Bid Number: GEM/2020/B/707175
Dated: 11-07-2020

Bid Document

Bid Details	
Bid End Date/Time	21-07-2020 21:00:00
Bid Opening Date/Time	21-07-2020 21:30:00
Bid Life Cycle (From Publish Date)	90 (Days)
Bid Offer Validity (From End Date)	75 (Days)
Ministry/State Name	Ministry Of Coal
Department Name	Materials Management
Organisation Name	South Eastern Coalfields Limited
Office Name	Secl Bilaspur Cg
Total Quantity	500
Item Category	Point of Care Diagnostic Test Kit- Syphilis Rapid Test Kits
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

ePBG Detail

Required	No

Splitting

Bid splitting not applied.

Point Of Care Diagnostic Test Kit- Syphilis Rapid Test Kits (500 Test)

Technical Specifications

* As per GeM Category Specification

Specification	Specification Name	Values	Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	Point of Care Diagnostic Test Kit-Syphilis Rapid Test Kits	*
	Clinical Purpose	For diagnosis of syphilis in all stages of infection by detecting antibodies to Treponema Pallidum	*
PRODUCT INFORMATION	**Result Type**	Qualitative	Qualitative, Quantitative
	Detects	Total anti-treponemal antibody (IgG,IgM & IgA)	*
	The assay shall have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens	Yes	*
	Testing Principle	Lateral flow chromatographic immunoassay	*
	Specimen required for testing	Whole Blood,Serum,Plasma	Whole Blood, Serum, Plasma
	Result Time	Less than 30 minutes	*
	Sensitivity	≥ 99 %	≥ 90 %, ≥ 95 %, ≥ 99 %
	Specificity	≥ 99 %	≥ 90 %, ≥ 95 %, ≥ 99 %
	Contains an internal control line for the confirmation that the test has been performed correctly	Yes	*
	The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer	Yes	*
	Storage temperature	-	*
	The supplier shall ensure maintenance of cold chain during storage and transportation of Kit at	Yes	*

	recommended temperature		
	Cold chain indicator to be provided	Yes	*
KIT CONTENTS	**Main item in test kit for performing the test**	Card	Card, Dip Strip
	Desiccant to absorb moisture so that the Card/strip do not get spoiled provided	Yes	*
	Disposable sample dropper/capillary pipette for collection of blood sample and transfer the sample to the test site provided with each card/strip	Yes	*
	Sample Diluent/Assay Buffer Provided	Not required	*
	Reactive and non reactive controls provided (minimum 10% of Pack size)	Yes	*
	Each test card/strip supplied with sterile auto retractable disposable lancet	Yes	*
	Each test card/strip supplied with alcohol soaked swabs	Yes	*
	Adequate literature in English detailing principle, components, methodologies, validity criteria, bio- safety, performance characteristics, storage conditions, limitation of assay, manufacture and expiry dates and methods of disposal to be provided	Yes	*
PACKAGING	Pack Size	-	*
	The test kit packed in such a way that there is proivision to conduct single test at a time	Yes	*
	Each test card/strip indivdually packed in a hermetically sealed	Yes	*

	and non-permeable pouch		
CERTIFICATIONS & REPORTS	Kit approved from the statutory authority in its country of origin	Yes	*
	Imported Kits registered and licensed in India by Central Drugs Standard Control Organization (CDSCO)	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 Central Drugs Standard Control Organization (CDSCO)	NA for imported Kits	*
	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 OEM or 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 accredited Lab as well inhouse test report from manufacturer to prove conformity to the declared specifications	Yes	*
	Kit evaluated from National Institute of	Yes	*

	Biologicals (NIB)		
	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**	18	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.
* 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	Sadaf .	484116,REGIONAL STORE, SOHAGPUR AREA, POST-AMLAI, BEHIND AMLAI POLICE STATION.	500	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---