

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	Sec1 Bilaspur Cg
Total Quantity	500
Item Category	Point of Care Diagnostic Test Kits - HIV 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
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ePBG Detail

Required	No
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Splitting

Bid splitting not applied.

Point Of Care Diagnostic Test Kits - HIV Rapid Test Kits (500 pieces)

Technical Specifications

* As per GeM Category Specification

Specification	Specification Name	Values	Bid Requirement (Allowed Values)
GENERAL FEATURES	Product Description	HIV Rapid Test Kit	*
	Clinical Purpose	To provide diagnosis of HIV infection	*
PRODUCT INFORMATION	Detects	HIV 1 Antibodies,HIV 2 Antibodies	HIV 1 Antibodies, HIV 2 Antibodies, HIV 1 p24 Ag
	The assay should have solid phase/ particles coated HIV 1 and 2 recombinant and/or synthetic peptide antigens	Yes	*
	Test can be performed on	Whole Blood,Serum,Plasma	Whole Blood, Serum, Plasma
	Type of Test	Qualitative	Qualitative, Quantitative
	Testing Principle	Immuno Chromatographic	Agglutination, Enzyme Immuno Assay, Immuno Chromatographic, Immuno concentration
	Result Time (minutes)	5-10	*
	Ability to Evaluate Negative or Positive test result	Yes	*
	The Assay should have sensitivity of > 99 point 5% and specificity of > 98%	Yes	*
	Contains an internal control band/dot for the confirmation that the test has been performed correctly	Yes	*
	The control dot/band should be able to detect the presence of human immunoglobulins and should not be just a "procedural control" or meant for merely checking the flow or reagents or integrity of the antigen except in kits using "lateral flow (Immunocytoflow) or	Yes	*

	flow through (Immunoconcentration) " technology		
	Storage temperature	2°C to 8°C	*
	The supplier should ensure maintenance of recommended temperature during storage and transportation of Kits The Cumulative time temperature indicator technology used should be pre qualified by WHO	Yes	*
	The kit should comply with all provisions of Drugs and cosmetics Act, 1940 and applicable rules there under	Yes	*
KIT CONTENTS	Main items in test kit for performing the test	Card	*
	Sample Dropper Provided with each card/device	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, details of antigen for antibody detection of HIV 1 and 2, methodologies, validity criteria, performance characteristics, bio-safety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal provided with each kit	Yes	*
	Provided with HIV positive and negative serum controls sufficient	Yes	Yes, No

	for conducting 20% of the tests (10 % negative and 10 % positive controls)		
	Individually 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	50 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 provision to conduct single test at a time	Yes	*
	Each test kit should be individually 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	Yes	*

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)	For sale or distribution	*
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 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	Yes	*

	demand)		
	Performance Evaluation Report issuing body	National Institute of Biological Sciences	*
	Name of the Performance Evaluation Report issuing body if other than specified institute	-	*
SHELF LIFE	Shelf Life (in months)	18	12, 18, 24, 30, 36
	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---