Bid Number: GEM/2020/B/703746
Dated: 10-07-2020

Bid Document

Bid Details	
Bid End Date/Time	20-07-2020 12:00:00
Bid Opening Date/Time	20-07-2020 12:30:00
Bid Life Cycle (From Publish Date)	90 (Days)
Bid Offer Validity (From End Date)	40 (Days)
Ministry/State Name	Ministry Of Labour And Employment
Department Name	Na
Organisation Name	Employees State Insurance Corporation (esic)
Office Name	Esic Medical College & Hospital, Gulbarga
Total Quantity	1500
Item Category	Real Time PCR (Polymerase Chain Reaction) Kits For Novel Coronavirus (SARS-CoV-2/COVID-19)
MSE Exemption for Years of Experience and Turnover	No
Startup Exemption for Years of Experience and Turnover	No
Document required from seller	Certificate (Requested in ATC) *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
Bid to RA enabled	No
Inspection Required	No

EMD Detail

Required	No

ePBG Detail

Required	No

Splitting

Bid splitting not applied.

Real Time PCR (Polymerase Chain Reaction) Kits For Novel Coronavirus (SARS-CoV-2/COVID-19) (1500 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) Kits 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	Gene specific for sub genus Sarbeco + Internal Control	*
	Confirmatory assay	One or more gene targets specific to SARS CoV-2	*
	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	*
	No cross reactivity	Yes	*
	Species Reactivity	Human	*
	Test compatible with	Upper Respiratory Specimens (Nasopharyngeal Swabs & Oropharyngeal Swabs),Lower Respiratory Specimens (Sputum)	*

Result Time	Less than 3 hours	*
Sensitivity	100	100.0 - 100.0 Or higher
Specificity	100	100.0 - 100.0 Or higher
All necessary reagents required to perform the test provided in the kit	Yes	*
Reagent included in the kit	Reagents for nucleic acid extraction from respiratory/sera specimens and Reagents for real time PCR	*
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)	TaqMan Probe	*
Control provided with each pack of kit	Internal control which validates sample quality, RNA extraction and RT PCR reaction,Positive control,Negative control	*
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 pri nciple,component,meth odology,validity criteria,result interpretation,cycle	Yes	*

	information,gene name,respective dye used,performance characteristic,biosafety,assay limitation,storage condition,mfg & exp date,disposal method provided		
	Original kit inserts in English should be provided with the kit	Yes	*
PACKAGING	Pack Size of the Kit	96 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 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	-	*
	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),GMP,WHO-GMP,GLP	*
	Product	EU-CE IVD (from	*

	Certifications/Approval	notified Body),US-FDA,Kit evaluated and validated by ICMR-NIV-Pune or equivalent institute of ICMR	
	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

Consignees/Reporting Officer and Quantity

S.No.	Consignee/Reporting Officer	Address	Quantity	Delivery Days
1	Anil Anilkumar@106	585106,SEDAM ROAD , NEAR GULBARGA UNIVERSITY GULBARGA	1500	30

Bid Specific Additional Terms and Conditions

1. Scope of supply (Bid price to include all cost components) : Only supply of Goods

This Bid is also governed by the General Terms and Conditions

---Thank You---