Bid Number: GEM/2020/B/707176
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 Kits - Hepatitis C Virus (HCV) 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 Kits - Hepatitis C Virus (HCV) Rapid Test Kits (500 pieces)

Technical Specifications

* As per GeM Category Specification

Specification	Specification Name	Values	Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	Hepatitis C Virus (HCV) Rapid Test Kit	*
	Clinical Purpose	To provide diagnosis of Hepatitis C Virus infection	*
PRODUCT INFORMATION	Detects	Antibodies specific to Hepatitis C Virus	*
	Type of Kit	3rd Generation	3rd Generation, 4th Generation
	Should be solid phase / particle coated with recombinant and / or synthetic peptide antigens for Core, NS3, NS 4, and NS5	Yes	*
	Test can be performed on	Serum,Plasma	Whole Blood, Serum, Plasma
	Type of Test	Qualitative	Qualitative, Quantitative
	Testing Principle	Lateral flow chromatographic immunoassay	Lateral flow chromatographic immunoassay, immunofiltration
	Result Time (minutes)	10-20	*
	Ability to Evaluate Negative or Positive test result	Yes	*
	Sensitivity (%)	-	*
	Specificity (%)	-	*
	Contains an internal control line/dot for the confirmation that the test has been performed correctly	Yes	*
	Storage temperature	2°C to 30°C	*
	The supplier should ensure maintenance of recommended temperature during storage and transportation of Kit	Yes	*
	The kit should comply with all provisions of	Yes	*

	Drugs and cosmentics Act, 1940 and applicable rules there under		
KIT CONTENTS	**Main items in test kit for performing the test**	Card	Card, Strip
	Sample Dropper Provided with each card/strip	Yes	*
	Dessicant to absorb moisture so that the Card/Strip do not get spoiled provided with each card	Yes	*
	Sample Diluent/Assay Buffer Provided	Yes	*
	Packaging insert in English detailing the principle, components, methodologies, validity criteria, performance c haracteristics,bio-safety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal Provided with each kit	Yes	*
	Reactive and non reactive controls provided with each kit in adequate volume (minimum 10% of pack size)	Yes	Yes, No
	Individualy packed sterile disposable lancets and disposable alcohol swabs provided with each test kit	No	Yes, No
	Other accessories and spares provided if any for standard pack in the kit	-	*
PACKAGING	Pack Size	-	*
	The packing and labelling should be as per Drugs and Cosmetics Act, 1940 and applicable rules	Yes	*

	there under		
	Each card (cassette) should have space for patients particulars and date of the test	Yes	*
	The test kit should be packed in such a way that there is proivision to conduct single test at a time	Yes	*
	Each test kit should be indivdually packed in a hermetically sealed and non-permeable pouch	Yes	*
CERTIFICATIONS & REPORTS	The kit should have approval of the statutory authority in its country of origin	Yes	*
	The Kit should be registered and licensed in India by DCGI in case of imported kits (Proof of the same to be submitted to buyer on demand)	-	*
	Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics act 1940	-	*
	Availability of valid drug license from competent authority defined under Drugs and Cosmetics Act, 1940 (Proof of the same to be submitted to buyer on demand)	-	*
	Drug License Number	-	*
	Drug License Date	-	*
	Manufacturer certifications (Proof of the same to be submitted to the buyer on demand)	GMP	*
	GMP/ WHO GMP Certification Number	-	*
	GMP/ WHO GMP	-	*

	Certification Date		
	ISO 13485 Certified Manufacturer (Proof of the same to be submitted to buyer on demand)	Yes	*
	Product Certifications (Proof of the same to be submitted to buyer on demand)	EU-CE (IVD)	*
	Four digit number of notified body If product is EU-CE certified	-	*
	Certificatiion Number	-	*
	Certificatiion Date	-	*
	Certification Issuing Authority	-	*
	Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification(proof of the same to be submitted to the buyer on demand)	Yes	*
	Availability of Performance Evaluation Report (Proof of the same to be submitted to the buyer on demand)	Yes	*
	Performance Evaluation Report issuing body	Any other govt approved lab	*
	Name of the Performance Evaluation Report issuing body if other than specified institute	-	*
SHELF LIFE	**Shelf Life (in months)**	24	24, 30, 36, 12, 18 Or higher
	The product should not have passed more than 1/6 of the total shelf life at the time of dispatch to the consignee	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---