

# HAFFKINE BIO PHARMACEUTICAL CORPORATION LIMITED

## **Procurement Cell**

(A Government of Maharashtra Undertaking)

Regd. Office: Acharya Donde Marg, Parel, Mumbai 400 012 (INDIA)

Phone No: 022- 24129320-23

Managing Director

Website: http://www.vaccinehaffkine.com

:022-24150628 E-mail% procurementcell@vaccinehaffkine.com

General Manager (Procurement Cell): 022-24100478

No. 4035

/Haffkine/Procurement Cell/ GeM Portal/

B-839358/ RTPCR/ 2020-21

Date: - 23 / 10 / 2020

To,

M/s. Trivitron Healthcare Pvt. Ltd.,

Ground Floor, Wing A, Old No.25,

New No. 15, Abhiramapuram, IVth Street,

Chennai -600018. Chennai, Tamil Nadu (India)-600018.

Tel No. 8527794405/8527794427/0442498505.

Email: - corporate@trivitron.com/jagnnath.singh@trivitron.com.

Rajiv.chawla@trivitron.com.

Sub: - Supply of Tender No. GEM/2020/B/839358/ Item Name: - Real Time PCR (Polymerase Chain Reaction) Kits For Novel Coronavirus

(SARS-CoV-2/COVID-19)

Ref: - 1. Tender No. GEM/2020/B/839358

With reference to the tender cited under reference no 1 your online bid has been accepted. Accordingly you are requested to supply the following goods as per details mentioned below to consignee list enclosed with this order.

| Sr.<br>No. | Name of the item  | Specification of item | Quantity          | Unit Rate including all taxes Rs. | Total Amount<br>Rs.(Inclusive<br>All Taxes) |
|------------|---|-----------------------|-------------------|-----------------------------------|---|
| 1          | Real Time PCR (Polymerase Chain Reaction) Kits For Novel Coronavirus (SARS-CoV- 2/COVID-19) | As Per<br>Annexure-A  | 9,00,000<br>Tests | 50=06/-<br>Per test               | 4,50,54,000/-                               |

(Rupees In Word: Four Crore Fifty Lakh Fifty Four Thousand only)

1. Delivery Period: The Delivery Period (As per Annexure-I) shall be the essence of the contract and delivery must be complited not later than such date(s). Any notification thereto shall be mutually agreed and incorporated in the Contract as par provisions of the GTC.

2. Terms of Delivery:-Free delivery at site including loading/Unloading. In respect of items requiring installation and/ or commissioning and other services in the scope of supply(As indicated in respective product category specification/STC/ATC), and cost of the same is also include in the contract price.

3. Samples of all batches which are going to be supplied must be sent to NIRRH( National Institute For Research in Reproductive Health) Address - Director, ICMR- NIRRH, Jehangir Merwanji Street, Parel, Mumbai-400 012.) within 3 days from date of Supply order. Supply of the same batches should begin on receipt of satisfactory Certification from the above said Institution.

4. Risk purchase clause: If the bidder fails to supply the stores within the stipulated delivery period inclusive of period with penalty, the order will stand cancelled. Undersigned shall be entitled to purchase such stores from any other source at such price which ordinarily should not be more than 10% of the tender price, unless otherwise properly satisfied by purchasing officer. The extra expenditure in such cases shall be recovered by Managing Director, Haffkine Bio Pharmaceutical Corporation Ltd.(Procurement Cell), Mumbai from the Supplier inclusive of recovery by Revenue recovery procedure.

- 5. Liquidated Damages:- If the Seller fails to deliver any or all of the Goods/ Services within the original/ re-fixed delivery period (s) specified in the contract, the Buyer will be entitled to deduct/ recover the Liquidated Damages for the delay, unless covered under Force Majeure conditions aforesaid, @ 0.5% per week or part of the week of delayed period as pre-estimated damages not exceeding 10% of the contract value without any controversy/dispute of any sort whatsoever. In case, service Level Agreement (SLA) is applicable the same shall be applicable for the Contract.
- 6. Payment Terms: 100 % Payment shall be paid on receipt & acceptance of stores in good conditions by the consignee
- 7. Acceptance & Receipt: In prescribed format enclosed .lt should be submitted in Original Certificate copy to the purchasing authority along with triplicate copies of the Invoice.
- 8. Certificate copy to the purchasing authority along with triplicate copies of the Invoice.
- Delivery Challan Should be sent in the name of consignee in duplicate. It should specify Name of Drugs/ Mfg. by / Expiry Date / packing & quantity.
   Invoice Copy Should be sent in triplicate on the Name of Managing Director, Haffkine Bio Pharmaceutical Corporation Ltd. (Procurement Cell), Mumbai
- 10. Other Terms :: As per GeM Portal Tender terms & conditions
- 11. Submit the Bank Guarantee of **Rs.13,51,620**/- (3% of total value) from Nationalized / Scheduled commercial bank in favor of Haffkine Bio-Pharmaceutical Corporation Ltd, Procurement Cell, Mumbai Validity of the Bank Guarantee should be minimum for the period 2 months from the date of expiry of warranty or expiry of medicine/item.

Consignee As per list enclosed (As per Annexure I)

Mfg.Licence No. Medical Device License No. MFG/IVD/2020/000053

Location of Factory

M/s. Trivitron Healthcare Pvt. Ltd.,
Ground Floor, Wing A, Old No.25,
New No. 15, Abhiramapuram, IVth Street,
Chennai -600018. Chennai, Tamil Nadu (India)6000 18.

(Dr. R. M. Kumbhar General Manager-1

Haffkine Bio Pharmaceutical Corporation Ltd. (Procurement Cell), Mumbai

Copy to: 1) Director, Directorate of Medical Education & Research, Mumbai.

- 2) Account Manager Haffkine Bio Pharmaceutical Corporation Limited Procurement Cell, Mumbai.
- 3) Office File

Copy to Consignee : As Per List.

They should accept Drug as per order & entry of the stock is to be taken in stock register as well as in e-Aushadhi.

Copy Submitted to: 1) Secretary, Medical Education and Drug Department Mantralaya, Mumbai

RTPCR KIT Page 2

### ANNEXURE I

#### M/s Trivitron Healthcare Pvt. Ltd., Consignee List For Real Time PCR (Polymerase Chain Reaction) Kits for Novel Coronavirus (SARS-CoV-2/COVID-19) 4035 / Haffkine/ Procurement Cell/ GeM No. Portal / B-839358/ RTPCR/ 2020-21 PO Reference No. Date- 27 / 10 /2020 7 days Delivery Period Name of Contact S Name of W.e.f W.e.f Name Of r. Person with **Postal Address** Officer 24/10/20 09/11/20 Total n Consignee Contact No. with O Contact No. 1)Dr. Vainav Scientist-E 9029010165 Dr. Smita Director, ICMR-Mahale, 2)Dr.Vikrant NIRRH NIRRH, Jehangir Director Scientist-D 1 86,000 86,000 1,72,000 Mumbai Merwanji Street, Parel, 022-9987036993 Mumbai-400 012. 24192000/24 3)Dr.Rajendra 132111/12 Sr.Technical Officer 9892757008 Dy. Director of Health Services, Mental Mr.Mahesh Dr. Gauri Hospital Compound, Deputy Hule rathod, Dv. 38,100 2 Director, Near Dyansadhana (Sr.Pharmacy 38,100 76,200 Director Thane College, Teen Hath Officer) 8928284072 Naka, Thane west-400 9004701309 Director NIV, 20 A Dr. Ambedkar Road. Dr. Priya Dr. Varsha 3 NIV Pune National Institute of Abraham Potdar 1,13,700 1,13,700 2,27,400 Virology, Pune-411 8940843532 9890307757 001. additional Director's, Add. Dr. D. N. Office State Family Director, Patil, State Mr.Umesh Welfare Bureau, Near 4 Family Immunisatio Jadhav 25,100 25,100 50,200 Naidu Hospital, Behind Welfare. n Officer. 9604116494 Pune Railway Station, Pune 9421407574 Kennedy Road, Pune. Dy. Director of Health Dr. Mrs. Varsha Services, Bhagwan Deputy Swapneel Aute Mahaveer Chowk, 5 Director, Kale, Dy. (Pharmacy 95,300 95,300 1,90,600 Aorogya Sankul, Aurangabad Director Officer) opposite to Baba Petrol 9421958419 9404872743 Pump, Aurangabad. Dy. Director of Health Mr.Damoodar Dr. Sanjay Deputy Services, Mata Jaiswal, Dy. Shivaji Kacheri, Diksha 6 Director, 91,800 91,800 1,83,600 Lokhande Director Nagpur Bhoomi Chowk, 9422150677 7276081150 Nagpur-440 022. TOTAL 4,50,000 4,50,000 9,00,000

(Dr. R. M. Kumbhar)

General Manager-1

Haffkine Bio Pharmaceutical Corporation Ltd. (Procurement Cell), Mumbai

# Annexure A

| Specification          | Title   | Specification  |
|------------------------|---|--|
| GENERAL<br>FEATURES    | Product Description                                 | Real Time PCR (Polymerase Chain<br>Reaction) Combo Kit for Novel<br>Coronavirus (SARS-CoV-2/COVID-19)  |
|                        | Purpose   | For diagnosis/detection of novel<br>Coronavirus (SARS-CoV-2/COVID-19)<br>infection   |
| PRODUCT<br>INFORMATION | Type of Kit   | Real Time Reverse Transcription PCR<br>Kit   |
|                        | Detection Type (in-vitro)                           | Qualitative  |
|                        | Testing Principle                                   | One-step RT-PCR  |
|                        | Number of viral gene targets on which test is based | 2 or more  |
|                        | Screening Assay                                     | NA   |
|                        | Confirmatory assay                                  | NA   |
|                        | Target genes detection                              | N gene specific to SARS-CoV-2,RdRp gene specific to SARS-CoV-2,E gene for all of Sarbecovirus including SARS-CoV-2,S gene of SARS-CoV-2,ORF gene of SARS-CoV-2,Multiplex detection in single tube should have at least 2 genes of the following: E/ORF/RdRP/N/S genes of SARS-CoV-2, along with human housekeeping gene or exogenous control as the internal control. Probe for each gene should have separate dye/fluorophore so that the result fo each gene can be read individually  |
|                        | No cross reactivity                                 | Yes  |
|                        | Species Reactivity                                  | Human  |
|                        | Test compatible with                                | Upper Respiratory Specimens (Nasopharyngeal Swabs & Oropharyngeal Swabs),Lower Respiratory Specimens (Sputum),Anterior Nasal Swabs,Mid- Turbinate Nasal Swabs,Nasal Washes,Nasal Aspirates,Broncho alveolar lavage fluid (BALF),Suitable for in-vitro qualitative detection of SARS-CoV-2 nucleic acids in throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasa swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and broncho alveolar lavage fluid (BALF) from individuals who are suspected of COVID-19 |

| Specification               | Title  | Specification   |
|-----------------------------|--|---|
|                             | Result Time  | 90 - 120 minutes  |
|                             | Sensitivity  | 100   |
|                             | Specificity  | 100   |
|                             | All necessary reagents required to perform the test provided in the kit  | Yes   |
|                             | Reagent included in the kit  | Primer, Probe, enzymes, internal control, positive control and negative control   |
|                             | Type of Fluorescent Probe used for the detection   | RT-PCR Kit for detecting SARS-CoV-2 should use fluorescent probe based TaqMan chemistry with multiplex reactions in a single tube. Probes should have reporter dyes in the range of spectral separation to have compatibility with common RT-PCR machines available. Probe for each gene should have separate dye/fluorophore so that the result for each gene can be read individually |
|                             | Control provided with each pack of kit   | Internal control which validates sample quality, RNA extraction and R PCR reaction,Positive control,Negative control,Internal control which validates sample qualit   |
|                             | Compatibility with Real Time PCR System  | Open  |
|                             | Assay robust and compatible with RNA extracted using different viral RNA extraction kits available in the market   | Yes   |
|                             | Storage and transportation of kits by the supplier to the consignee  | Under cold chain strictly as per the OEM instructions   |
|                             | The cumulative time temperature indicator technology shall be used on each kit and prequalified by WHO   | Yes   |
|                             | Document detailing principle,component,methodology,validity criteria,result interpretation,cycle information,gene name,respective dye used,performance characteristic,biosafety,assay limitation,storage condition,mfg & exp date,disposal method provided | Yes   |
|                             | Original kit inserts in English should be provided with the kit  | Yes   |
| PACKAGING                   | Pack Size of the Kit   | 100 Tests or Rxn  |
| CERTIFICATIONS<br>& REPORTS | The kit approved from the statutory authority in its country of origin   | Yes   |

| Specification     | Title  | Specification   |
|-------------------|--|---|
|                   | Imported kits registered and licensed in India by DCGI & Indigenous manufactured kits licensed by the authority defined under Drugs and Cosmetics act 1940 and Medical Devices Rules, 2017 as amended till date  | Yes   |
|                   | Availability of certificate/License from the Drugs Controller General of India (DCGI) for import (in case of imported kits) and marketing of the intended item   | Yes   |
|                   | Availability of valid Drug license for the product issued from the competent authority defined under Drugs & Cosmetics Act, 1940 and Medical Devices Rules, 2017 as amended till date  | Yes   |
|                   | Drug License Number  | UP3220B000327   |
|                   | Availability of Test report of each batch of the product to prove the conformity to the declared specification   | In house Test report from the manufacturer  |
|                   | Manufacturer facility certifications   | ISO:13485 (Latest),GMP  |
|                   | Product Certifications/Approval  | Kit evaluated and validated by ICMR-<br>NIV-Pune or any other designated<br>ICMR validation institute |
|                   | Availability of performance evaluation report  | Yes   |
|                   | Submission of all required certifications, licenses, test reports and any other specific certification requirement as imposed by country of origin to the buyer at the time of bidding in case of bidding/ at the time of supply in case of direct order | Yes   |
| SHELF LIFE        | Shelf life from the date of manufacture (in months)  | 12  |
|                   | Minimum shelf life of the product at the time of delivery to the consignee   | 3/4 th of total shelf life  |
| ADVANCE<br>SAMPLE | Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding   | Yes   |



General Manager-1
Haffkine Bio Pharmaceutical Corporation Ltd.
(Procurement Cell), Mumbai