



**OFFICE OF THE DISTRICT MEDICAL OFFICER (MS) CUM  
SUPERINTENDENT**

**DIST. HEAD QUARTERS HOSPITAL KORAPUT at JEYPORE-764001**

**(An ISO 9001:2008 Certified Hospital) Certificate No.9624**

**Email - dhhkptjeypore@gmail.com**



Advt. No. 2140/21

Date: 29/10/2021

**TENDER NOTICE**

Sealed Tenders in prescribed format are invited from the Manufacturers/ Authorized Distributors for supply of Laboratory Reagents, Laboratory Consumables for District Head Quarter Hospital, Koraput at jeypore.

The Bidders should submit two separate sealed packets i.e. one for Technical Bid and another for Financial Bid to be super scribed on the cover of the packets separately and to be kept in a single cover which should be super scribed as Tender for Laboratory reagents and Consumables for District head Quarter Hospital, Koraput at jeypore. The list of all the items with detail specification, eligibility criteria and Tender Terms and Conditions may be downloaded from District website [www.koraput.nic.in](http://www.koraput.nic.in).

The sealed Tender will be received through Speed Post/ Reg. Post/ Quorier only on or before 24.11.2021 till 05.00pm by DMO (Ms ) Cum superintendent ,DHH Koraput at Jeypore and the said tender will be opened on 25.11.2021at 12.00pm in presence of Bidders or their Authorized Representatives in the office of DMO (Ms ) Cum superintendent ,DHH Koraput at Jeypore and absence of any of them will not be bar to open the quotation. Tenders received incomplete or after the scheduled date & time shall be rejected.

Rate should be quoted for each item in F.O.R destination including all incidental charges, GST.

The undersigned has reserve right to reject any or all tenders without assigning any reason thereof. All legal disputes if any relating to the quotations are subject to Jurisdiction in the Court of Law situated at Jeypore, Koraput, Odisha only.

*[Handwritten Signature]*  
DMO-(MS) Cum Superintendent  
DHH, Koraput, at Jeypore

**TENDER DOCUMENT FOR SUPPLY OF LABORATORY ITEMS  
(REAGENTS, CHEMICALS, RAPID DIAGNOSTIC KITS &  
CONSUMABLES ECT.) FOR THE YEAR OF**

**DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore  
(HEALTH & F.W.DEPTT., GOVT. OF ODISHA)**

**DATE OF COMMENCEMENT OF THE BID DOCUMENT :**

**PRE-BID DATE AND TIME:**

**LAST DATE & TIME OF RECEIPT OF BID DOCUMENT:** 24/11/2021, 05.00 PM

**DATE & TIME OF OPENING OF COVER-A ( Technical Bid):** 25/11/2021, 12.00 PM

**DATE OF OPENING OF COVER-B (Price Bid):** Will be notified later on.

**PLACE OF OPENING OF BID DOCUMENT  
AND  
ADDRESS FOR COMMUNICATION  
AND  
RECEIPT OF BID DOCUMENT:**

**Office Chamber,  
DMO-(MS)-cum-Superintendent,  
DHH Koraput at Jeypore**

**Tel:**

**06852-295678**

**Email:-**

**[dhhkptjeypore@gmail.com](mailto:dhhkptjeypore@gmail.com)**

**DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore.**

## **NOTICE INVITING BID DOCUMENT**

Sealed tenders are invited from different bidders having valid GST registration & PAN certificate for supply of laboratory Items (Reagents, Chemicals, Rapid Diagnostic Kits & Consumables Etc.) as per the specification given by DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore.

The Bidders download the tender Document directly from the WEBSITE available at [www.koraput.nic.in](http://www.koraput.nic.in). The tender cost fee of Rs.1000/- (Onethousand) only the EMD cost for the tender will be Rs.10000/- (Ten Thousand) only by Demand Draft drawn in favors DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore should be enclosed along –with the Technical Bid. The Bidders should specifically super scribe, **“DOWNLOADED FROM THE WEBSITE”** on the top left corner of the outer envelope containing Technical Bid and Price Bid separately. The Tender cost fee and the EMD amount should be submitted separately and clarification, responsibility lies with the bidders to collect the same from the district website. The DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore shall have no responsibility for any delay/omission on part of the bidder.

Price of bid document: Rs.2000.00(Non-refundable)

**The tender paper will be rejected if the bidder changes any clause or Annexure of the bid document downloaded from the website.**

## SECTION – 1

### **TERMS AND CONDITION FOR SUPPLY OF LABORATORY ITEMS (REAGENTS, CHEMICALS, RAPID DIAGNOSTIC KIT & CONSUMABLES Etc.)**

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1.1 Sealed tenders will be received by date.24.11.2021 Up to 05.00 P.M by the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore in the office of the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore for the purchase of laboratory Items ( reagents, Chemicals, Rapid Diagnostic Kits & Consumables etc. ). Any tender received after the due date & time will be rejected/ return to the sender unopened. **The tender will be received through Regd. Post/Courier services/ Speed Post only.**

**The bidder(s) are to submit their tenders in separate sealed covered envelops for technical bid and price bid by super scribing Cover “ A “ ( Technical Bid ) & Cover “ B “ ( price Bid) and both the sealed covers should be put into a third outer Cover, which should be super scribed as “ TENDER FOR SUPPLY OF LABORATORY ITEMS ( REAGENTS, CHEMICALS, RAPID DIAGNOSTIC KITS & CONSUMABLES ECT.)” to the Office of the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore, Odisha “ & Tender reference No..... DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore .**

1.2 The Sealed tenders “Cover “ A “ ( Technical Bid ) submitted by the tenders will be opened by the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore in the office chamber of the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore .The tenderer or their duly authorized representatives are allowed to be present during the opening of the tenders if they so like.

1.3 The undersigned shall have the right for rejection all or any of the tender without assigning any reason thereof.

1.4 All communication will be through official e-mail. No other method of communication will be followed.

## ELIGIBILITY CRITERIA

2.1 MANUFACTURING UNITS/Authorized Distributer/Suppliers are eligible to participate in the tender provided, they have

- i. Valid Manufacturing license of the manufacture for manufacturing unit & valid Authorization Certificate for Authorized distributor.
- ii. Manufacture shall have valid GMP Certificate (as applicable).
- iii. Proof of Average annual turnover of the manufacturing firm/Authorised Distributer/Supplier of Rs.0.5 Core or more in last three (3) financial years.i.e.,2018-19,2019-20 & 2020-21.
- iv. Bidder must be registered under GST Act.
- v. Bidder / Manufacturing/Supplier unit who has been blacklisted either by the Tender inviting authority or by any state Govt. Or Central Govt. Organization are not eligible to participate in the tender for that item during the period of blacklisting.
- vi. The manufacturer should be ISO/NABL certified.

2.2 Authorized distributors/Supplier are eligible to participate in the tender provided:

- i. They submit manufacturer's authorization and power of attorney to transact business on behalf of the manufacturer as per the format at **Annexure- V**. The authorized distributor may raise bill, if specially authorized by the manufacturer.
- ii. The authorized distributor/ Suppliers will submit the entire document in **Support of eligibility of the manufacturer** as mentioned in clause No. 2.1 along with the tender.

The following documents should be enclosed in Cover "A" (technical Bid) by the tenderer. All the Photocopies are to be self – attested.

## TECHNICAL BID:

- 3.1 Checklist with details of the documents enclosed in **Cover "A"** (as per **Annexure – I**) with page number. The document should be **serially arranged** as per this **Annexure – I** and should be securely tied and bound.

- 3.2 list of item (s) Quoted with name of the Manufacture. (Annexure - II)
- 3.3 Tender document free of Rs. 2000/- in shape of Demand Draft payable to SBI Jeypore (Bazar Branch).
- 3.4 Earnest Money Deposit of Rs.20, 000/- in shape of Demand Draft payable to SBI Jeypore (Bazar Branch).
- 3.5 Details name, Address, telephone no., Fax, e-mail of the manufacturer / authorized distributor/Supplier (Annexure – III).
- 3.6 The declaration from in Annexure – IV duly signed by the tenderer before Notary Public / Executive magistrate.
- 3.7 manufacturer's Authorization format in Annexure – V (In case the bidder is not the manufacturer)
- 3.8 Certificate duly filled by the Auditor/ Chartered Accountant ( as per Annexure – VI ) that the average annual turnover of the manufacturing firm is Rs.0.5 Crore or more in the last 3 ( here ) financial years.
- 3.10 Copy of ISO / NABL certificate of manufacturer.
- 3.11 Copy of valid GMP Certificate of Manufacturer (as applicable.)
- 3.12 Copy of Valid manufacturing License of the manufacturer (As mention in clause no. 2.1(i).
- 3.13 Copy of valid GST registration certificate
- 3.14 Copy of PAN Card.
- 3.15 Required Diagnostic Reagent, Chemicals, Kits and Consumables ect. Along with the Quality standards and general description of the products is listed in **SPECIFICATION** which should be meticulously followed by the Tenderer.
- 3.16 The Original Tender Book with Conditions and the schedules signed by the tenderer at the bottom of each page with his official seal duly affixed.

### **Sample Verification of the Items(s):**

Sample verification of the item is a part of the technical evaluation. before opening of the Price Bid, the sample of the item ( s ) submitted by the technically qualified bidders ( based on document submitted) shall be verified by the Tender committee in order to verify the quality standard as asked in the technical specification. The Tender Committee shall examine the sample and also verify the dimensional parameters mentioned in the technical specification.

Failure to submit the sample before the stipulated date of sample submission or if the samples submitted will be found to be not as per technical specification will lead to automatic rejection of the bid and such bidders shall not be considered for opening of their price bids.

After the sample verification by the technical committee, the Biochemical reagents shall be tested at integrated laboratory of DHH Koraput in presence of the bidders or their representatives.

In case of "Rapid Test Kits", the bidders / their representatives are to be instructed for demonstration of kits.

If any bidder or their representative will fail to be present during Lab Test / demonstration period, their products will not be taken into consideration for further process. Also, the products ( of individual bidders) found to be not as per technical specification during sample verification / lab test will not be considered for further process i.e. the price bid of those items will not be taken into consideration while preparing the comparison statement.

**N.B:** Valid means the certificate should be valid on the date of opening of tender (Cover – A).

### **COVER – B (PRICE BID)**

4. The tender format giving the quoted rate for Lab reagents, chemicals, RDK ect. Should be sent in a separate sealed cover hereafter called **Cover "B "(Price Bid).**  
**Cover – B (Price Bid) will be opened only of the tenderers who qualify in technical Bid.**
- 4.1 The price of the items should be quoted inclusive FOR destination. The GST and entry tax charges (if any) should be quoted in a separate column. The rate should be quoted for *each item* both in figures and words. **In case of difference in words and figures, words will be taken into consideration for evaluation.**
- 4.2 The Cover " B " of successful tenderers who qualifies in their technical bid will be opened at the office chamber of the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore by the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore in the presence of the tenderers or their authorized representatives which will be notified later.

### **EARNEST MONEY DEPOSIT**

- 5.1 The Earnest Money deposit referred to at will be submitted in the shape of demand Draft only in favour of DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore from any Nationalized / Scheduled bank payable at SBI (Bazar Branch) Jeypore, Koraput for rs.20,000/- Rupees.

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- 5.2 The EMD of the unsuccessful tenderers will be returned back without interest, and EMD of successful tendered will be returned after successfully supply of purchase order.

### **TENDER CONDITIONS:**

- 6.1 The *list of the lab items are mentioned in Section II.*
- 6.2 Tenders should be type written or computerized and every correction in the tender should invariably be attested with signature by the tenderer with date before submission, failing which the tender will be ineligible for further consideration. Rates inclusive F.O.R. destination (*door delivery basis.*) GST & Entry Taxes if) **should be mentioned in separate columns.** The rates quoted should be in **Indian Rupees Only.**
- 6.3 If there is difference between figures & words, words will be taken into consideration.
- 6.4 In the event of the date being declared as a holiday by Govt. Of Odisha, the due date of submission of bids and opening of bids will be the following working day at the appointed place & time.
- 6.5 To ensure sustained supply without any interruption the tender inviting authority reserves the right to spilt orders for supplying the requirements among more than one tenderer if the lowest eligible bidder fails to supply in scheduled time and L<sub>2</sub>& L<sub>3</sub> firms agree to match the L<sub>1</sub> rate.
- 6.6 The rate quoted and accepted will be binding on the tenderer for a period of one year from the date of placement of purchase order and on no account any increase in the price will be entertained till the completion of this tender period.
- 6.7 No tenderer shall be allowed at any time on any ground whatsoever to claim revision of or modification in the rate quoted by him. Clerical error / typographical error, ect. Committed by the tenderers in the tender forms shall not be considered after opening of tenders.
- 6.8 If at any time during the period of contract, the price of tender item os reduce or brought down the by any law or act of the Central or state Government or the tenderer, the tenderer shall be morally and statutorily bound to inform the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore immediately about such reduction in the contracted price. The DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore Odisha is empowered to unilaterally effect such reduction in rate in case the tenderer fails to notify or fails to agree for such reduction of rate.

- 6.9 Bidders qualifying the technical bid (based on the documents submitted) will be intimated to submit the samples within a stipulated time period before opening of Price bid.
- 6.10 Approved rate with terms, conditions & the quoted price of the tender shall remain valid for a period of 12 months from the date issue of the purchase order or till issue of next tender for these items whichever is earlier.
- 6.11 If any information or documents furnished by the tenderer with the tender paper are found to be misleading or incorrect at any stage the tender of the relevant items on the approved list shall be cancelled and steps will be taken to blacklist the said firm.
- 6.12 Both Cover-A and Cover-B should have an **index and page number** of all the documents submitted inside that cover.
- 6.13 The tax will be charged as per the guidelines given by the Finance Deptt. Govt. of odisha from time to time. In case of entry Tax the supplier has to deposit the original receipt to claim it, if finished goods are brought from outside the State. The GST & Entry tax components should be shown **separately** in the Price Schedule.
- 6.14 In the event of any dispute arising out of the tender, such disputes would be subject to the jurisdiction of the Civil Court Dist. Koraput or Higher Court of Odisha.

## **ACCEPTANCE OF TENDER AND SUPPLY**

### **CONDITIONS:**

- 7.1 The DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore , Odisha reserves the right to reject the tenders or he accept the tenders for the supply of the items tendered without assigning any reason thereof.
- 7.2 The DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore Orissa will be liberty to terminate the contract either wholly or in part without assigning any reasons thereof. The tenderers will not be entitled to any compensation whatsoever for such termination.
- 7.3 The supply should be completed within 30 days from the date of issue of purchase order unless otherwise specified. If no supply is received even after 30 days from the date of issue of the purchase orders from the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore such orders will stand cancelled automatically without further notice. The approved firm shall also suffer forfeiture of the EMD.

- 7.4 If the approved supplier fails to execute the supply within the stipulated time, the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore is empowered to purchase the same items from L<sub>2</sub> or L<sub>3</sub> tenderer on negotiation basis.

### **TERMS OF PAYMENT:**

- 8.1 No advance payments towards cost of Lab Items will be made to the tenderer.
- 8.2 No claim shall be made against the DMO-(MS)-cum-superintendent, DHH Koraput at Jeypore in respect of interest on earnest money deposit or may delayed payment.
- 8.3 Payments in shape of Draft or e/payment / on-line transfer to the supplier.

## SECTION -II

### List of Items

Sl. No.	Reagents / Chemicals / RDK etc.	Unit of measure	Unit / Pack Size	Mfd Firm
1	(N/10) Hydrochloride Solution (Haemoglobin Estimation)	In ml	500	
		In ml	1000	
2	Haematology test Reagent for Automated Haematology Analyzer (3 Part)			
	Lyse	In ml	5000	
	Diluent	In ml	20000	
2.1	Haematology test Reagent for Automated Haematology Analyzer (5 Part)			
	Sulpholyser	In ml	5000	
	Diluent	In ml	20000	
	Stomatolyser	In ml	5000	
3	Haematology test under microscope			
3.1	WBC Diluting Fluid (TLC)	In ml	100	
3.2	Total Eosinophil Count Fluid	In ml	100	
3.3	RBC Diluting Fluid (Total Blood Cell Count)	In ml	100	
3.4	Platelet diluting Fluid (Platelet Count)	In ml	100	
3.5	Distil Water	In ml	500	
		In ml	1000	
		In ml	5000	
4	Blood Grouping (ABO-RH typing)(Anti-A, Anti-B, ANTI-AB, ANTI-D, ANTI-H, ANTI-A1, BOVINE ALBUMIN, Antigen for Red Cell Pannel)	In ml	10	
		In ml	5	
5	JSB Stain-I, JSB Stain-II (Malaria Parasite)	In unit	500	
		In unit	125	
6	3.8% Sodium Citrate Solution (ESR)	In ml	500	
		In ml	100	
7	Coombs Reagent (Direct & Indirect) (AHG Anti C3d monoclonal)	In ml	10	
		In ml	5	
8	Laboratory Stain (Giemsa Stain, Leishman Stain)			
8.1	Giemsa Stain	In ml	250	
		In ml	500	
		In ml	1000	
8.2	Leishman Stain	In ml	500	
		In ml	1000	
9	Immersion Oil (Microscope)	In ml	30	
10	Occult Blood	In Unit	50	
			25	
			10	
11	PT Reagent (Prothombin Time)	In ml	3	

RAPID AND PACKED KITS				
Sl. No.	Reagents / Chemicals / RDK etc.	Unit of measure	Unit / Pack Size	Mfd Firm
1	RPR Card (Syphilis)	In Unit	100	
		In Unit	50	
		In Unit	20	
2	HIV Rapid	In Unit	100	
		In Unit	50	
		In Unit	10	
3	Rheumatois Factor	In Unit	100	
4	ASO	In Unit	100	
5	HbsAg (Rapid)	In Unit	100	
6	CRP	In Unit	50	
7	Uri-Stick	In Unit	100	
		In Unit	50	
		In Unit	25	
8	Pregnancy Kit	In Unit	100	
		In Unit	50	
		In Unit	25	
9	Widal Kit	In Unit	100	
		In Unit	50	
10	Malaria Rapid	In Unit	100	
		In Unit	50	
		In Unit	25	
11	Dengue	In Unit	100	
12	Toxoplasma (Rapid)	In Unit	50	
		In Unit	10	
13	Hepatitis B Card Test	In Unit	100	
		In Unit	50	
14	Hepatitis C Card Test	In Unit	100	
		In Unit	50	
15	Troponin-I	In Unit	10	
16	H2S Strip	In Unit	50	
		In Unit	10	
BIOCHEMICAL REAGENTS (SEMI AUTO & FULLY AUTO ANALYZER)				
1.a	Blood Sugar (Lab method)	In ml	1000	
		In ml	500	
1.b	Blood sugar (Glucometer Strip)	In Unit	100	
		In Unit	50	
		In Unit	25	
1.c	Blood sugar (Glucometer Strip with Lancet)	In Unit	115	
		In Unit	55	
		In Unit	30	
2	Blood urea	In ml	1000	
		In ml	500	
		In ml	200	

3	S.Creatinin	In ml	1000	
		In ml	200	
		In ml	100	
4	S.Bilirubin (T)	In ml	1000	
		In ml	200	
		In ml	100	
5	S.Bilirubin (D)	In ml	1000	
		In ml	200	
		In ml	100	
6	SGOT	In ml	500	
		In ml	200	
		In ml	50	
7	SGPT	In ml	500	
		In ml	200	
		In ml	50	
8	S.Alkaline Phosphate	In ml	500	
		In ml	250	
		In ml	50	
9	Serum Total Protein	In ml	50	
		In ml	250	
		In ml	500	
10	Serum Albumin	In ml	200	
		In ml	100	
		In ml	50	
11	S. Calcium	In ml	50	
		In ml	100	
		In ml	200	
12	S. Pottasium	In ml	50	
		In ml	100	
		In ml	200	
13	S. Sodium	In ml	50	
		In ml	100	
		In ml	200	
14	S. LDH	In ml	50	
		In ml	200	
15	S. Amylase	In ml	25	
		In ml	50	
		In ml	100	
16	S. Uric Acid	In ml	25	
		In ml	50	
		In ml	100	
17	S. Cholesterol	In ml	25	
		In ml	50	
		In ml	100	
18	S. Triglyceride	In ml	25	
		In ml	50	
		In ml	100	

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19	S. VLDL	In ml	100	
		In ml	50	
20	S. HDL	In ml	25	
		In ml	50	

**OTHER CONSUMABLES**

Sl. No.	Reagents / Chemicals / RDK etc.	Unit of measure	Unit / Pack Size	Mfd Firm
1	Glass Slide	In unit	50	
2	Micro Tips (Yellow/ Blue)	In unit	1000	
3	Urine Collection bottle	In unit	each	
4	NVEDTA K3 2ml Sample Tube	2ml	each	
5	NVEDTA K2 2ml	2ml	each	
6	Plain Vial	5ml	each	
7	Test Tube (Big)	In Unit	Each	
8	Test Tube (Small)	In Unit	Each	
9	Test Tube Stand	In Unit	Each	
10	Test tube holder	In Unit	Each	
11	Clotting Vial	In Unit	Each	
12	ESR Stand	In Unit	Each	
13	ESR Tube	In Unit	Each	
14	Micro Pipette(10-200)	In Unit	Each	
15	Micro Pipette(5-50)	In Unit	Each	
16	Micro Pipette(10-100)	In Unit	Each	
17	Micro Pipette(100-1000)	In Unit	Each	
18	Tissue paper roll	In Unit	roll	
19	Fluoride vial	In Unit	Each	
20	Spirit Lamp	In Unit	Each	

## Technical Specification

### 1. Hemoglobin Estimation:

Reagent/Chemicals:

- ❖ (N/10) Hydrochloride Solutions (HCL)
- ❖ Pack Size: 500ml/1000ml
- ❖ Packed in a narrow mouth polyethylene bottle.
- ❖ Manufacturer should be ISO 13485 certified
- ❖ Product should be CE certified as per IVD directive

### 2. Total Leukocytes counts-

Chemicals:

- ❖ WBC Diluting Fluid
- ❖ pH value within 2.00-2.40
- ❖ Concentration:
- ❖ Pack Size: 100ml/500ml
- ❖ Packed in a narrow mouth high density polyethylene bottle.
- ❖ Manufacturer should be ISO13485 certified
- ❖ Product should be CE certified as per IVD directive

### 3. Different Leucocytes Count

#### 4. Malaria parasite:

##### 1 JSB Stain-I

- i. Methylene Blue (Medicinal) : 0.5 gm
- ii. Sulphuric Acid (H<sub>2</sub>SO<sub>4</sub>) 1% : 3 c.c.
- iii. Potassium Dichromate (K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>): 0.5 gm
- iv. Disodium Hydrogen Phosphate: 3.5 gm Dehydrate (Na<sub>2</sub>HPO<sub>4</sub>2H<sub>2</sub>O)
- v. Distilled Water: 500 c.c.

##### 2 JSB Stain-II

- i. Eosin Yellow (Water soluble): 1.0 gm
- ii. Distilled water: 500 c.c.

ii) **Packing:** Each bottle of JSB Stain-I & II will contain 125 ml of stain in a glass or plastic bottle.

- ❖ Manufacturer should be ISO13485 certified
- ❖ Product should be CE certified as per IVD directive

### 5. E.S.R (Erythrocyte Sedimentation Rate):

- ❖ 3.8% Sodium Citrate solution
  - ❖ PH vale lies between 7.8-8.0
  - ❖ Concentration : 3.70%- 3.90%
  - ❖ Pack Size: 100/500ml
  - ❖ Packed in a narrow mouth high density polyethylene bottle.
  - ❖ Manufacturer should be ISO13485 certified
  - ❖ Product should be CE certified as per IVD directive

### 6. Distilled water.

- Laboratory grade distil water
- micron filtered
- pH value :5-7.5
- Packed in transparent

7. Blood Grouping (ABO-RH typing)

ANTI-A	Monoclonal IgM reagent for forward grouping	Anti A consists of blood grouping reagent for slide and tube tests. The reagent is murine monoclonal IgM for forward grouping. Ready to use solution containing IgM (murine monoclonal) class antibodies specific to the 'A' antigen on the R.B.C Specificity: ANTI-A-100% to A , and A antigens Pack Size:5ml/10ml <b>Unopened kit:2-8OC</b> <b>Opened kit : 2-8OC</b> Self-life:24months
ANTI-B	Monoclonal IgM reagent for forward grouping	Anti B consists of blood grouping reagent for slide and tube tests. The reagent is monoclonal IgM for forward grouping. Ready to use solution containing IgM (murine monoclonal) class antibodies specific to the 'B' antigen on the R.B.C Specificity: ANTI-B-100% to B antigens, negative reaction with Acquired B characteristics Pack Size:5ml/10ml <b>Unopened kit:2-8OC</b> <b>Opened kit : 2-8OC</b> Self-life:24months
ANTI-A,B	Monoclonal IgM reagent for forward grouping	Anti A,B consists of blood grouping reagent for slide and tube tests. The reagent is monoclonal IgM for forward grouping. Ready to use solution containing IgM (murine monoclonal) class antibodies specific to the 'A'and 'B'antigens on the R.B.C Specificity: ANTI-A,B-100% to A and B antigens, negative reaction with Acquired B characteristics Pack Size:5ml/10ml <b>Unopened kit:2-8OC</b> <b>Opened kit : 2-8OC</b> Self-life:24months
ANTI-D	Polyclonal IgG reagent for Rh (D) typing	Anti D (IgG) consists of blood grouping reagent for slide and tube tests. The reagent is monoclonal IgG for Rho (D) typing & Du testing. Ready to use solution containing IgG (human monoclonal) class antibodies specific to the 'D' antigen on the R.B.C Specificity: ANTI-D (IgG) - 100% to Rho(D) antigen <b>Unopened kit:2-8OC</b> <b>Opened kit : 2-8OC</b> Self-life:24months



ANTI-H	Monoclonal IgM reagent for Rho (D) typing	Anti H (IgM) consists of blood grouping reagent for slide and modified tube tests. Used for recognition of the H antigen on human red blood cells. It is useful, especially for assessing the H secretor status of group 'O' individuals and also in differential grouping of A subgroup along with Anti- int A lectin. Ready to use solution containing IgM (human monoclonal) class antibodies <b>Specificity:</b> Negative reacting with 'O' phenotype <b>Reactivity:</b> Graded reactivity with different red cells, O>A >A B>B>A >A B Unopened kit:2-8OC Opened kit : 2-8OC Self-life:24months
ANTI-A1	Monoclonal IgM reagent for Rho (D) typing	Used for differentiation of A1 and A2 subgroups and can be used either for slide or tubetest. Specificity:A1 antigen on human RBCs Unopened kit:2-8OC Opened kit : 2-8OC Self-life:24months
Bovine Albumin for Grouping & Cross matching		Bovine Albumin is primarily used to enhance the reactivity of blood group antibodies, either in direct agglutination tests or indirect antiglobulin test. Pack sizes 5 ml/10ml dropper vial. Stability : at 2-80 C Self-life: 24 months. The reagent should contain 0.1% sodium azide as a preservative. protein concentration : Adjustable to 22% Adjustable pH of 7.1(± 0.1)
Antigen For Red Cell Panels	Used to detect expected ABO blood group antibodies in patient and donor samples.	High quality 3% & 5% Reagent Red Blood Cells. Four-vial set consisting of one vial each of A1, A2, B, and group O cells. Vial of 4x10ml
<ul style="list-style-type: none"> <li>❖ Manufacturer should be ISO13485 certified</li> <li>❖ Product should be CE certified as per IVD directive</li> </ul>		

8. Total Eosinophil count: Absolute Eosinophil Count fluid, size: 100ml, stable at Room temperature.

9. Total red blood Cell Count: RBC diluting Fluid, Size: 100ml, stable at Room temperature.

10. Platelet Count: Platelet Diluting Fluid, 100ml, stable at Room Temperature.

### 11. Packed Cell Volume:

1. Graduated Wintrobe Tube. Length of 110 mm and has 100 markings, each at the interval of 1 mm. Internal diameter is 3 mm. It can hold about 3 ml of blood.

2. Pasteur pipette with a rubber bulb and a sufficient length of capillary to reach the bottom of the Wintrobe tube.

- ❖ Manufacturer should be ISO13485 certified
- ❖ Product should be CE certified as per IVD directive
- ❖ Packet of 10 nos

**12. Occult Blood:** The FOB Rapid Test Device (Feces) is a rapid visual immunoassay for the qualitative presumptive detection of human hemoglobin in human fecal specimens. This kit is intended to be used as an aid in the diagnosis of lower gastrointestinal (g.i.) pathologies.

#### KIT COMPONENTS

- Individually packed test strips: Each strip contains colored conjugates and reactive reagents pre-speeded at the corresponding regions.
- Specimens' collection cards: For specimens collection use.
- Specimen's dilution tube with buffer: Each contains 2 ml of 0.1 M Phosphate buffered saline (PBS) and 0.02% sodium azide.
- Storage Condition:
- Self-life:

#### Laboratory Stains

1. Giemsa Stain Solution: Pack size of 250ml/500ml/1000ml, Buffer solution of pH value lies :6.9-7.2, Self life minimum 24months.
2. Leishman : Pack size of 250ml/500ml/1000ml, Buffer solution pH value lies: 6.4-7.00, Self life minimum 12months.

### 13. Coombs Reagent (Direct & Indirect)

Kit for Anti human Globulin Serum with monoclonal Anti C3d for Direct and Indirect Coombs test;

- ❖ Ready to use reagent containing antibodies reactive with human complement component C3d.
- ❖ The anti-complement antibodies are IgM class monoclonal and they impart the required sensitivity.
- ❖ Pack Size: 5ml/10ml
- ❖ Self-life: One year
- ❖ Supplied with Coombs Control solution of 5ml pack

#### AHG Anti C3d monoclonal

1. Antisera must be appropriate for tube technique
2. Should give clear positive reactions with appropriately sensitized cells
3. Should give clear negative reactions with unsensitized cells
4. should not haemolyse the cells.
5. Should not produce rouleaux
6. Titer :
  - a. For polyspecific minimum 128 for IgG and minimum 4 for C3d;
  - b. for monospecific anti-IgG minimum 256
  - c. for monospecific Anti C3d minimum 16
7. Must be evaluated and approved by NIB and IVD (EC)

## Technical Specification Rapid test Kits

### Quality Standard:

The following standards and criteria's are applicable to all the following products.

- The bidder/manufacturer shall furnish a certificate from the competent FDRA (Food and Drug Reactions anaphylaxis) that the manufacturer of the pharmaceutical or vaccine product covered by this Invitation for Bids is licensed to manufacture these products
- All products must meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin.
- Must undergo strict raw material inspection, in process checks, appropriate material handling to eliminate cross contamination (of molecules) and final product testing to ensure quality and consistency of the products.
- All reagents/Rapid KITS should be with suitable control.
- The manufacturer should be ISO13485 certified
- Manufacturer should be GMP Certified.
- All the kits should approved by CE(IVD) /USFDA & GMP
- All the Kit should be DCGI approved.

### **1. RPR Card test for syphilis**

**Intend of Use:** The assay should allow for qualitative and semi quantitative determination of reagin antibodies in serum or plasma for serodiagnosis of syphilis based on flocculation principle using non treponemal antigens.

#### **Technical Characteristics:**

- The assay should be suitable to perform with either serum or plasma
  - The assay should have sensitivity of 80% or more in primary syphilis and a specificity of 90% or more
  - The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from manufacturer.
  - The test should be able to yield results within 20 minutes.
  - The pack size of RPR test kit should be 50 tests per kit
  - The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls)
  - The kit should have all essential accessories required for the test such as cards, droppers, applicator, etc. in adequate quantities for the number of tests to be performed.
  - The kit should have more than 60% residual shelf-life or 10 months (whichever is more) at the time of dispatch to the consignee
  - The kit should have a storage temperature of 2 0C to 8 0C and supplier/ local agent should have the facility to store kits at 2 0C to 8 0C
  - Cumulative Time Temperature Indicator should be part of the kit as per specifications defined in the terms and conditions.
  - Literature, detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing and expiry dates should be provided with each kit.
- **KIT COMPONENTS PROVIDED**
- 1) RPR Carbon Antigen (Red Label): Carbon particles coated with a lipid complex (cardiolipin, lecithin and cholesterol) in phosphate buffer 20 mmol/L, pH 7.0 containing a preservative.
  - 2) RPR Positive Control: Artificial serum with reagin titer 1/4.
  - 3) RPR Negative Control: Animal serum containing a preservative
  - 4) Dispensing bottle (1 x 2 ml).
  - 5) Dispensing Needle (x1).
  - 6) Disposable agglutination slides.
  - 7) Plastic stirrers.

### **2. HIV (Rapid) Whole Blood Finger Prick Test Kits**

**Intended of Use:** The assay should be able to detect antibodies of HIV1, HIV2 and all the subtypes by detection of antibodies by the agglutination/ Enzyme  
**Should be 3rd generation**

1. The assay should have sensitivity of 100% or more and specificity of 100% or more as per data from an identified national reference laboratory.
2. The assay should have solid phase/ particles coated with synthetic and/ or recombination or both types of antigens of HIV1 & HIV2.
3. Total procedure time should not be more than 30 minutes.
4. The manufacturers should ensure that:
  - d) The test kit should be packed such that there is a provision to conduct single test at a time;
  - e) The assay components should include HIV positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls); and
  - f) The pack size of HIV rapid test kits should be 30 tests per Kit.

### **3. Rheumatoid Factor**

**Intended Of Use:** Rapid qualitative or semi-quantitative detection of IgM Rheumatoid Factor in serum.

- Visual reading
- Results output <2 minutes
- Ready-to-use
- High sensitivity : 98.75%
- Specificity : 98.37%
- The kit should meet all safety requirements with positive and negative controls.

#### **KIT Configuration:**

1. **RF Reagent:** A suspension of uniform polystyrene particles coated with IgG (human) in glycine buffer, pH 8.2; reagent sensitivity is standardized with the World Health Organization RF Standard.
2. **RF Positive Control Serum:** A stabilized, prediluted human serum containing at least 30IU/mL/ 8 IU/mL of RF.
3. **RF Negative Control Serum:** A stabilized, prediluted human serum containing less than 8 IU/mL of RF.
4. **Glycine-Saline Buffer (20x):** pH 8.2 ± 0.1M glycine and 0.15M NaCl
5. Reaction Slide.
6. Pipette
7. Disposable Stir Sticks.

Pack Size of the Kit:50 test/100Test

### **4.ASO**

**Intend of Use:** For the qualitative measurement of antibodies to streptococcal exoenzymes in human serum.

Sensitivity of the test should be minimum: 200 IU/ml

#### **Kit Configuration:**

1. ASO Latex Reagent: Contains polystyrene latex particles coated with Streptolysin O in a stabilized buffer with less than 0.1% sodium azide as preservative.
2. ASO Positive Control: Human serum containing more than 200 IU/ml ASO with less than 0.1% sodium azide as preservative.
3. ASO Negative Control: Human serum that has been diluted and stabilized with buffer and contains less than 0.1% sodium azide as preservative.
4. Disposable pipettes
5. Disposable agglutination Slides.

### **5. HBsAg (Rapid test)**

**Intended Of Use:** HBsAg/HCV Ab Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) and anti-Hepatitis C virus antibodies (IgG, IgM, IgA) in human serum, plasma and whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Hepatitis B virus (HBV) and Hepatitis C virus (HCV).

- Should be immunoassay/capture principle
- Should be lateral flow device
- Should have in built quality control band or dot
- Should have short interpretation time not more than 30 minutes
- Should have specificity and sensitivity of 100 %
- Must be evaluated and approved by NIB

**Kit Configuration**

1. Diagnostics Rapid Card
2. HBsAg colloidal gold rapid test strips, each placed in white plastic cassette and packed in foil pouch.
3. Instructions for use.
4. 1 vial of sample diluent.

**Sensitivity 100 %**

**Specificity 100 %**

**6. CRP: C-REACTIVE PROTEIN (CRP) - SLIDE**

**Intended of Use:** CRP TEST is intended to be used for the qualitative screening and semi-quantitative determination of C - reactive protein antibodies (CRP) in serum

**Kit Configuration:**

1. CRP Reagent: Contains polystyrene latex particles coated with anti-human CRP in a stabilized buffer with less than 0.1% sodium azide as preservative.
  2. CRP Positive Control: Human Serum that contains more than 6mg/L CRP and less than 0.1% sodium azide as preservative.
  3. CRP Negative Control: Human serum that has been diluted and stabilized with buffer and contains less than 0.1% sodium azide as preservative.
  4. Glycine-saline Buffer: (20X) Concentrate To be diluted 1:20 with distilled water.
  5. Disposable pipettes and test slides.
- Pack Size:50test/100test

**7. URINE Complete rapid test reagent strips :**

- Urine Reagent Strips are for in vitro diagnostic use only.
- Indications for urine test strips:
  - Screening for prevention
  - Treatment monitoring
  - Patient self-testing
- Urine Reagent Strips provide tests for the following parameters:
  1. Glucose
  2. Bilirubin
  3. Ketone (Acetoacetic acid)
  4. Specific Gravity
  5. Blood
  6. pH
  7. Protein
  8. Urobilinogen
  9. Nitrite
  10. Leukocytes
  11. Ascorbic Acid in Urine.
- The Urine Reagent Strips should be packaged along with a drying agent in a plastic bottle with a cap to provide complete air tight.
- Each strip should be stable and ready to use upon removal from the bottle.
- The entire reagent strip should be disposable.
- Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label.
- All the reagent strips should be withstand at a room temperature between 15°-30°C (59°-86°F) and out of direct sunlight.

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- The minimum self-life of the urine strips should be 1 year unopened and minimum 3 months once it is opened.
- The required controlled shall be provided along with the strip packet.
- The strip pack sizes should be of 25/50/100 sizes.
- Urinalysis test strips types
  1. Ketones- Single test
  2. Glucose, Protein & pH- Three parameter
  3. Glucose, Protein pH, Leukocytes, Nitrites, Ketones, Bilirubin, Blood, Urobilinogen, and Specific Gravity-10 parameter
  4. Leukocytes and Nitrite-Special parameter
- Quality Standards:**
  - The manufacturer should be ISO 13485 certified.
  - The strips should be USFDA/CE (IVD) approved.
  - The strips should be DCGI approved.

### **8. Urine Pregnancy Test:**

**Intended of Use:** One step hCG Serum/Urine Combo Rapi-Card rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in serum and urine.

- Serum/Urine Combo Pregnancy Test Cassette is a rapid test that qualitatively detects the presence of hCG in serum and urine specimens at the sensitivity of 20mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG
- Result should be produced with 1 minute.
- Accuracy: 99%
- Sensitivity: 20mIU/mL
- The test strips should have inbuilt quality control to achieve the above accuracy.

### **Kit Configuration**

1. Urine Pregnancy Test Rapid Card
2. Disposable pipette
3. Instructions for use

Storage condition 2-30 degree

### **Quality Standards:**

- The manufacturer should be ISO 13485 certified.
- The strips should be USFDA/CE (IVD) approved.
- The strips should be DCGI approved.

### **9. Widal test KIT**

**The test kit should have the following configuration**

1. 'O' Antigen 5ml
  2. 'H' Antigen 5ml
  3. AH' Antigen 5ml
  4. BH' Antigen 5ml
  5. Positive control 5ml
  6. Negative control 5ml
  7. Test Serum Sample 2 ml
  8. Glass Slide 1 No. RT
  9. Disposable Mixing Sticks
- Result should be within 3 minutes
  - Homologues antigen antibody reaction with no cross reactivity with other salmonellar groups
  - High specificity: 98%
  - Higher sensitivity: 98%
  - Self-life 1 year

### **10A. Dengue Rapid KIT (Dengue NS1 Ag Rapid)**

- Should be a rapid test based on lateral flow technique.



- Test must be able to detect Dengue virus NS1 Ag from Day 1 of fever.
- Should be able to detect all the 4 Dengue serotypes (DEN-1, DEN-2, DEN-3, and DEN-4).
- Test should provide results within 20 minutes
- Should have long shelf life: 24 months.
- It should have a convenient pack size : 25 tests
- Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit
- The kit to be procured should have approval of the statutory authority in its country of origin
- In case of imported kits it should be registered and licensed in India by DCG (I)
- In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I)
- Sensitivity- > 95% and Specificity- 99%

#### **10.B.Dengue IgM/ IgG Rapid**

- Test should be a solid phase in vitro immunochromatographic test for the qualitative and differential detection of IgG and IgM antibodies to dengue virus serotype DEN-1, 2, 3 and 4 in human serum, plasma or whole blood
- The test should be able to differentially detect IgG and IgM antibodies against all 4 serotypes of Dengue virus
- Results should be available in 15-20min.
- Test should be able to give a presumptive differentiation between primary & secondary dengue infections
- Test should have no cross reactivity with other Flavivirus group mediated and mosquitoes-borne disease
- Dengue IgG/IgM (Plasma Serum WB) : Sensitivity 94%, Specificity  $\geq$  96% Adequate documents detailing the principle, components, bio-safety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit
- The kit to be procured should have approval of the statutory authority in its country of origin
- In case of imported kits it should be registered and licensed in India by DCG (I)
- In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I)
- Kit should have minimum shelf life of 60% or 12 months (whichever is more at the port of discharge of consignees)

#### **11.Malaria Rapid Kit(Malaria Antigen Rapid (Pan Specific / pf))**

- Should be a rapid Immuno chromatographic test
- Test should be able to detect and differentiate between Antigen of P.falciparum (HRP-2/ LDH) and Pan Plasmodia against P.falciparum, P.vivax, P.ovale, P.malariae (LDH) from human serum or plasma or whole blood
- The test should be based on the principle of capture of parasite antigen from blood using monoclonal antibodies
- specific for antigen target
- Each test kit should contain all the material required for conducting the
- Each batch of Rapid tests should be tested during time of delivery to ensure sensitivity and specificity of > 99%.
- Each kit should be packed in a hermetically sealed and nonpermeable pouch and should have moisture adsorbent material
- Kit should have a pack size of 25 such test cards/strips
- Result should be available in 20 minutes

- Adequate literature detailing the components methodologies, validity criteria, storage conditions, expiry
- date and limitations of test should be provided
- The kit to be procured should have approval of the statutory authority in its country of origin
- In case of imported kits it should be registered and licensed in India by DCG (I)
- In case of indigenous manufacturers they should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 after appropriate evaluation by the centers approved by DCG(I)
- Kit should have minimum shelf life of 12 months (whichever is more at the port of discharge of consignees)

### **12. Troponin-I (Card Test)**

**Troponin I** test is a rapid, qualitative test for the detection of cardiac troponin I (cTnI) in serum, plasma, whole blood as an aid in the diagnosis of myocardial infarction of a patient.

Test principle: Immuno-chromatographic.

Detection of: Cardiac troponin I (cTnI)

It should detect cardiac Troponin I at a concentration of >0.5ng/ml

Sample Type: Serum, Plasma, whole blood

Specificity: 98.9%

Sensitivity: 96.9%-

Time to result: 10-15 minutes

Storage Condition: 2-30°C

Self-Life: 24 months

Pack Size: 10test cards individually sealed/packed in a box.

The box should contain

1-Test Device

2-Disposable droppers

3-Buffer Solution

4-Package insert

CE marked as per IVD

Manufacturer Should be ISO13485 certified.

### **13. Troponin T**

**Qualitative detection of troponin in anticoagulated**

(EDTA or heparin) venous whole blood

- Reaction time < 15 min.
- Positive result from a threshold (cut-off) of 100 ng/L
- Storage at 2 to 8°C
- Test can be used immediately after removal from the refrigerator
- Self-life: 1month

Pack Size:

1. Disposable test strips (individually sealed)
- 2.5 pipettes (150 µL)
3. Disposable labels
- 4.1 package insert
5. 1 vial of negative control solution (lyophilized) for 6 determinations

**Bio-chemical Reagents for in-vitro diagnostics in human samples for professional use only**

**Quality Standards and general description of the reagents packs**

- All reagent kits should be liquid stable & ready to use.
- Reagent should be free from all carcinogenic & hazardous material.
- Reagent should be used for all open biochemistry analyzer systems (Both Semiautomatic & Fully automatic irrespective of make & model)
- Reagents must be approved by a reputed regulatory body like CE(IVD)/USFDA
- Manufacturer should be ISO13485 approved.
- Manufacturer should be GMP Certified.
- The entire reagent should be DCGI approved.
- Calibrators traceable to Certified Reference Material (CRM)
- Standardization of reagent kits traceable to Standard Reference Material (SRM).
- Calibrators and Controls preferably of human matrix.
- Reagent methodology should be traceable to some reference method, e.g., IFCC, CDC, etc.
- Results should be correlated with Gold Standard Methods.
- Reagents CV% should be less than 4 – 5%.
- Reagents specificity should be within 90 – 100%.
- Purity of the reagent should be 98-99%
- Sensitivity mentioned should be excellent enough to ensure measurement of very low analyte present in the sample.
- Reagents should ensure wide linearity for proper interpretation.
- All reagents should be with suitable control.
- The reagents should not be older than one sixth (1/6th) of its shelf life from the date of manufacture.

15	S.Cholesterol	25/50/100 R1,R2-Standvial	Endpoint	0.3 mg/dL	800-900mg/dL
Sl. No	Name of the Reagent	Pack Size(in ml)	Method	Sensitivity	Linearity
1	Blood Sugar	100/200/500/1000	End point	0.6mg/dl	400mg/dl
2	Blood urea,	200/500/1000	End point	2.5mg/dl	300-350mg/dl
3	S. creatinin	100/200/1000 R1,R2,R3-Stanard (Vial)	2-point	0.05mg/dl	Upto 30mg/dl
4	S.Bilirubin (T)	50/100/200/1000 R1,R2-Direct Nitrite Vial	End Point	0.1mg/dl	20mg/dl
5	Bilirubin (D)	100/200/1000	End Point	0.2mg/dl	25mg/dl
6	SGOT	50/200/500	Kinetic	8u/l	Up to 800U/l
7	SGPT	50/200/500	Kinetic	5u/l	Up to 800U/l
8	S.Alkaline Phosphate	50/200/500	Kinetic	8.8U/L	Up to 700U/l
9	S.Total Protein	50/250/500 R1,R2-Standard(vial)	End point	0.17g/dl	Upto 18g/dl
10	S.Albumin	50/250/500 R1,R2-Standard(Vial)	End point	0.1g/dl	.6-.7g/dl
11	S.Calcium/Potacium /Sodium	50/100/200 R1,R2-Standvial	End point	0.12mg/dl	25mg/dl
12	S.LDH	50/200	Kinetic	0.13mg/dl	20-1000mg/dl
13	S.Amaylase	25/ 50/100	kinetic	0.03	1300U/l
14	S.Uric Acid	25/50 R1,R2-Standvial	Endpoint	0.02mg/dl	Up to 25mg/dl
16	S.Triglyceride	25/ 50/100	Endpoint	1.6 mg/dL	600-700 mg/dL

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17	S.VLDL	100	End Point	0.28 mg/dL	990 mg/dL
18	S.HDL	25/50	End Point	3.0 mg/dL	150 mg/dL

Study ID	Study Name	Study Type	Study Status	Study Dates	Study Location
1	Study 1	Phase I	Completed	2010-2011	USA
2	Study 2	Phase II	Ongoing	2012-2013	USA
3	Study 3	Phase III	Completed	2014-2015	USA
4	Study 4	Phase I	Completed	2016-2017	USA
5	Study 5	Phase II	Ongoing	2018-2019	USA
6	Study 6	Phase III	Completed	2020-2021	USA
7	Study 7	Phase I	Completed	2022-2023	USA
8	Study 8	Phase II	Ongoing	2024-2025	USA
9	Study 9	Phase III	Completed	2026-2027	USA
10	Study 10	Phase I	Completed	2028-2029	USA
11	Study 11	Phase II	Ongoing	2030-2031	USA
12	Study 12	Phase III	Completed	2032-2033	USA
13	Study 13	Phase I	Completed	2034-2035	USA
14	Study 14	Phase II	Ongoing	2036-2037	USA
15	Study 15	Phase III	Completed	2038-2039	USA
16	Study 16	Phase I	Completed	2040-2041	USA
17	Study 17	Phase II	Ongoing	2042-2043	USA
18	Study 18	Phase III	Completed	2044-2045	USA
19	Study 19	Phase I	Completed	2046-2047	USA
20	Study 20	Phase II	Ongoing	2048-2049	USA

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# SECTION -III

## ANNEXURES

**CHECK LIST**  
(To be submitted in Technical Bid)

**Note : The documents has to be arranged serially as per the order mentioned in the check list**

Please put ✓ in the respective box

**COVER – A (TECHNICAL BID)**

**DOCUMENTS : SUBMITTED OR NOT**

1.	List of Item (s) – Annexure II	Page No	Yes	No
2.	Tender document Fee	Page No	Yes	No
3.	Earnest Money Deposit	Page No.	Yes	No
4.	Details of Manufacturing Unit / contract person Liaisioning agent (Annexure III) No.	Page	Yes	No
5.	Declaration form (Annexure -IV) signed by the Tenderer & affidavit before Notary Public / Executive Magistrate	Page No.	Yes	No
6.	Manufacturer's Authorization Format (Annexure – V)	Page No.	Yes	No
7.	Proof of avg. Annual turnover of Rs.0.5 Crore or more for preceding 3 financial years (Annexure - VI )	Page No.	Yes	No.
8.	Copy of valid GMP Certificate	Page	Yes	No
9.	GST Copy	Page No.	Yes	No
10.	Copy of Manufacturing License	Page No.	Yes	No
11.	Copy of Valid USFDA/CE Certificate	Page No	Yes	No

12. Copy of valid ISO 13485 certificate

Page		Yes		No	
No.					

13. Photocopy of PAN

Page		Yes		No	
No.					

15 Copy of original Tender, duly signed by the Tenderer

Page		Yes		No.	
No.					





**ANNEXURE – III**  
(Refer Clause No. 3.5)

(To be submitted in Cover A -Technical Bid)

**DETAILS OF THE TENDERER & LOCAL CONTACT PERSON**

	<b>Corporate Office (The address in which the purchase orders and payment details will be communicated)</b>	<b>Local Contact Person / Branch Office / Zonal Office .</b>
Name & Full Address		
Telephone Nos., landline		
Mobile		
Fax		
E – Mail		

**Signature of the Tenderer :  
with seal**

**Date :**

**Official Seal :**

L-30

(To be submitted in Cover A -Technical Bid)

**DECLARATION FORM**

I / We .....having  
My / our .....office  
at.....do declare that I / We have  
carefully read all the terms & conditions of tender of the \_\_\_\_\_, Orissa for the  
supply of medicines and consumables. The approved rate will remain valid for a period of  
one year from the date of approval. I will abide with **all the terms & conditions** set forth in  
the **Tender Reference no.** \_\_\_\_\_

I/We do hereby declare I/We have not been de-recognized / black listed by any State  
Govt. / Union Territory / Govt. of India / Govt. Organization / Govt. Health Institutions for  
supply of Not of Standard Quality (NSQ) items / non-supply.

I/We agree that the Tender Inviting Authority can forfeit the Earnest Money Deposit t  
and blacklist me/us for a period of 2 years if, any information furnished by us proved to be  
false at the time of inspection / verification and not complying with the Tender terms &  
conditions.

Seal

Signature of the bidder :

Date :

Name & Address of the Firm:

Affidavit before Executive Magistrate / Notary Public.

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(To be submitted in Cover A -Technical Bid)

**MANUFACTURER'S AUTHORISATION FORMAT**

To

The C.D.M.&P.H.O Jajpur  
Deptt. of Health & Family Welfare  
Govt. of Orissa.

Ref: Tender No. \_\_\_\_\_ Dated \_\_\_\_\_ for

Dear Sir,

We, ----- are the manufacturers of -----  
----- (name of Medicines/ Medical consumables having factories  
at -----.

1. Messrs ----- (name and address of the agent) is our authorized agent for sale and supply of ----- (name of reagent,chemical,rdk,etc.
2. We confirm that Messrs. ----- (name of the above agent) is authorized to submit a tender, and enter into a contract with for the above items manufactured by us.
3. We will provide test reports of supply items, if required by the purchaser.

Yours faithfully,

-----  
-----

(Signature with date, name and designation)

For and on behalf of Messrs -----  
(Name & address of the manufacturers)

Seal

Note :

1. This letter should be on the *letterhead* of the *manufacturer* and should be signed by a person having the power of attorney to legally bind the manufacturer.
2. Original letter shall be attached to the technical bid.

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(To be submitted in Cover A -Technical Bid)

**ANNEXURE – VI**  
(Refer Clause No. 3.8)

(To be furnished in the letter head of the Auditor)

**ANNUAL TURN OVER STATEMENT**

The Annual Turnover for products of  
M/s \_\_\_\_\_

who is a manufacturing unit/Authorized distributor for the last 03 years are given below and certified that the statement is true and correct.

Sl.No.	Year	Turnover in Crores (Rs.)
1.		
2.		
3.		

**Average Annual Turnover** (for the above three years) in Crores (Rs.) \_\_\_\_\_

Date:  
Place:

Signature of Auditor/  
Chartered Accountant  
(Name in Capital)

Seal

Membership No.-  
Registration No. of Firm

**Note:**

- To be issued in the letter head of the Auditor.
- Separate certificates should be furnished for different manufacturer in case the bidder is quoting products of different manufacturers.

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**ANNEXDEE-VII**  
(Refer Clause No. 4.1)

**(PRICE SCHEDULE)**

SI No	Name of the Items	Specification / Strength	Name of the Manufacture	Unit/Pack size as per section-II	Rate/unit	GST	Total Price

Signature of the bidder  
Name :  
Seal

Date :  
Place :

Rates should be quoted both in figures & words and if there is any discrepancy, the quoted rates in words will be taken for evaluation

17/34  
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