prequalified firms are required to participate in RFP/bidding process announced by any procuring agency under administrative control of Primary & Secondary Healthcare Department. In case of failure to participate, procuring agency may disqualify respective firm (fully or in partially) from pre-qualification 2020-21 and may initiate legal proceeding against the said firm.

3. Eligible Applicants

- 3.1 An Applicant can be a private or public entity registered with FBR having NTN & SRTN Registration.
- 3.2 If Government of Pakistan prohibits commercial relations with any Country, the firms dealing with such countries are ineligible to apply.
- 3.3 A firm declared disqualified / blacklisted / debarred by any of the public sector organization in Pakistan shall be ineligible for prequalification

B. Contents of the Prequalification Documents

4. Sections of Prequalification Documents

- 4.1 The documents for the prequalification of Applicants (hereinafter - "prequalification documents") consists of all the sections indicated below, and should be read in conjunction with any Addendum if issued.
 - Section I. Instructions to Applicants (ITA)
 - Section II. Prequalification criteria
 - Section III. A: Application Form
B: Application affidavit
- 4.2 The "Invitation for Prequalification Applications" (IPA) issued by the Procuring Agency is part of the prequalification documents.
- 4.3 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of The Punjab accepts no responsibility for the completeness of the prequalification documents and its addenda unless the original receipt of the fee deposit slip is attached with the documents.

- 4.4 The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Documents and to furnish all information or documentation required by the Prequalification Documents.
- 5. Clarification of Prequalification Document**
- 5.1 A prospective Applicant requiring any clarification of the Prequalification Documents shall contact the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab in writing at the address indicated in the **Invitation for Pre-Qualification of Drugs/Medicines & Non-Drugs/Medical Devices**. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will respond in writing to any request for clarification provided that such request is received no later than Ten (10) days prior to the deadline for submission of applications. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab shall forward copies of its response to all applicants who have acquired the prequalification documents through its official website including a description of the inquiry but without identifying its source. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab deemed it necessary to amend the prequalification documents as a result of a clarification it shall do under intimation to all the applicants who have obtained the prequalification documents through its official website.
- 6. Amendment of Prequalification Document**
- 6.1 At any time prior to the deadline for submission of applications, the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab may amend the Prequalification Documents by issuing addenda/Corrigendum.
- 6.2 Any addendum/corrigendum/minutes of pre-application conference issued shall be part of the Prequalification Documents and shall be communicated in writing to all who have obtained the prequalification documents from the Primary & Secondary Healthcare Department. The minutes shall also be uploaded on the official websites of Director General Health Services Punjab and Primary & Secondary Healthcare Department Government of the Punjab
- 6.3 To give prospective Applicants reasonable time to take an addendum/corrigendum into account in preparing their applications, the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab may, at its discretion, extend the deadline for the submission of applications

C. Preparation of Applications

- 7. Cost of Applications**
- 7.1 The Applicant shall bear all costs associated with the preparation and submission of its application. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the prequalification process.
- 7.2 Payment Receipt may be collected from Accounts Branch, Directorate General of Health Services Punjab, 24 Cooper Road, Lahore after submitting fee of Rs:10,000/- with providing request letter on firm's original letter head as per specimen of request letter attached in **Annexure-1**.

- 8. Language of Application**
- 8.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, shall be written in the language specified in the **Prequalification Documents**. Supporting documents and printed literature that are part of the application may be in another language, provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **Prequalification Documents**, in which case, for purposes of interpretation of the application, the translation shall govern.
- 9. Documents Comprising the Application (Hard copy)**
- 9.1 The application shall comprise the following:
- a. Application Submission Form, in accordance with Information To Applicants (ITA);
 - b. Documentary evidence establishing the Applicant's eligibility to prequalify, in accordance with ITA & Prequalification Criteria;
 - c. Documentary evidence establishing the Applicant's qualifications, in accordance with ITA and & Prequalification Criteria
 - d. Any other document required as specified in the Prequalification Documents.
 - e. **All information, statements and description contained in the Application (hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided submitted in hard copy.**
- 10. Application Submission Form**
- 10.1 The printed application along with necessary documents shall be submitted (in tape binding) by hand in Purchase Cell Directorate General of Health Services Punjab, 24 Cooper Road, Lahore before date and time mentioned in the advertisement.
- 11. Application Submission**
- 11.1 To establish its qualifications the Applicant shall provide the information requested in the corresponding Information Sheets included in Section III, Prequalification Criteria
- 12. Documents Establishing the Qualifications of the Applicant**
- 12.1 The Applicant shall prepare and submit the application for prequalification as described in ITA & Prequalification Documents. The application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant.
- 13. Signing of the Application**
- 13.1 The Applicant shall prepare and submit the application for prequalification as described in ITA & Prequalification Documents. The application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant.

D. Submission of Applications

14. Sealing and Identification of Applications

- 14.1 The Procuring Agency will accept no responsibility for not processing any envelope that was not identified as required.
- 14.2 Applicants will submit their applications (Hard Copy) by hand. Applications shall be received by the Purchase Cell Directorate General of Health Services Punjab-24 Cooper Road, Lahore at the address and no later than the deadline indicated in the **Invitation for Prequalification**.

15. Deadline for Submission of Applications

- 15.1 The Director General of Health Services Punjab Primary & Secondary Healthcare Department may, at its discretion, extend the deadline for the submission of applications by amending the Prequalification Documents in which case all rights and obligations of the Director General of Health Services Punjab, Primary & Secondary Healthcare Department and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.
- 15.2 Any application received by the Director General of Health Services Punjab, Primary & Secondary Healthcare Department after the deadline for submission of applications will not be entertained as indicated in the **Invitation for Prequalification**.

16. Late Applications

- 16.1 The Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall open all Applications at the date, time and place specified in the **Invitation for Prequalification**. Late Applications shall be treated in accordance with ITA.

17. Opening of Applications

- 17.1 Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall prepare a record of the opening of applications that shall include the name and other details of the Applicant. A copy of the record shall be distributed to all Applicants.
- 17.2 Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall prepare a record of the opening of applications that shall include the name and other details of the Applicant. A copy of the record shall be distributed to all Applicants.

E. Procedures for Evaluation of Applications

- | | | |
|---|------|---|
| 18. Confidentiality | 18.1 | From the deadline for submission of applications to the time of notification of the results of the prequalification, any Applicant that wishes to contact the Director General of Health Services Punjab, Primary & Secondary Healthcare Department on any matter related to the prequalification process, may do so but only in writing. |
| | 18.2 | To assist in the evaluation of applications, the Director General of Health Services Punjab, Primary & Secondary Healthcare Department may, at its discretion, ask any Applicant for a clarification of its application (b hard copy) which shall be submitted within a stated reasonable period of time. Any request for clarification and all clarifications shall be in writing. |
| 19. Clarification of Applications | 19.1 | If an Applicant does not provide clarifications of the information requested by the deadline, the application shall be evaluated based on the information and documents available at the time of evaluation of the application. |
| | 19.2 | All applications not responsive to the requirements of the prequalification document shall be rejected. |
| 20. Responsiveness of Applications | 20.1 | A margin of preference for domestic bidders shall not apply in the bidding process resulting from this prequalification. |
| 21. Domestic Bidder Preference | 21.1 | A margin of preference for domestic bidders shall not apply in the bidding process resulting from this prequalification. |

F. Evaluation of Applications and Prequalification of Applicants

22. Evaluation of application	22.1	The Prequalification will be item wise/section wise/firm wise, however in case of any addition in the formulary, the qualification against prequalification section will be considered and in certain cases where any principal of procurement will going to be violated, the procuring agency may invite open competitive bidding in best public interests.
	22.2	The Director General of Health Services Punjab, Primary & Secondary Healthcare Department reserves the right to accept or reject all the applications, and to annul the prequalification process, without thereby incurring any liability to Applicants.
23. Right to accept or reject the applications	23.1	All Applicants whose applications have met the specified requirements will, to the exclusion of all others, be prequalified by DGHS the Primary & Secondary Healthcare Department.
24. prequalification of applicants	24.1	Once the Director General of Health Services Punjab, Primary & Secondary Healthcare Department has completed the evaluation of the applications it shall notify all Applicants in writing/through Official websites of DGHS & P&SHD indicating their Section/Item wise status as to prequalified or disqualified or ineligible.
25. Notification of prequalification	25.1	The Pre-Qualification shall be valid for FINANCIAL YEAR 2020-21
26. Validity of Pre-Qualification	26.1	

Annex-1 (On firm's Original Letter Head)

**Request Application for Prequalification Documents (2020-21)
Kits/Non-Drugs/Medical Devices**

Ref. No.:

Dated:

The Director General Health Services Punjab,
Primary & Secondary Health Care Department
Govt. of The Punjab.

Subject: **Request Application for Prequalification Documents (2020-21) Kits/Non-Drugs/Medical Devices**

Dear Sir,

With reference to your advertisement regarding prequalification of Kits/Non-Drugs/Medical Devices (2020-21) advertised on ----- in the Daily ----- Newspaper, it is requested to provide the Prequalification Documents against the following categories.

(Tick Appropriate Box)

1. Local Manufacturers (Non-Drugs/Medical Devices)

☐

2. Sole Agents (Non-Drugs/Medical Devices)

☐

M/s _____ hereby authorizes Mr./Ms. _____

Designation _____ CNIC No. _____

Official Email _____ (**For Login I.D.**), Mobile No. _____ (for sms alerts) to fill/complete/submit the prequalification application

Firm's NTN: _____

Firm's STN: _____

Authorized By

Name _____

Signature _____

Designation _____

Contact No. _____

Stamp _____

PREQUALIFICATION CRITERIA

(ANTI-HCV PCR TESTING KITS/DEVICES FOR HEPATITIS PREVENTION AND INFECTION CONTROL PROGRAM)

Prequalification 2020-2021

COMPULSORY PARAMETERS

- a. Original Prequalification Purchase Receipt obtained by Depositing Rs. 10,000/- (Non-Refundable) to Cashier, Accounts Branch, DGHS.
- b. Valid Drugs Manufacturing License (for manufacturers) / Establishment Registration Certificate (for Sole Agents / Authorized agent). However, the registration holding firm will be responsible for quantity & quality of the product.
- c. Valid Drug Sale Licenses. (Where applicable)
- d. Valid Drug Registration Certificate / Drug Enlistment Certificate, whichever is applicable as per Medical Devices Rules 2018 of the quoted product issued by DRAP Pakistan.
- e. Valid GMP certificate issued by DRAP (for local manufacturer)
- f. Valid quality certification of CE/JHMLW /US FDA/ WHO prequalified/approval of the quoted product. (If the product is CE marked the Country of origin mandatorily be USA, Europe or Japan only).
- g. The firm undertakes that currently it is not Blacklisted / Debarred any Government, or its organization or project on valid Rs.100 judicial stamp paper duly verified by notary public.
- h. National Tax Number (NTN) and General Sales Tax Number with documentary proof shall have to be provided by the bidder(s).
- i. The bid must comply with the advertised technical specifications of the quoted item. Incomplete offer will straightaway be rejected. Firm will also submit documentary evidence of complete specification along with affidavit on 100 Rupees judicial stamp paper that it will full fill all equipment mentioned in Specification after successful in bidding process.
- j. Applicant will provide cumulative Financial Turnover of last three consecutive financial years (i.e. 2016-17, 2017-18 & 2018-19) must not be less than 300 Million Rupees. Firm will provide FBR sale tax return for three last financial years i.e. 2016-17/2017-18/2018-19 (total good or service supplied locally including reduced rates sales).
- k. The applicant will submit an affidavit on Rs. 100/- judicial stamp paper (Notarized) stating the applicant accepts all the terms and conditions as mentioned in Prequalification Documents.
- l. The firm shall undertake on Rs.100/- judicial stamp paper legally notarized that the Information provided by the firm at Annexure-A, B, C, D and any other information provided by the firm are in accordance with terms & conditions of the prequalification documents.
- **In case of failure to comply with any above-mentioned parameter, the bidder will be declared as “not prequalified”:**

Note:

- 1) To establish its qualification, the firm shall provide the information requested in the respective annexures and requirements with documentary proof.
- 2) The firm will be prequalified for the particular item/ brand.

GENERAL FIRM'S INFORMATION

(Kit/Medical Device)

I. Company Profile.

1. Name of company : _____

Year established : _____

Form of company : ☐ Individual
☐ Partnership
☐ Corporation
☐ Other (specify)

Legal status : _____

Trade registers number : _____

NTN & Sales Tax number (If applicable): : _____

Mfg. License Number : _____

(attach valid copy)

2. Address : _____

Telephone : _____ Telefax: _____

E-mail: : _____

3. Employees:

S. No.	Category	Quantity
1	Management	
2	R &D	
3	Sales	
4	Administrative	
5	Production and quality control	
6	Others (specify)	
	Total	

Please attach the company organizational chart

II. Product Information

Please provide the information as per Annexure-A or B

1. Are all manufacturing operations (processing, packaging, labeling) carried out internally?
☐ YES ☐ NO

If "No," attach a list of pharmaceuticals and/or raw materials manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

S. No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product:

S. No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

III. QUALITY DEPARTMENT

1. Do you maintain your own quality control laboratory?
☐ YES ☐ NO (if NO please provide details of alternate arrangements)
2. Number of specialized personnel working in your quality control, quality assurance and microbiological laboratory/ies (excluding administrative personnel). Provide their academic and professional details on a separate sheet.
- Pharmacists : _____
- Chemists : _____
- Others : _____
3. List of Equipment installed in quality control, quality assurance and microbiological laboratory/ies for quality assurance as per BP/USP.
- _____
- _____
4. Are these equipment calibrated & validated.
☐ YES ☐ NO
5. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?
☐ YES ☐ NO ☐ Certificate of Analysis

6. Are control samples of each batch retained?

☐ YES

☐ NO

7. Name and title of the authorized person (s) responsible for batch release:

Name: _____

Title: _____

Experience in pharmaceuticals: _____ years

8. Name and qualification of the head of the Quality Control department:

Name: _____

Qualification: _____

Experience in pharmaceuticals: _____ years

9. Describe your storage facilities:

The firm will provide logistics/distribution network in Punjab.

The firm will provide human resource regarding logistics/distribution network in Punjab.

Annexure "B"

Authorized Sole Agent for Foreign Principal (Kit/Medical Device)

Product applied for:

S. No. of the item	Name of Item	Name of Manufacturer	Country of Origin	Quality Compliance standards

Name of firm _____

Address _____

Phone _____ Fax _____

E-mail _____ URL http://www. _____

Type of firm: ☐ Sole Proprietor ☐ Partner Ship ☐ Limited

Other _____ Date of establishment _____

List of Board of Directors, Partners, Key Management Personnel (both Technical, Sales & Management - include position, professional qualification, experience).

Total area of the firm premises _____ ☐ Owned ☐ Rented

Total Area of ware house _____

Facilities in ware house _____

Total no. of Employees: Technical _____ Non - Technical _____

National Tax Number _____ Date _____

General Tax Number _____ Date _____

Registrations / Prequalification with other departments: _____

Detail of Head / Branch Office / Workshop (s):

Address: _____

Phone _____ Fax _____

Address _____

Phone _____ Fax _____

Sales / Marketing Staff:

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm	Training Detail (Local & abroad)

Technical Staff:

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm

Name & Capacity of the Authorized Contact Person: _____

Signature of the Authorized Contact Person: _____

Date: _____ Stamp of the Firm: _____

DOCUMENTS TO BE ATTACHED (COPIES)

The firm must attached relevant documents

NAME OF APPLICANT FIRM (Local Manufacturer) _____

Item Code	Generic Name	Section	Quoted Brand	D/ Form	Volume (ml)	Quoted strength	Pack Size	Mfg By	Mfg for	MRP fixed by DRAP	Drug Reg. No	Drug Reg. Date	Mfg Capacity/ day (quoted item in finished units)	Section (Validation/c alibration	Required Storage tem pt(quoted item)	Spurious sampl e (last 3 years)	DTL Subst andard (Not over 5%) Fro m(01-01-2018)	Subst andard Batch Recall Histor y (01-01-2018)	Punitive Action by DRAP from (01-01-2018)	Punitive Action by PQCB from (01-01-2018)	Convicted by Drug Court from (01-01-2018)
1																					
2																					

NAME OF APPLICANT FIRM (Sole Agent) _____

Item Cod e	Generic Name	Section	Quoted Brand	Quoted strength /size	pack Size	Country of Origin	Mfg By	Mfg for	MRP (Rs)	Quality Compliance Standards	Required Storage tempt (quoted item)	Valid Sole Agency Agreement	Date of Sole agency agreement	Product 3-years’ experience in Pakistan	Verified/ Not Verified (Valid sole agency Authorizati on)
1															
2															

LIST OF ITEMS & TECHNICAL SPECIFICATIONS

SR #	NAME OF THE ITEM WITH DETAILED SPECIFICATION
1.	<p>HCV PCR TESTS SPECIFICATIONS:</p> <p>One set (as applicable) = Extraction Kit + Amplification Kit + Consumables + Controls + Calibration Standards capable of detecting HCV IUs across all 7 genotypes of HCV. Limit of Detection must be less than 15 IU/ml. Kits must be for In-vitro Human diagnostics (IVD).</p> <p>The Product/Kit must be US FDA (United States Food & Drug Administration) approved as per online published approval letter document available on official website of United States Food & Drug Administration.</p> <p>If the product is CE marked the Country of origin mandatorily be USA, Europe or Japan only.</p> <p>Real time PCR test kit, ready to use, complete kit with all disposables and consumables as per needs put forth by procuring agency i.e. essential reagents (set of RNA extraction and amplification reagents in correct proportionate quantity), disposable/single use sterile clinical/lab grade filter tips 10 µL, 100 µL, 200 µL, 1000 µL, powder free nitrile molecular grade gloves, secondary tubes, and any other material (personal protective equipment, plastic ware/plastic bags/yellow/red color waste bags, glassware, equipment such as micropipettes) as well as any chemical such as ethanol/distilled water/disinfectant and cleaning solutions required for assay performance/instrument maintenance/lab decontamination compatible with kits/machines as per recommendations of the manufacturer and as agreed upon by procuring agency.</p> <p>Number of tests counted in each kit shall be those which are performed for diagnosis exclusively, controls and any other measures consuming reagents shall not be counted in number of tests. Furthermore, reagents/tests lost due to instrumentation error, including but not limited to errors/unsatisfactory performance caused by contamination issues, any precedented/ unprecedented technical errors, installation shortcomings, loss of power backup before stipulated backup time shall be compensated in full to procuring agency. Tests lost due to human/operator error shall be compensated as well but number of tests compensated against kits lost to human/operator may not exceed 5% of total tests purchased by procuring agency.</p> <p>Machines/platforms for the usage of said kits will be provided by supplier as well, along with installation and troubleshooting services as well as regular calibration, maintenance, upkeep, repair, and decontamination of said machinery. Additionally, supplier shall be responsible for provision of sufficient power backup per instrument as well as attached ancillary/auxiliary equipment directly impacting machine operation and result transmission/test lookup/query etc. to avoid kit break/ samples loss while the batch is being processed. The contractor shall provide the system(s) with enough throughput as to perform at least 300 tests or more per eight (8) hours shifts. Supplier shall provide identical instruments to increase throughput as deemed necessary by the procuring agency, having combined throughput of 900 tests or more per 8-hour shift. Instruments offered shall be the latest generation as currently being marketed anywhere in the world. Wherein latest generation refers to either subsequent iteration of same equipment even if the iteration differs only in terms of a software upgrade, alternatively latest generation may refer to an entirely different/new range of equipment/new technology detecting same analyte i.e. HCV Nucleic Acid. Wherein marketed refers to deployment of a technology/system/equipment in a clinical diagnostic setting wherein supplier is being compensated financially by the deployment of said technology/system/equipment.</p> <p>Machinery must be capable of receiving and processing open primary and secondary sample tubes with automated barcode reading capability post-loading as well as being LIS Connectivity compatible for both uni- and bi- directional communication using HL7 standard protocol. Additionally, vendor shall provide access to raw analytical results output by instrument for validation purposes. Supplier will be responsible for technical support for interfacing of Machine software with procuring agency's Lab Information System. Supplier will be responsible for replacement of any non-functional machinery and/or machinery parts within stipulated timeframe depending on workload.</p> <p>Supplier will be responsible for initial training and refresher training of user staff in terms of machine usage as well as biosafety procedures and decontamination protocols as and when required.</p> <p>Technical Specifications for the above- mentioned accessories (items other than extraction and amplification kits) must be compatible with the offered kits and machinery shall comply with technical specifications/samples provided by procuring agency as well.</p> <p>The bidder will ensure shipping of the kits directly from the manufacturer from the country of origin to the consignee in batches on quarterly basis or as per demand (with maintenance of cold chain throughout), however the bidder may act as a local agent of the manufacturer ensuring provision of technical, maintenance, replacement, training, troubleshooting and supply services.</p> <p>Supplier shall be responsible in terms of expenditure for sample transport via 3600 round trips from across Punjab wherein transport vessel shall be a Vaccine Box weighing no more than 15 kg and having External dimensions H x W x D (mm) 437 x 588 x 288 and wherein transit time to HCP Central Lab/alternate destination designated by procuring agency from origin of samples shall not exceed 48 hours while transit time from HCP Central Lab/alternate destination designated by procuring agency to return destination/Hepatitis Clinic shall not exceed 96 hours, door to door. Sample shipment must be carried out via a reputable courier service familiar with technicalities of cold chain, shipment method must include online tracking for monitoring of transit time by procuring agency.</p>

Section III: Application Forms

Application Submission Form

Date: __/__/2020

To

**Director General Health Services Punjab
Government of the Punjab
Primary & Secondary Healthcare Department.**

I/we, the undersigned, apply to be prequalified for the referenced Pre-qualification and declare that:

- (a) I/we have examined and have no reservations to the Prequalification Documents, including Addendum(s). (if any) issued in accordance with Instructions to Applicants (ITA) *[insert the number and issuing date of each addendum]*.
- (b) I/we, have nationalities from eligible countries, in accordance with ITA *[insert the nationality of the Applicant, including that of all partners in case of a Joint Venture /Consortium if applicable]*;
- (c) I/we, for any part of the application resulting from this prequalification, do not have any conflict of interest;
- (d) I/we for any part of the contract resulting from this prequalification, have not been declared disqualified / blacklisted by any of the public organization of the Procuring Agency's country
- (e) I/we understand that you may cancel the prequalification process at any time, the prequalification does not bound the procuring agency to call for the bids from the prequalified firms.
- (f) All information, statements and description contained in the Application (hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided and submitted in hard copy.

Signed *[insert signature(s) of an authorized representative(s) of the*

Applicant] Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf

of: Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country/ address]*

Dated on __/__/2020

Affidavit

(Pak Rs.100/-)

a) Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as described in the documents.

b) Applicants confirming not having been involved in any litigation during last three years.

Signed *[insert signature(s) of an authorized representative(s) of the Applicant]* Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf of: Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country/ address]*

Dated on _ -/_ -_/2020