

Bid Number: GEM/2020/B/707149

Dated: 11-07-2020

Bid Document

:
ds Limited
st Kit (RA Test Kit)

EMD Detail

Required	No

ePBG Detail

Required	No

Splitting

Bid splitting not applied.

Rheumatoid Factor Test Kit (RA Test Kit) (100 Test)

Technical Specifications

* As per GeM Category Specification

Specification	Specification Name	Values	Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	Rheumatoid Factor Test Kit (RA Test Kit)	*
	Purpose	For detection of Rheumatoid factor in patients	*
PRODUCT INFORMATION	Result Type	Qualitative	Qualitative, Semi- Quantitative, Quantitative
	Species Reactivity	Human	*
	Sample Type Required	Serum	Serum, Plasma, Whole Blood
	Testing principle	Latex Agglutination Slide Method	Latex Agglutination Slide Method, Immuno Turbidimetric Method
	Sensitivity	≥ 98%	*
	Specificity	≥ 98%	*
	Result Time	Less than 3 minutes	*
	Storage temperature of reagents	-	*
	The supplier shall ensure maintenance of recommended temperature during transportation of kit at the final destination	Yes	*
	The kit supplied complete with all necessary accessories required for the test	Yes	*
	Cold Chain indicator to be provided with the kit	Yes	*
KIT CONTENTS	RF Latex Reagent	Yes	*
	Positive Control	Yes	Yes, Not required for immuno turbidimetric method
	Negative Control	Yes	Yes, Not required for immuno turbidimetric method
	Slide	Yes	Yes, Not required for immuno turbidimetric method
	Applicator sticks	Yes	Yes, Not required for immuno turbidimetric method

	Calibrator provided	Yes	Yes, Not required for agglutination slide method
	Adequate literature detailing the components, methodologies, validity criteria, storage conditions, expiry date and limitations of test provided	Yes	*
PACKAGING	Pack Size	-	*
CERTIFICATIONS & REPORTS	Kit approved from the statutory authority in its country of origin	Yes	*
	Imported Kits registered and licensed in India by DCGI	NA for indigenous manufactured Kits	*
	Indigenous manufacturers licensed by the competent authority defined under Drugs and Cosmetics Act, 1940 and Rules, 1945 after appropriate evaluation by the centers approved by DCGI	Yes	*
	Availability of valid drug license for the product issued from competent authority defined under Drugs and Cosmetics Act, 1940 and Rules, 1945 (Manufacture for sale license in case of authorized reseller)	Yes	*
	Drug license number	-	*
	Manufacturer certifications	-	*
	Product certifications	NA	*
	Four digit number of notified body If product is EU-CE certified	-	*
	Availability of Test report of each batch to be supplied from central GOVT/NABL/ILAC	Yes	*

	accredited Lab as well inhouse test report from manufacturer to prove conformity to the declared specifications		
	Submission of all necessary certifications, licenses and test reports to the buyer along with supplies	Yes	*
SHELF LIFE	Shelf life from the date of manufacture	24	12, 18, 24 Or higher
	The product should have atleast 3/4 of the total shelf life at the time of delivery to the consignee	Yes	*
ADVANCE SAMPLE	Agree to provide advance sample of the Kit for buyer's approval before commencement of bulk supply	Yes	*

^{*} Specifications highlighted in bold are the Golden Parameters.

Additional Specification Documents

Consignees/Reporting Officer and Quantity

S.No.	Consignee/Reporti ng Officer	Address	Quantity	Delivery Days
1	Sadaf .	484116,REGIONAL STORE, SOHAGPUR AREA, POST- AMLAI, BEHIND AMLAI POLICE STATION.	100	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---

^{*} 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.