

Bid Number: GEM/2020/B/695254

Dated: 02-07-2020

Bid Document

| Bid Document | | | | |
|--------------|--|--|--|--|
| Bid Details | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| imited | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| imit | | | | |

EMD Detail

| Required | No |
|----------|----|

ePBG Detail

| Required | No |
|----------|----|
|----------|----|

Splitting

Bid splitting not applied.

MSE Purchase Preference

| MCE Durchass Durchauses | Voc |
|-------------------------|-----|
| MSE Purchase Preference | res |

1. Purchase preference to Micro and Small Enterprises (MSEs): Purchase preference will be given to MSEs as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent

Orders/Notifications issued by concerned Ministry. If the bidder wants to avail the Purchase preference, the bidder must be the manufacturer of the offered product in case of bid for supply of goods. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises. In respect of bid for Services, the bidder must be the Service provider of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the offered product or service. If L-1 is not an MSE and MSE Seller (s) has/have quoted price within L-1+ 15% of margin of purchase preference /price band defined in relevant policy, such Seller shall be given opportunity to match L-1 price and contract will be awarded for percentage of 25% of total value.

HIV (ELISA) Test Kits (384 pieces)

Technical Specifications

* As per GeM Category Specification

| Specification | Specification Name | Values | Bid Requirement (Allowed Values) |
|---------------|--|--|--|
| PRODUCT | Type of Kit | 4 th generation | 4 th generation |
| INFORMATION | Detects | HIV 1 Antibodies,HIV 2 Antibodies,HIV 1 p24 Ag | HIV 1 Antibodies, HIV 2 Antibodies, HIV 1 p24 Ag |
| | Detection Type | Qualitative | Qualitative |
| | The assay should be solid phase microplate coated HIV 1 and 2 recombinant and/or synthetic peptide antigens | Yes | * |
| | Test can be performed on | Serum,Plasma | Serum, Plasma |
| | Assay Procedure Time (minutes) | 90 | * |
| | The Assay should have sensitivity of ≥ 99 point 5% and specificity of ≥ 98% | Yes | * |
| | The assay component should include reactive and non reactive control with each kit | Yes | * |
| | Storage temperature | 2°C to 8°C | * |
| | The supplier should ensure maintenance of cold chain during storage and transportation of Kits at 2°C to 8°C | Yes | * |

| I | | l., | l ste |
|------------------|--|---------------------------------------|-------|
| | Cold Chain indicator provided with the kits | Yes | * |
| | A cumulative time/temperature indicator should indicate the exposure to temperature in the range of 2°C to 8°C | Yes | * |
| | The cumulative time temperature indicator technology used should be pre qualified by WHO | Yes | * |
| | Adequate documents in english detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2, methodologies, validity criteria, performance c haracteristics, biosafety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal provided with each kit | Yes | * |
| | The Kit Should be compatible to both semi automated and fully automated Elisa analyzers | Yes | * |
| | The volume of all the chemicals used should be adequate enough for automated Elisa analyze | Yes | * |
| | The volume should cover the dead volume for automated ELISA system | Yes | * |
| | The kit should comply with all provisions of Drugs and cosmentics Act, 1940 and applicable rules there under | Yes | * |
| GENERAL FEATURES | Product Description | HIV ELISA Testing Kits | * |
| | Clinical Purpose | To provide diagnosis of HIV infection | * |

| PACKAGING | Pack Size | - | * |
|--------------------------|--|---------------------------------------|---|
| | The packing and labelling of the kit should be as per Drugs and Cosmetics Act, 1940 and applicable rules there under | Yes | * |
| CERTIFICATIONS & REPORTS | The kit should have approval of the statutory authority in its country of origin | Yes | * |
| | The Kit should be registered and licensed in India by DCGI in case of imported kits (Proof of the same to be submitted to buyer on demand) | NA for domestically manufactured kits | * |
| | Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 | Yes | * |
| | Availability of valid drug license from competent authority defined under Drugs and Cosmetics Act, 1940 (Proof of the same to be submitted to buyer on demand) | - | * |
| | Drug License Number | - | * |
| | Drug License Date | - | * |
| | Manufacturer certifications (Proof of the same to be submitted to the buyer on demand) | GMP | * |
| | GMP/ WHO GMP Certification Number | - | * |
| | GMP/ WHO GMP Certification Date | - | * |
| | ISO 13485 Certified Manufacturer (Proof of the same to be submitted to buyer on demand) | Yes | * |
| | Product Certifications (Proof of the same to | NA | * |

| | be submitted to buyer on demand) | | |
|-------------------|---|---|----|
| | Four digit number of notified body If product is EU-CE certified | - | * |
| | Certificatiion Number | - | * |
| | Certificatiion Date | - | * |
| | Certification Issuing Authority | - | * |
| | Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification(proof of the same to be submitted to the buyer on demand) | Yes | * |
| | Availability of Performance Evaluation Report (Proof of the same to be submitted to the buyer on demand) | Yes | * |
| | Performance Evaluation Report issuing body | National Insitute of Biological Sciences | * |
| | Name of the Performance Evaluation Report issuing body if other than specified institute | - | * |
| SHELF LIFE | Shelf Life from the date of manufacture (in months) | 12 | 12 |
| | The product should have atleast 3/4 of the total shelf life at the time of dispatch to the consignee | Yes | * |
| * Bidders may not | ghlighted in bold are the Golde e that In respect of non-golden be preferred over 'Bid require | Parameters, the specif | |
| Additional Specif | ication Documents | | |

Consignees/Reporting Officer and Quantity

| S.No. Consignee/Report | Address | Quantity | Delivery Days |
|------------------------|---------|----------|---------------|
|------------------------|---------|----------|---------------|

| 1 | Gyan Mal Khatik | 323303,Contracts & Material Management, Rawatbhata Rajasthan Site, Anushakti Via-Kota (Rajasthan) Phone No. 01475-242002, 242048 Which is about 60 Kms. away from Kota. | 384 | 30 |
|---|-----------------|---|-----|----|
|---|-----------------|---|-----|----|

Bid Specific Additional Terms and Conditions

- 1. Scope of supply (Bid price to include all cost components): Only supply of Goods
- 2. Purchase preference to Micro and Small Enterprises (MSEs): Purchase preference will be given to MSEs as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail the Purchase preference, the bidder must be the manufacturer of the offered product in case of bid for supply of goods. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises. In respect of bid for Services, the bidder must be the Service provider of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the offered product or service. If L-1 is not an MSE and MSE Seller (s) has/have quoted price within L-1+ 15% of margin of purchase preference /price band defined in relevant policy, such Seller shall be given opportunity to match L-1 price and contract will be awarded for percentage of 25% of total value.

This Bid is also governed by the General Terms and Conditions

---Thank You---