Bid Number: GEM/2020/B/716508 Dated: 18-07-2020



Bid Document

Bid Document				
Bid Details				
21-07-2020 17:00:00				
21-07-2020 17:30:00				
90 (Days)				
45 (Days)				
Ministry Of Home Affairs				
Central Armed Police Forces				
Indo Tibetan Border Police (itbp)				
Commandant 49 Bn Itbp Basar				
500				
Rapid Antigen Test Kits for Novel Corona Virus (SARS-CoV-2/COVID-19)				
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) (500 Test) Technical Specifications

* As per GeM Category Specification

Specification	Specification Name		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 condition, mfg and exp date & method of disposal provided Positive and negative	Yes	*

	controls provided with each pack of kit		
INTERPRETATION OF	Reading of results	Visually	*
RESULTS	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	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.

Additional Specification Documents

Consignees/Reporting Officer and Quantity

S.No.	Consignee/Reporting Officer	Address	Quantity	Delivery Days
1	Pabitra Deori	787059,LO Transit camp 49th Bn I.T.B.Police Likhabali C/O Post Box No - 01 Post Master Silapather, Dhemaji, 787059	500	10

Bid Specific Additional Terms and Conditions

- 1.Scope of supply (Bid price to include all cost components) : Only supply of Goods
- 2.IMPORTED PRODUCTS: In case of imported products, OEM or Authorized Seller of OEM should have a registered office in India to provide after sales service support in India. The certificate to this effect should be submitted.

This Bid is also governed by the General Terms and Conditions

---Thank You---

^{*} 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.