Bid Number: GEM/2020/B/707170
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	96
Item Category	HIV (ELISA) 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.

HIV (ELISA) Test Kits (96 pieces)

Technical Specifications

[* As per GeM Category Specification]

Specification	Specification Name	Values	Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Type of Kit**	4 th generation	3 rd generation, 4 th generation
	Detects	HIV 1 Antibodies,HIV 2 Antibodies,HIV 1 p24 Ag	HIV 1 Antibodies, HIV 2 Antibodies, HIV 1 p24 Ag
	Detection Type	Quantitative	Qualitative, Quantitative
	The assay should be solid phase microplate coated HIV 1 and 2 recombinant and/or synthetic peptide antigens	Yes	*
	Test can be performed on	Serum,Plasma	Whole Blood, Serum, Plasma
	Assay Procedure Time (minutes)	90	*
	The Assay should have sensitivity of ≥ 99 point 5% and specificity of ≥ 98%	Yes	*
	The assay component should include reactive and non reactive control with each kit	Yes	*
	Storage temperature	2°C to 8°C	*
	The supplier should ensure maintenance of cold chain during storage and transportation of Kits at 2°C to 8°C	Yes	*
	Cold Chain indicator provided with the kits	Yes	*
	A cumulative time/temperature indicator should indicate the exposure to temperature in the range of 2°C to 8°C	Yes	*
	The cumulative time temperature indicator technology used should be pre qualified by WHO	Yes	*

	Adequate documents in english detailing the principle, components, details of antigen for antibody detection of HIV 1 and 2, 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	*
	The Kit Should be compatible to both semi automated and fully automated Elisa analyzers	Yes	*
	The volume of all the chemicals used should be adequate enough for automated Elisa analyze	Yes	*
	The volume should cover the dead volume for automated ELISA system	Yes	*
	The kit should comply with all provisions of Drugs and cosmentics Act, 1940 and applicable rules there under	Yes	*
GENERAL FEATURES	Product Description	HIV ELISA Testing Kits	*
	Clinical Purpose	To provide diagnosis of HIV infection	*
PACKAGING	Pack Size	-	*
	The packing and labelling of the kit should be as per Drugs and Cosmetics Act, 1940 and applicable rules there under	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	Yes	*

	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	Yes	*
	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)	US-FDA	*
	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	Yes	*

	accredited Lab to prove the conformity to the declared specification(proof of the same to be submitted to the buyer on demand)		
	Availability of Performance Evaluation Report (Proof of the same to be submitted to the buyer on demand)	Yes	*
	Performance Evaluation Report issuing body	National Insitute of Biological Sciences	*
	Name of the Performance Evaluation Report issuing body if other than specified institute	-	*
SHELF LIFE	**Shelf Life from the date of manufacture (in months)**	24	24, 36, 12, 18, 30
	The product should have atleast 3/4 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.	96	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---