Bid Number: GEM/2020/B/705826
Dated: 10-07-2020

# Bid Document

| Bid Details | |
|---|---|
| Bid End Date/Time | 24-07-2020 13:00:00 |
| Bid Opening Date/Time | 24-07-2020 13:30:00 |
| Bid Life Cycle (From Publish Date) | 90 (Days) |
| Bid Offer Validity (From End Date) | 75 (Days) |
| Ministry/State Name | Ministry Of Health And Family Welfare |
| Department Name | Department Of Health And Family Welfare |
| Organisation Name | Hll Infra Tech Services Limited |
| Office Name | Hites |
| Total Quantity | 3000000 |
| Item Category | Real Time PCR (Polymerase Chain Reaction) Kits For Novel Coronavirus (SARS-CoV-2/COVID-19) |
| Bidder Turnover (Last 3 Years) | 1350 Lakh (s) |
| OEM Average Turnover (Last 3 Years) | 1350 Lakh (s) |
| Experience Criteria | 3 Year (s) |
| MSE Exemption for Years Of Experience and Turnover | Yes |
| Startup Exemption for Years Of Experience and Turnover | Yes |
| Document required from seller | Experience Criteria,Past Performance,Bidder Turnover,Certificate (Requested in ATC),OEM Authorization Certificate,OEM Annual Turnover<br>*In case any bidder is seeking exemption from Experience / Turnover Criteria, the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer |
| Past Performance | 10 % |
| Bid to RA enabled | No |
| Inspection Required | Yes |
| Inspection to be carried out by Buyers own empanelled agency | Yes |
| Type Of Inspection | Post Dispatch |
| Name of the Empanelled Inspection Agency/ Authority | Board of Officers |
| Estimated Bid Value | 1350000000 |

**EMD Detail**

| | |
|---|---|
| Advisory Bank | HDFC Bank |
| EMD Percentage(%) | 2.00 |
| EMD Amount | 27000000 |

**ePBG Detail**

| | |
|---|---|
| Advisory Bank | HDFC Bank |
| ePBG Percentage(%) | 5.00 |
| Duration of ePBG required (Months). | 14 |

(a). EMD EXEMPTION: The bidder seeking EMD exemption, must submit the valid supporting document for the relevant category as per GeM GTC with the bid. Under MSE category, only manufacturers for goods and Service Providers for Services are eligible for exemption from EMD. Traders are excluded from the purview of this Policy.

(b). EMD & Performance security should be in favour of Beneficiary, wherever it is applicable.

**Beneficiary:**
CEO HITES
HITES, Department of Health and Family Welfare, HLL INFRA TECH SERVICES Limited, Ministry of Health and Family Welfare
(Sanjai Kumar Agrawal)

**Splitting**

Bid splitting not applied.

1. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM {themselves or through reseller(s)} should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU / Public Listed Company for number of years as indicated in the bid document before the bid opening date. Copies of relevant contracts to be submitted along with bid in support of having supplied some quantity during each of the year. In case of bunch bids, the category of primary product having highest value should meet this criterion.
2. OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.
3. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar Category Products for 10% of bid quantity, in at least one of the last three years before the bid opening date to any Central / State Govt Organization / PSU / Public Listed Company. Copies of relevant contracts (proving supply of cumulative order quantity in any one

year) to be submitted along with bid in support of quantity supplied in the relevant year. In case of bunch bids, the category related to primary product having highest bid value should meet this criterion.

**Pre Bid Detail(s)**

| Pre-Bid Date and Time | Pre-Bid Venue |
|---|---|
| 14-07-2020 14:00:00 | Link for joining Video Conference shall be uploaded in http://hllhites.com/ |

## Real Time PCR (Polymerase Chain Reaction) Kits For Novel Coronavirus (SARS-CoV-2/COVID-19) ( 3000000 Test )

**Technical Specifications**

* As per GeM Category Specification

| Specification | Specification Name | Values | Bid Requirement (Allowed Values) |
|---|---|---|---|
| GENERAL FEATURES | **Product Description** | Real Time PCR (Polymerase Chain Reaction) Combo Kit for Novel Coronavirus (SARS-CoV-2/COVID-19) | Real Time PCR (Polymerase Chain Reaction) Combo Kit for Novel Coronavirus (SARS-CoV-2/COVID-19) |
| | Purpose | For diagnosis/detection of novel Coronavirus (SARS-CoV-2/COVID-19) infection | * |
| PRODUCT INFORMATION | Type of Kit | Real Time Reverse Transcription PCR Kit | * |
| | **Detection Type (in-vitro)** | Qualitative | Qualitative |
| | **Testing Principle** | One-step RT-PCR | One-step RT-PCR |
| | Number of viral gene targets on which test is based (Test Based on Multiplex Reaction) | 2 or more | * |
| | **Screening Assay** | NA | NA |
| | **Confirmatory assay** | NA | NA |
| | **Target genes detection** | 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 | 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 for each gene can be read individually | with human housekeeping gene or exogenous control as the internal control. Probe for each gene should have separate dye/fluorophore so that the result for each gene can be read individually |
| No cross reactivity | Yes | * |
| Species Reactivity | Human | * |
| **Test compatible with** | Suitable for in-vitro qualitative detection of SARS-CoV-2 nucleic acids in throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and broncho alveolar lavage fluid (BALF) from individuals who are suspected of COVID-19 | Suitable for in-vitro qualitative detection of SARS-CoV-2 nucleic acids in throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and broncho alveolar lavage fluid (BALF) from individuals who are suspected of COVID-19 |
| **Result Time** | 90 - 120 minutes | 90 - 120 minutes |
| **Sensitivity** | 95 | 95.0 - 100.0 Or higher |
| **Specificity** | 99 | 99.0 - 100.0 Or higher |
| 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 | Primer, Probe, enzymes, internal control, positive control and negative control |
| **Type of Fluorescent Probe used for the detection (Probes shall have reporter dyes in the range of spectral separation to have compatibility with common RT-PCR machines available)** | 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 | 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 | the result for each gene can be read individually |
| | **Control provided with each pack of kit** | Positive control,Negative control,Internal control which validates sample quality | Positive control, Negative control, Internal control which validates sample quality |
| | **Compatibility with Real Time PCR System** | Open | 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 & REPORTS | The kit approved from the statutory authority in its country of origin | Yes | * |
| | Imported kits registered and licensed in India by DCGI & Indigenous manufactured kits licensed by the | Yes | * |

| | | | |
|---|---|---|---|
| | authority defined under Drugs and Cosmetics act 1940 and Medical Devices Rules, 2017 as amended till date | | |
| | 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 | - | * |
| | 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,Test Report from NABL Accredited Lab | * |
| | Manufacturer facility certifications | ISO:13485 (Latest) | * |
| | Product Certifications/Approval | Kit evaluated and validated by ICMR-NIV-Pune or any other designated 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 | 12, 18, 24 Or higher |

| | | | |
|---|---|---|---|
| | Minimum shelf life of the product at the time of delivery to the consignee | 3/4 th of total shelf life | * |
| ADVANCE SAMPLE | Agree to provide advance sample of the product for buyer's approval before commencement of supply in case of bidding | Yes | * |

* Specifications highlighted in bold are the Golden Parameters.
* Bidders may note that In respect of non-golden Parameters, the specifications 'Values' chosen by Buyer will generally be preferred over 'Bid requirement ( allowed Values) by the Buyer.

**Additional Specification Documents**

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**Consignees/Reporting Officer and Quantity**

| S.No. | Consignee/Reporting Officer | Address | Quantity | Delivery Days |
|---|---|---|---|---|
| 1 | Arundhati Kandwal | 201307,B 14A, Sector 62, Noida | 3000000 | 30 |

# Bid Specific Additional Terms and Conditions

1. **Upload Manufacturer authorization:** Wherever Authorised Distributors are submitting the bid, Manufacturers Authorisation Form (MAF)/Certificate with OEM details such as name, designation, address, e-mail Id and Phone No. required to be furnished along with the bid.
2. Data Sheet of the product(s) offered in the bid, are to be uploaded along with the bid documents. Buyers can match and verify the Data Sheet with the product specifications offered. In case of any unexplained mismatch of technical parameters, the bid is liable for rejection.
3. The bidder is required to upload, along with the bid, all relevant certificates such as BIS licence, type test certificate, approval certificates and other certificates as prescribed in the Product Specification given in the bid document.
4. Experience Certificate for the supply of the same to any Govt/ PSU/ any renowned private organisation along with Supply/ Purchase Order.
5. For fulfilling the experience criteria any one of the following documents may be considered as valid proof for meeting the experience criteria:
   a. Purchase Order copy along with Invoice(s) with self-certification by the bidder that supplies against the invoices have been executed.
   b. Execution certificate by client with order value.
   c. Any other document in support of order execution like Third Party Inspection release note, etc.
6. Bidder Turn Over Criteria: The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the bidder is less than 3 year old, the

average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.

7. Make in india specific authorisation certificate needs to be enclosed.
8. Bid reserved for Make In India products: Procurement under this bid is reserved for purchase from Class 1 local suppliers as defined in public procurement (Preference to Make in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Nodal Ministry for specific Goods/Products. The minimum local content to qualify as a class 1 local supplier is denoted in the bid document 50%. All bidders must upload a certificate from the OEM regarding the percentage of the local content and the details of locations at which the local value addition is made along with their bid, failing which the bid is liable to be rejected. In case the bid value is more than Rs 10 Crore, the declaration relating to percentage of local content shall be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or a chartered accountant for OEMs other than companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020 . In case Buyer has selected Purchase preference to Micro and Small Enterprises clause in the bid, the same will get precedence over this clause.
9. Bidder's offer is liable to be rejected if they don't upload any of the certificates / documents sought in the Bid document, ATC and Corrigendum if any.
10. Material Test Certificate Should Be Sent Along with The Supply. The Material Will Be Checked by Buyer’s Lab & the Results of the Lab will be the Sole Criteria for Acceptance of the Item.
11. Without prejudice to Buyer’s right to price adjustment by way of discount or any other right or remedy available to Buyer, Buyer may terminate the Contract or any part thereof by a written notice to the Seller, if:
    i) The Seller fails to comply with any material term of the Contract.
    ii) The Seller informs Buyer of its inability to deliver the Material(s) or any part thereof within the stipulated Delivery Period or such inability otherwise becomes apparent.
    iii) The Seller fails to deliver the Material(s) or any part thereof within the stipulated Delivery Period and/or to replace/rectify any rejected or defective Material(s) promptly.
    iv) The Seller becomes bankrupt or goes into liquidation.
    v) The Seller makes a general assignment for the benefit of creditors.
    vi) A receiver is appointed for any substantial property owned by the Seller.
    vii) The Seller has misrepresented to Buyer, acting on which misrepresentation Buyer has placed the Purchase Order on the Seller.
12. OPTION CLAUSE: The Purchaser reserves the right to increase or decrease the quantity to be ordered up to 25 percent at the time of placement of contract. The purchaser also reserves the right to increase the ordered quantity by up to 25% of the contracted quantity during the currency of the contract at the contracted rates. Bidders are bound to accept the orders accordingly.
13. WORLD BANK TERMS AND CONDITIONS: Special Terms and Conditions as defined by world bank at click here will also be applicable. APPLICABLE ONLY IN CASE OF WORLD BANK FUNDED PROJECTS.

This Bid is also governed by the General Terms and Conditions

**---Thank You---**