Bid Number: GEM/2020/B/715238
Dated: 17-07-2020

Bid Document

Bid Details	
Bid End Date/Time	20-07-2020 17:00:00
Bid Opening Date/Time	20-07-2020 17:30:00
Bid Life Cycle (From Publish Date)	90 (Days)
Bid Offer Validity (From End Date)	30 (Days)
Ministry/State Name	Ministry Of Railways
Department Name	Na
Organisation Name	Diesel Locomotive Works Varanasi
Office Name	Dlw Varanasi
Total Quantity	1000
Item Category	Rapid Antigen Test Kits for Novel Corona Virus (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	OEM Authorization Certificate *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.

Rapid Antigen Test Kits For Novel Corona Virus (SARS-CoV-2/COVID-19) (1000 Test)

Technical Specifications

* As per GeM Category Specification

Specification	Specification Name	Values	Bid Requirement (Allowed Values)
GENERAL FEATURES	Type of Kit	Rapid Antigen Test Kit for Novel Coronavirus (SARS-CoV-2/COVID-19)	*
	Purpose	For in-vitro diagnosis/detection of novel coronavirus (SARS-CoV-2/COVID-19) infection	*
PRODUCT INFORMATION	Detects	Antigen specific for SARS-CoV-2	*
	Detection Method	Qualitative	*
	Testing Principle	Lateral flow chromatographic immunoassay	*
	Species Reactivity	Human	*
	Test can be performed using	Nasopharyngeal swab,Nasal swab	*
	Result reading time	With in 10 to 30 minutes	*
	Ability to evaluate negative or positive test result	Yes	*
	Contains an internal control Line/dot/band for the confirmation that the test has been performed correctly	Yes	*
	Assay Sensitivity	84	*
	Assay Specificity	100	*
	Declared sensitivity and specificity shall be claimed by the manufacturer in the kit literature	Yes	*
	No cross reactivity	Yes	*
	Storage temperature of Kit	2 to 30° C	*
	Shipping Condition	At Room Temperature	*
KIT CONTENTS	Kit contents per test	1 Test cassette with desiccant, 1 sterile swab, 1 Extraction tube with buffer (if any) and 1 nozzle cap/dropper	*
	Type of Swab provided	Nasopharyngeal swab	*
	Material of Swab	Synthetic fibre swab (nylon, polyester, rayon, or dacron) with plastic shafts or wire shaft (flexible shaft)	*
	All the components shall be in the quantity as per pack size	Yes	*
	Adequate document in English detailing principle, components, methodologies, validity criteria, interpretation of result, performance characteristic, bio-safety, limitation of assay, storage	Yes	*

	condition, mfg and exp date & method of disposal provided		
	Positive and negative controls provided with each pack of kit	No	*
INTERPRETATION OF RESULTS	Reading of results	Visually	*
	For all the samples tested, the control line shall be visible at the end of the test	Yes	*
	Test will be regarded as invalid if the control line is not visible at the end of the test	Yes	*
	Test will be regarded as positive If test line is visible along with the control line	Yes	*
PACKAGING	Pack size of the kit	25 Tests	*
	The test kit packed in such a way that there is proivision to conduct single test at a time	Yes	*
	Packing of test cassette	Each test cassette with desiccant individually packed in a hermetically sealed and non-permeable pouch	*
	Packing of Swab	Each swab individually packed in easy to open peel pouches	*
ADDITIONAL REQUIREMENT	Additional Requirement	NA	*
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	-	*

	Product certifications/approvals	Kit evaluated and validated by ICMR-NIV-Pune or any other ICMR validation centres,EU-CE IVD (From Notified Body)	*
	Manufacturer facility certifications	ISO:13485 (Latest)	*
	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	*
	Availability of validation report	Yes	*
	Submission of all required certifications, license , 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**	24	12, 18, 24 Or higher
	Minimum shelf life of the product at the time of delivery to the consignee	3/4 of the 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	No	*

* 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	Rajiv Ranjan Kumar	221004,OFFICE OF PCMM DLW VARANASI	1000	15

Bid Specific Additional Terms and Conditions

1. Scope of supply (Bid price to include all cost components) : Only supply of Goods
2. To be eligible for award of contract, Bidder / OEM must possess following Certificates / Test Reports on the date of bid opening (to be uploaded with bid): offer from OEM or seller having Bid Specific authorization from OEM m/s SD BioSensor Ltd will be accepted.
3. **Nominated Inspection Agency:** On behalf of the Buyer organization, any one of the following Inspection Agency would be conducting inspection of stores before acceptance:
   Pre-dispatch Inspection at Seller Premises (applicable only if pre-dispatch inspection clause has been selected in ATC): NA
   Post Receipt Inspection at consignee site before acceptance of stores: By DMO after receipt of material

This Bid is also governed by the General Terms and Conditions

---Thank You---