CHIEF DISTRICT MEDICAL AND PUBLIC HEALTH OFFICER
MAYURBHANJ

Tel: 06792-252671
e-mail : dpmumbj@gmail.com,

Tender Reference No. CDM &PHO/2018-19/4899

TENDER DOCUMENT
FOR

Bio-chemical Reagents and Rapid Testing Kits

Address for Correspondence-
Office of the Chief District Medical and Public Health Officer, Mayurbhanj
At/Po-Baripada, Dist- Mayurbhanj, Odisha
Pin-757001

SECTION -I

NOTICE INVITING TENDER

Tender Reference No. : . CDM &PHO/2018-19/4899 Dated: 24.12.2018

TENDERS ARE INVITED FROM ELIGIBLE BIDDERS AS PER THE ELIGIBILITY CRITERIA FOR SUPPLY OF BIO-CHEMICAL REAGENTS AND RAPID TESTING KITS

.

1	Period of Availability of Tender Document	From **26.12.2018 TO 15.01.2019** (Downloadable from website: www.mayurbhanj.nic.in) In case of any bid amendment and clarification, responsibility lies with the bidders to collect the same from the above mentioned website before last date of submission of tender document and the tender inviting authority shall have no responsibility for any delay / omission on part of the bidder.
2	Date, time & place of Pre-bid meeting	Date : **29.12.2018**, Time : 11.00 AM Place : Office chamber of The Chief District Medical and Public Health Officer, Mayurbhanj
3	Last date & time for submission of Tender	**Date: 15.01.2019 Time: 4.00 PM** **Address of Submission of Bid:** OFFICE OF THE CHIEF DISTRICT MEDICAL AND PUBLIC HEALTH OFFICER, MAYURBHANJ ***At/Po- Baripada, Dist- Mayurbhanj, Pin- 757001*** ***(Through Speed post / Registered post / courier service)***
4	Date, time and place of opening of Tender	**A. Technical Bid (Cover A) opening 16.01.2019 at 11.00 AM in the address mentioned above.** **B. Financial Bid (Cover B):** *The date of opening of financial bid will be intimated to the firms found successful in the technical bid evaluation.* ***(Venue is mentioned at the address mentioned above)*** ***(Bidders / authorized representative may remain present at the time of opening of bid)***

IMPORTANT INSTRUCTIONS TO BE NOTED CAREFULLY BY THE TENDERERS

Purchaser:- Chief District Medical & Public Health Officer, Dist. Mayurbhanj

Consignee:- Chief District Medical & Public Health Officer, Dist. Mayurbhanj

Delivery Period:-	**Within 30 days from the issue of Purchase Order**
Mode of Delivery:-	**By Air / Road / Rail (On Door Delivery Basis)**
Tender Document Cost:-	**Rs. 5,000/- (Five thousand only) in shape of D.D. in favour of ZSS NON NRHM, Mayurbhanj payable at Bariapda from any Nationalised Bank / Scheduled Bank**
Earnest Money Deposit:-	**Rs.20,000/- (Rupees Twenty Thousand) only in shape of D.D. in favour of ZSS NON NRHM, Mayurbhanj payable at Bariapda from any Nationalised Bank / Scheduled Bank.**

TERMS, CONDITIONS & SPECIFICATION FOR SUPPLY OF BIO-CHEMICAL REAGENTS AND RAPID TESTING KITS

1) Sealed tender will be received up to 4 P.M. on dt.15.01.2019 by the CDM & PHO Mayurbhanj for the purchase of Bio-chemical Reagents and Rapid Testing Kits. Any tender received after the due date & time will be rejected / returned to the sender unopened. The tender will be received only through Regd. Post / Speed Post / Courier service. The bidders are to download the tender documents from district web Site www.mayurbhanj.nic.in.

2) The bidders are to submit their tenders in separate sealed cover envelope for technical bid and price bid by super scribing **Technical Bid** (Cover-A) & **Price Bid** (Cover-B) and both the sealed cover should be put into a third outer cover which should be Super scribed as **" Tender For Supply of Bio-chemical Reagents and Rapid Testing Kits.**

3) Only the Financial bids of technical qualified bidders will open and the date will intimated accordingly.

4) The sealed tender submitted by the tenderer will be opened by the purchase committee at the office chamber of the Chief District Medical & Public Health Officer, Mayurbhanj at 11 A.M on 16.01.2018. The tenderer or their duly authorised representatives are allowed to be present during the opening of tenders if they so like. In the event of last date being holiday the last date of submission of tender and opening of tender will be the next working day at the same time.

5) The authority reserves all the rights to cancel the whole or a part of the tender without assigning any reason thereof.

ELIGIBILITY CRIETRIA FOR TECHNICAL BID

Manufacturer of Bio-chemical Reagents, Rapid Testing Kits or its authorised dealers / distributors / suppliers are eligible to participate in tender provided they fulfil the following conditions.

Manufacturing Units

i) Valid ISO Certificate

ii) Valid GMP / WHO GMP Certificate

iii) GST Registration certificate

iv) Copy of PAN Card

v) Average annual Turnover of Rs.5 Crore or more for last three financial years (2015-16, 2016-17, 2017-18) duly filed by Auditor / Chartered Accountant as per **Annexure-III** format attached.

vi) Proof of Supply (Executed directly or through distributor) to any Govt. Organisation / Corporate Hospital / PSU Hospitals / UN Agencies and purchase order copies in support of that in last three years. Successfully executed certificate from concerned head of the institutions.

vii) The firm who have been blacklisted either by tender inviting authority or by any district / state govt. or central govt. within the last five years are not eligible to participate any tender. Notary Affidavit of the same to be submitted neither stating that the firm has neither been black listed nor any criminal cases pending against them as per the **Annexure-II** attached.

viii) The Manufacturing unit should furnish the non conviction certificate from Health & FW Department or from Drug Controller.

ix) Regarding SSI / MSME unit the terms and conditions will be applicable as per the rule of Govt. of Odisha.

Authorised Distributors:-

i) They submit manufacturer's authorisation to transact business on behalf of manufacturer. **(Annexure-IV)**

ii) They must submit the manufacturing license of the manufacturing firm.

iii) They should submit the Proof of Average Annual Turnover of Rs.1 Crores or more in last three financial years (from 2015-16, 2016-17, 2017-18) and duly filed by Auditor / Chartered Accountant as per **Annexure-III** attached.

iv) Proof of Supply Order copies with end user certificate from minimum three different district health authorities. (from 2015-16, 2016-17, 2017-18)

v) The authorised distributor will submit the following documents in support of the Manufacturer along with the tender

a. Valid ISO Certificate
b. Valid GMP / WHO GMP Certificate
c. GST Registration certificate.
d. Copy of PAN Card.
e. Product authorisation certificate

vi) The firm who have been blacklisted either by tender inviting authority or by any district / state govt. or central govt. within the last five years are not eligible to participate any tender. Notary Affidavit of the same to be submitted stating that the firm has neither been black listed nor any criminal cases pending against them as per the **Annexure-II** attached.

TECHNICAL BID (COVER-A) DOCUMNTS TO BE SUBMITTED

- Checklist **(Annexure-I)** with detail of the documents enclosed in **Cover "A"** must be page marked. The document should be serially arranged with page mark and should be securely tied and bound on the front of the tender.
- Tender document fee of Rs.5,000/-(Rupees Five Thousand only) is to be submitted in shape of bank draft in favour of **ZSS Non-NRHM, Mayurbhanj payable at Bariapda from any Nationalised Bank / Scheduled Bank** Payable at Baripada.
- Earnest Money Deposit of Rs 20,000/- (Rupees Twenty thousand only) in shape of Demand Draft in favour of **ZSS Non- NRHM,Mayurbhanj payable at Bariapda from any Nationalised Bank / Scheduled Bank** Payable at Bariapda.
- The declaration form in **Annexure - II** duly signed by the tenderer before Notary Public / Executive Magistrate to be submitted in original.

- Manufacturer's Authorization Letter **Annexure-IV** (In case the bidder is not the manufacturer)
- Proof of Average annual turnover of Manufacturer of Rs. 5 Crore or more for the last three financial years. In Case of Bidder is not Manufacturer the Annual average turnover of Rs.1 Crore or more in last three financial years duly certified by Auditor / Chartered Accountants. **Annexure-III**
- Proof of Supply Order copies with end user certificate from minimum three different district health authorities. (from 2015-16, 2016-17, 2017-18) as a successful supplier.
- Copy of Valid Manufacturing License of the manufacturer (s)
- Copy of Valid ISO certificate and GMP / WHO GMP Certificate
- Copy of GST Registration Certificate
- The Original Tender Book duly signed by the tenderer at the bottom of each page with his official seal duly affixed.
- All the tender documents should carry signature and seal of the bidder.
- All the supported documents should be attested from Notary.

COVER – B (PRICE BID)

The tender format giving the quoted rate for Laboratory Bio-chemical reagents and Rapid Testing Kits 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 after qualify in Technical Bid (Cover – A) and as per tender specification**.
- The tender format (Price Schedule) must be submitted in Cover-B. The price of the item should be quoted inclusive of all taxes along with the cost of, insurance, packing, forwarding, freight (door delivery). The GST & other tax (if any) should be quoted in a separate column. The tenderer must quote the rate of items as per the price schedule provided in the tender format. **Annexure – V.**

- The Cover “B” of successful tenderers who qualifies in their technical bid, will be opened at the office chamber of the CDM & PHO, Mayurbhanj in the presence of the tenderers or their authorized representative if so desired.

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

REJECTION OF TENDER

The tender submitted by the bidder is rejected, if any of the following documents are not submitted with the tender.

i) Checklist as per **Annexure-I.**

ii) Tender paper cost.

iii) Earnest Money Deposit (EMD)

iv) Copy of valid GST regd. & PAN

v) Valid ISO Certificate of Manufacturer with GMP / WHO GMP Certificate

vi) The declaration form in **Annexure - II** duly signed by the tenderer before Notary Public / Executive Magistrate.

vii) Proof of Average annual turnover of Manufacturer (if the bidder is manufacturer) of Rs. 5 Crore or more for the last three financial years (2015-16, 2016-17, 2017-18) certified by the Auditor / Chartered Accountants as per the **Annexure-III.**

viii) Proof of Annual Average turnover of Rs. 1 Crore or more for the last three financial year (2015-16, 2016-17, 2017-18) for bidders who are authorised distributor of the Manufacturer which is duly certified by Auditor / Chartered Accountants as per the **Annexure-III.**

ix) Manufacturer’s Authorisation in case of Distributor as per **Annexure-IV**

x) Proof of Supply Order copies with end user certificate from minimum three different district health authorities. (from 2015-16, 2016-17, 2017-18) as a successful supplier.

xi) The absence of bidders signature, seal, page marking in each page of the tender book.

xii) Price bid as per **Annexure-V.**

GENERAL TERMS AND CONDITIONS

1) Rs.20,000/-(Rupees Twenty thousand) only per tender as **Earnest Money Deposit (EMD)** will be submitted in shape of Demand Draft in favour of **ZSS Non-NRHM, Mayurbhanj payable at Bariapda** from any Nationalised Bank along with the tender paper in technical bid and tender cost fee in shape of demand draft is also to be submitted in technical bid.

2) The EMD of the unsuccessful bidders will be returned back without interest after publication of the approved list and EMD of successful tenderer will be returned without interest after expiry of tender or publish the next tender whichever is earlier.

3)The EMD will be forfeited if the tenderer withdraws the tender or doesn't accept the approved list or doesn't supply the full items within the stipulated time period.

4)Financial bid should be submitted as per format (Annexure - V) with signature and seal.

5) No Compromise will be made for quality of reagent chemical and Consumables and the views of technical experts will be given preference towards acceptance of the Products.

8) Approved rate with terms, conditions & the quoted price of the tender shall remain valid for a period of **one year** from date of issue of the approved list.

9)The tenderer must attach the declaration form duly filled along with the tender paper as per Annexure-II while taking part in the tender bid signed by the tenderer and affidavit before Notary Public / executive magistrate.

10)The tenderer must affix his signature and seal in each page of the tender paper & all supporting documents must be attested by notary.

11) Purchase Orders may be placed to the authorised distributor / firm and bills can be raised by the authorised agency on behalf of the manufacturer.

12) Incomplete tender and non-submission of documents asked for is liable for rejection.

13) The tender paper will be rejected if the bidder changes or omit any clause or Annexure of the bid documents.

14) The tender paper must be page marked and the check list must be attached to the tender documents.

15) If any information or documents furnished by the tenderer with the tender papers are found to be misleading or incorrect at any stage the tender of the relevant items in the approved list shall be cancelled and steps will be taken to blacklist the said firm for five (5) years.

SUPPLY CONDITIONS

1) All the packaging should be primary (New). The supplier shall provide such packaging of the goods as is required to prevent their damage or deterioration during transit to their final destination. The packaging shall be sufficient to withstand without limitation, rough handling during transit and exposure to extreme temperature, salt and precipitation during transit and upon storage.

2) At the time of receipt of reagent at least 5/6th self life should be there in each item.

3) The Supply is to be made in less number of batches (less than 3) and maximum two phase. The Supply should be made in good packing condition and labelling.

4) The supplier must be ready to execute complete supply within 15 to 30 days from the date of issue of the purchase order. Any delay in supply must be intimated to the indenting officer before the time period is over.

5) Any items if found of not standard quality must be replaced in part or as whole by the approved firm / supplier within 30 days.

6) The District authority will also do random testing of the supplied reagent in NABL approved laboratory for which quality testing, packing & forwarding charges if any will be borne by the supplier in case of tender items.

7) The supply must be made door delivery in good conditions. Undersigned will not be held responsible for any damage or loss of the goods during transportation.

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.
- 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.

If selected, demonstration of all reagents should be provided by the company with demo kits.

Chief District Medical and Public Health Officer
Mayurbhanj

ANNEXURE –I

CHECK LIST

(To be submitted in **Cover A Technical Bid**)

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

COVER – A (TECHNICAL BID)

Sl. No.	Name of the documents	Page no.
1	Tender Document Fee	
2	Earnest Money Deposit	
3	Photocopy of PAN	
4	Photocopy of GST regd. Cert.	
5	Declaration Form **(Annexure-II)**	
6	Proof of Avg. Annual Turnover **(Annexure-III)**	
7	Manufacturer's Authorization **(Annexure-IV)**	
8	Copy of Valid ISO Certificate	
9	Copy of Valid GMP/WHO GMP certificate	
10	Copy of Purchase Order & End User Certificate	
11	Copy of Downloaded Tender paper duly signed by the tenderer	

ANNEXURE-II

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 C.D.M & P.H.O, Mayurbhanj, Odisha for the supply of Bio-chemical Reagents and Rapid Testing Kits. 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 paper Reference no.

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

I/We agree that the Tender Inviting Authority can forfeit the Earnest Money Deposit and black list me/us if, any information furnished by us proved to be false at the time of inspection / Verification and not complying with the Tender terms & conditions.

I / We further declare that I / We possess valid manufacturing licence / authorised distributor bearing no……. Valid up to……. I / We……. do hereby declare that I / we will supply the _____ as per terms, conditions & specifications of the tender document.

Signature of the bidder :
Date :
Name & Address of the Firm:
Seal

ANNEXURE – III

(To be submitted in **Cover A -Technical Bid**)
*(To be furnished in the **letter head** of the Auditor/ Chartered Accountant)*

ANNUAL TURN OVER STATEMENT

The Annual Turnover for the last three financial years of M/s_____ who is a Manufacturer /Distributor/Importer *(Pl. tick whichever is applicable)* are given below and certified that the statement is true and correct_____

Sl.No.	Year	Turnover in (Rs.)
1.	2015 - 2016	-
2.	2016- 2017	-
3.	2017 – 2018	-

Average Annual Turnover (for the above three years) in **(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/Chartered Accountant mentioning the Membership no.*

ANNEXURE – IV

(To be submitted in ***Cover A -Technical Bid***)
MANUFACTURER'S AUTHORISATION FORMAT

To

_____
_____

Ref: Tender No. _____ Dated. _____ for _____.

Dear Sir,

We, ---------- are the manufacturers of ---------- (name of drugs/consumable/lab chemical and have the manufacturing factory at ---------

1. Messrs ---------- (name and address of the agent) is our authorized distributor for sale of ---------- (name of the item(s))

2. We confirm that **Messrs** ---------- (name of the above distributor) is authorized to submit a tender and enter into a contract with you for the above goods manufactured by us.

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 *letter head* of the *manufacturer* and should be signed by a person having the power of attorney to legally bind the manufacturer.**

Original letter shall be attached to the technical bid.

ANNEXURE-V

TEDNER FORMAT FOR PRICE BID (COVER-B)

Sl No.	Name of the items	Strength / Specification	Unit	Manufacturing Firm	Unit Price Including all taxes along with cost of Transportation, Packing, Insurance	GST %)	Amount of GST	Remarks
1	2	3	4	5	6	7	8	10

N.B. price to be quoted in Indian rupees only.

BIO-CHEMICAL REAGENTS

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
15	S.Cholesterol	25/50/100 R1,R2-Standvial	Endpoint	0.3 mg/dL	800-900mg/dL
16	S.Triglyceride	25/ 50/100	Endpoint	1.6 mg/dL	600-700 mg/dL
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

REAGENT BOTTLES

Sl. No.	Name of the item	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	1. **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	**2. Different Leucocytes Count**	
4	**Malaria parasite**	**JSB Stain-I** i. Methylene Blue (Medicinal) : 0.5 gm ii. Sulphuric Acid (H2SO4) 1% : 3 c.c. iii. Potassium Dichromate (K2Cr2O7): 0.5 gm iv. Disodium Hydrogen Phosphate: 3.5 gm Dehydrate (Na2HPO42H2O) v. Distilled Water: 500 c.c. **2 JSB Stain-II1** 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	**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	ESR stand (minimum 10 pipette)	
7	ESR pipette ()	
8	Vial :	Florid vial Clot activator vial Plan vial screw cap K3 EDTA vial
9	**Distilled water.**	Laboratory grade disttle water 0.1 micron filtered pH value :5-7.5 Packed in transparent in 5lt Jar
10	**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 unsensitised cells 4. should not haemolyse the cells. 5. Should not produce rouleaux **6. Titre** : 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)
11	**OccultBlood:**	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. Leishman : Pack size of 250ml/500ml/1000ml,Buffer solution pH value lies: 6.4-7.00, Self life minimum 12months
12	Total Eosinophil count:	Absolute Eosinophil Count fluid, size: 100ml, stable at Room temperature.
13	Total red blood Cell Count:	RBC diluting Fluid, Size: 100ml, stable at Room temperature. 10.
14	Platelet Count:	Platelet Diluting Fluid, 100ml, stable at Room Temperature. 11.
15	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

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 **Unopened kit:**2-8OC **Opened kit :** 2-8OC 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 **Unopened kit:**2-8OC **Opened kit :** 2-8OC 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 **Unopened kit:**2-8OC **Opened kit :** 2-8OC 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 **Unopened kit:**2-8OC **Opened kit :** 2-8OC 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 **Specificity:** Negative reacting with 'O ' phenotype Reactivity: 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
❖ Manufacturer should be ISO13485 certified ❖ Product should be CE certified as per IVD directive		

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 ISO 13485 certified
- All the kits should approved by CE(IVD) /USFDA/GMP
- All the Kit should be DCGI approved.
- If selected, demonstration of all Kits should be provided by the company with demo kits

Sl. No.	Name of the item	Specification
1	RPR Card test for syphilis	Intend of Use:The assay should allow for qualitative and semi quantitative determination of regain 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 aspreservative. 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: ➢ Glucose ➢ Bilirubin ➢ Ketone (Acetoacetic acid) ➢ Specific Gravity ➢ Blood ➢ pH ➢ Protein ➢ Urobilinogen ➢ Nitrite ➢ Leukocytes ➢ 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. The minimum self-life of the urine strips should be 1year unopened and minimum 3months 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 Ketones- Single test Glucose, Protein &pH-Three parameter Glucose, Protein pH, Leukocytes, Nitrites, Ketones, Bilirubin, Blood, Urobilinogen, and Specific Gravity-10 parameter 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 1minute. Accuracy:99% Sensitivity:20mIU/mL The test strips should have inbuilt quality control to achieve the above accuracy. **Kit Configuration** ➢ Urine Pregnancy Test Rapid Card ➢ Disposable pipette ➢ 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 ➢ Homologuesantigen antibody reaction with no cross reactivity with other salmonellar groups ➢ High specificity:98% ➢ Higher sensitivity:98%

		➢ Self-life 1year
10	**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%
11	**DengueIgM/ IgG Rapid**	Test should be a solid phase in vitroimmunochromatographic test for the qualitative anddifferential detection of IgG and IgM antibodies to denguevirus serotype DEN-1, 2, 3 and 4 in human serum, plasmaor whole blood The test should be able to differentially detect IgG and IgMantibodies against all 4 serotypes of Dengue virus Results should be available in 15-20min. Test should be able to give a presumptive

		differentiationbetween primary & secondary dengue infections Test should have no cross reactivity with other Flavivirusgroup mediated and mosquitoes-borne disease Dengue IgG/IgM (Plasma Serum WB) : Sensitivity 94%, Specificity ≥ 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 thestatutory authority in its country of origin In case of imported kits it should be registered and licensedin India by DCG (I) In case of indigenous manufacturers they should belicensed by the competent authority defined under Drugsand Cosmetics act 1940 after appropriate evaluation by thecenters 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
12	**Malaria Rapid Kit**(Malaria Antigen Rapid (Pan Specific / pf))	Should be a rapid Immunochromatographic 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 componentsmethodologies,

		validity criteria, storage conditions, expiry date and limitations of test should be provided The kit to be procured should have approval of thestatutory authority in its country of origin In case of imported kits it should be registered and licensedin India by DCG (I) In case of indigenous manufacturers they should belicensed by the competent authority defined under Drugsand Cosmetics act 1940 after appropriate evaluation by thecenters approved by DCG(I) Kit should have minimum shelf life of 12 months(whichever is more at the port of discharge of consignees
13	**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:10-15minutes 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.
14	**Troponin T**	**Qualitative detection of troponin in anticoagulated** (EDTA or heparin) venous whole blood o Reaction time< 15 min. o Positive result from a threshold (cut-off) of 100 ng/L o Storage at 2 to 8°C o Test can be used immediately after removal from therefrigerator o 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