

### Bid Document

Bid Details	
Bid End Date/Time	21-07-2020 14:00:00
Bid Opening Date/Time	21-07-2020 14:30:00
Bid Life Cycle (From Publish Date)	90 (Days)
Bid Offer Validity (From End Date)	30 (Days)
Ministry/State Name	Ministry Of Health And Family Welfare
Department Name	Department Of Health And Family Welfare
Organisation Name	N/a
Office Name	Dr. Ram Manohar Lohia Hospital, New Delhi
Total Quantity	2000
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
Bid to RA enabled	No
Inspection Required	No

#### EMD Detail

Required	No
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#### ePBG Detail

Required	No
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#### Splitting

Bid splitting not applied.

### Rapid Antigen Test Kits For Novel Corona Virus (SARS-CoV-2/COVID-19) ( 2000 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	No	*

	controls provided with each pack of kit		
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 provision 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	<b>Shelf life from the date of manufacture</b>	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

#### Consignees/Reporting Officer and Quantity

S.No.	Consignee/Reporting Officer	Address	Quantity	Delivery Days
1	Deepak Singh	110001,dr. ram manohar lohia hospital baba khark singh marg new delhi	2000	7

#### 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---