Bid Number: GEM/2020/B/707167
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)	30 (Days)
Ministry/State Name	Ministry Of Coal
Department Name	Materials Management
Organisation Name	South Eastern Coalfields Limited
Office Name	Secl Bilaspur Cg
Total Quantity	300
Item Category	Point of Care Diagnostic Test Kit - Dengue 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 - Dengue Rapid Test Kits (300 pieces)

Technical Specifications

[* As per GeM Category Specification]

Specification	Specification Name	Values	Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	Dengue Rapid Test Kit	*
	Clinical Purpose	To provide early diagnosis of acute dengue infection	*
PRODUCT INFORMATION	**Detects**	IgM + IgG Antibodies to Dengue Virus,NS1 Ag to Dengue Virus from Day 1 of fever	IgM + IgG Antibodies to Dengue Virus, NS1 Ag to Dengue Virus from Day 1 of fever
	Type of Test	Qualitative	*
	Testing Principle	Lateral flow chromatographic immunoassay	*
	Kit should be able to detect all the 4 serotypes of dengue viruses (DEN-1, DEN-2, DEN-3, and DEN-4)	Yes	*
	The test should be able to differentially detect IgG and IgM Antibodies against all 4 serotypes of Dengue virus	Yes	*
	Test should be able to give a presumptive differentiation between primary & secondary dengue infections"	Yes	*
	Test should have no cross reactivity with other Flavivirus group mediated and mosquitoes-borne disease	Yes	*
	Specimen required for testing	Serum,Plasma	*
	Result Time (min)	10-20	*
	Ability to Evaluate Negative or Positive test result	Yes	*
	Sensitivity for Dengue NS1 Ag (%)	≥ 95%	*
	Specificity for Dengue NS1 Ag (%)	≥ 99%	*
	Sensitivity for Dengue IgM/IgG Antibody (%)	≥ 94%	*

	Specificity for Dengue IgM/IgG Antibody (%)	≥ 96%	*
	Contains an internal control line for the confirmation that the test has been performed correctly	Yes	*
	Storage temperature	2°Cto 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 Drugs and cosmentics Act, 1940 and applicable rules there under	Yes	*
KIT CONTENTS	Main item in test kit for performing the test	Card	*
	Sample Dropper Provided with each card	Yes	*
	Dessicant to absorb moisture so that the Card 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	10 Tests Pack	*
	The packing and labelling should be as per Drugs and Cosmetics Act, 1940 and applicable rules there under	Yes	*
	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)	Yes	*
	Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics act 1940	Yes	*
	Availability of valid drug license from competent authority	For sale or distribution	*

	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,WHO GMP,NA	*
	GMP/ WHO GMP Certification Number	-	*
	GMP/ WHO GMP Certification Date	-	*
	ISO 13485/ ICMED 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	-	*
	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 institutes	-	*

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.	300	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---