RA Number: GEM/2020/RA/45542
Dated: 18-07-2020

RA Document

RA Details	
RA Technical End Date/Time	21-07-2020 12:00:00
RA Opening Date/Time	21-07-2020 12:30:00
RA Life Cycle (From Publish Date)	90 (Days)
RA Offer Validity (From End Date)	60 (Days)
Ministry/State Name	Ministry Of Railways
Department Name	Na
Organisation Name	N/a
Office Name	Office Of The Principal Chief Materials Manager, East Coast Railway, North Block, 2nd Floor, Chandrasekharpur, Bhubaneswar-751017.
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
Inspection Required	No

EMD Detail

Required	No

ePBG Detail

Required	No

Splitting

RA 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	*
	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 condition, mfg and exp date & method of disposal provided	Yes	*
	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	Additional Requirement	NA	*

REQUIREMENT			
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	Yes	*

	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		
SHELF LIFE	**Shelf life from the date of manufacture**	24	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

Consignee/Reporting Officer and Quantity

S.No.	Consignee/Reporting Officer	Address	Quantity	Delivery Days	
1	Mogilipuri Mahesh Kumar	530016,Office of the Chief Medical Superintendent, Station Road, DRM Office, Maharajupeta, Dondaparthy, Visakhapatanam-530016	1000	15	

Bid Specific Additional Terms and Conditions

1. 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.
2. **Registration / Empanelment Requirement:** Contract shall be awarded to only such sellers , who are registered / empanelled / approved / enlisted with ICMR GUIDELINES DT. 23.06.20 APPLICABLE for the required goods / service category on the date of bid opening. Prospective bidders (if not already registered), are advised to get themselves registered with the said registration authority before bid opening date. (It is certified that the registration is granted by the registering agency as per Rule 150 of GFR following a fair, transparent and reasonable procedure.)
3. Scope of supply (Bid price to include all cost components) : Only supply of Goods

This RA is also governed by the General Terms and Conditions

---Thank You---