OFFICE OF THE CHIEF DISTRICT MEDICAL & PUBLIC HEALTH OFFICER,
SONEPUR
E-Mail: smosubarnapur@gmail.com,
Phone No- 06654-220999

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Letter No 3060 / Date 31.7.18

OFFICE OF THE CHIEF DISTRICT MEDICAL & PUBLIC HEALTH OFFICER, SONEPUR

No. /
DWH / 02 / LABCHEM / 18-19 **Tender Call Notice** Date31.07.2018

Sealed tenders are invited from authorized Manufacturers / Suppliers / Distributors for **supply of Laboratory Chemicals & Other Items under NIDAAN** to Subarnapur district. The details are available in the district website: **www.subarnapur.nic.in**. The tender paper cost of Rs1000/- + (Non-Refundable) in shape of Demand Draft from any nationalized Bank in favour of **ZSS NON NRHM, Sonepur** payable at **SBI Sonepur(1085),** Odisha. The eligible bidders may submit their tender papers **on or before 21.08.2018 till 01.00 PM** through **Registered Post / Speed Post** only to the undersigned. The tender documents will be opened on **21.08.2018 at 02.00 PM.** in the office chamber of the undersigned. The bidders or their representatives may present at the time of opening. **The undersigned reserves the right to accept or reject any or all the tender without assigning any reason thereof.**

Sd/- (Dr. B L Guru)
Chief District Medical & Public Health Officer
Subarnapur

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Chief Dist. Medical & Public Health Officer
Subarnapur

TERMS & CONDITIONS FOR
SUPPLY OF Laboratory Chemicals & Other Items
Chief District Medical& Public Health Officer, Subarnapur
(HEALTH & F.W. DEPTT., GOVT. OF ORISSA)

Bid Reference No. – C.D.M. &P.H.O. (Subarnapur) – DWH / 02 / LABCHEM / 18-19

TENDER DOCUMENT FOR SUPPLY OF *Laboratory Chemicals & Other Items under NIDAAN*

LAST DATE & TIME OF RECEIPT OF BID DOCUMENTS : 21.08.2018 till 01.00 P.M

DATE & TIME OF OPENING OF TENDER : 21.08.2018 at 02.00 PM.

PLACE OF OPENING OF BID DOCUMENTS: **OFFICE CHAMBER OF CDM & PHO, SUBARNAPUR**

ADDRESS FOR COMMUNICATION AND RECEIPT OF BID DOCUMENTS

O/o. C.D.M & PHO, SUBARNAPUR
(Central Drug Ware House)
Subarnapur – 767017.

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SALE OF TENDER / BID DOCUMENT

Sealed tender are invited from the manufacturers / Suppliers/ Distributors for supply of Laboratory Chemicals & Other Items under NIDAAN. The Bidders have to download the Tender Documents directly from the district WEBSITE available at **www.subarnapur.nic.in** within the stipulated period The tender paper cost of **Rs1000/-** (Non-refundable) & EMD for an amount of **Rs10,000**/- (Refundable) in shape of Demand Drafts separately drawn from any Nationalized Bank in favour of **ZSS Non-NRHM, Sonepur** payable at SBI, Sonepur (**1085**) must be enclosed along-with the Technical Bid. The envelope must be super-scribed with, "**Tender for Supply of Laboratory Chemicals & Other Items under NIDAAN & Last date of receipt 21.08.2018 till 01 PM**" on the top of the outer envelope containing Technical Bid (Bid-A) and Price Bid (Bid-B) separately. The authority i.e C.D.M & P.H.O, Subarnapur shall have no responsibility for any delay / omission on part of the bidder. **The tender paper will be rejected if the bidder changes any clause or Annexure of the bid document downloaded from the website.**

IMPORTANT INSTRUCTIONS TO BE NOTED CAREFULLY BY THE TENDERERS

1. Purchaser : **Health & F.W. Department**
2. Indenter : **C.D.M. & P.H.O, Subarnapur**
3. Consignee : **C.D.M. & P.H.O, Subarnapur**
4. Delivery Period : Within 30days from issue of the purchase order.
5. Mode of Delivery : By Air / Road / Rail (**On door delivery basis**)
6. **EMD**

. The Earnest Money Deposit (EMD) for an amount of Rs.10000/- (Rupees Ten Thousand) only per tender must be submitted in the shape of demand Draft only in favour of **ZSS Non-NRHM** , Sonepur, from any Nationalized Bank payable at SBI, Sonepur (**1085**). The EMD will be refunded to the unsuccessful bidders and the EMD of qualifying bidders will be refunded after successful completion of supply of items within the stipulated time-period.

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7. **General Conditions for supply:**

a) Under no circumstances, the organization shall appoint any sub contractor or sublease the contract. If it is found that the organization has violated these conditions the contract will be terminated forthwith without any notice and security deposited (EMD) by the organization shall be forfeited.

b) The supply should be made in good packing condition & labeling **"Orissa Govt. Supply, NOT FOR SALE"**. **MRP should not** be mentioned anywhere in Bottle / Packet etc.

c) All bills should be super – scribed as **Supply of Laboratory Chemicals & other Items under NIDAAN** & bill should be prepared on values of the goods + all taxes.

d) The quoted price must be **inclusive of all taxes**.

e) All bills should contain the **GST number.**

f) Liquidated demurrage will be charged @ 0.5% on order value per week beyond 30 days & upto 44 days from the date of issue of the purchase order. The order will automatically stand cancelled after the due period & no further communication will be made in this regard.

g) Xerox Copy of PAN card must be attached.

h) The manufacturer should be ISO 13485 certified & the product should be USFDA/CE (IVD) approved.

i) Copy of Income Tax statement for the last three financial year i.e.2014-15, 2015-16 & 2016-17.

j) Photocopy of the **GST registration** certificate.

k) The manufacturer / supplier should have **three years** market standing experience in supplying to Govt./Corporate/PSU Hospitals in India. The copy of purchase orders (**at least three for each year**) must be submitted in support of the market standing experience.

l) The average annual turnover must not be less than 1.5 crores for the last three consecutive years & the audited balance sheet must be submitted.

l) Bidders who have been blacklisted either by the Tender inviting authority or by any district/state Govt. or Central Govt. organization for the quoted item is not eligible to participate in the tender during the period of blacklisting. **Affidavit of the same from the Notary Public to be submitted stating that "the firm has neither been black listed nor any criminal cases pending against them"**.

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GENERAL TERMS AND CONDITIONS:

1. Sealed tenders will be received up to 21.08.2018 till 01:00 PM at the office of C.D.M. & P H.O. Subarnapur for the purchase of Laboratory Chemicals & Other Items under NIDAN. Any tender received after the due date & time will be rejected / returned to the sender unopened. **The tenders will be received through Regd. Post / Speed Post only.**
2. The bidders have to submit their tenders in separate sealed covered envelope for technical bid and financial bid by subscribing "**Technical Bid**" in cover "A" and "**Financial Bid**" in cover "B" and both covers should be put in third cover which should be subscribed as "**Tender for Supply of Laboratory Chemicals & Other Items under NIDAAN & Last date of receipt 21.08.2018 till 01 PM**".
3. The sealed tender of Cover "A" (Technical bid) submitted by the tenderer will be opened before the purchase committee in the office chamber of the CDM&PHO, Subarnapur, on dated 21.08.2018 at 02.00 PM. The bidder or his representative may present at the time of opening of the tender.
4. The Financial Bid will be opened of only those who have technically qualified.
5. Delivery Period within 30 days from the issue of the supply order.
6. Rate quoted must be **inclusive of all taxes** & will be valid for a **period of one year** from the date of approval.,
7. The quoted rates must be computerized both in **words & figure**.
8. If there is difference between figures & words, **words will be taken** into consideration.
9. The price quoted by the bidders must not in any case, exceed the controlled price, if any, fixed by the Central / State Government / DGS&D and the MRP.
10. The undersigned reserves the right to place the order in phases.
11. On all Bottles/Packets/ Boxes /Cartoons etc the words " **ORISSA GOVT. SUPPLY, NOT FOR SALE** " will be mentioned & there **must not be any MRP** on any supplied items.
12. All the documents must be self attested.
13. The selection will be made considering the quality & cost of the product & the decision of the purchase committee is final.
14. **The undersigned reserves the right to reject any or all the tender without any reason thereof.**

Sd/- (Dr B L Guru)
Chief District Medical & Public Health Officer
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Chief Dist. Medical & Public Health Officer
Subarnapur

Check List

Please put √ in the respective box

Application for Supply of Drugs & Consumables to Subarnapur District.

Sl No	Details	To be filled up	Remarks
1	Name of the Firm with Complete Correspondence Address with mobile no		
2	whether tender paper cost in shape of DD worth of Rs 1000 /- to be submitted along with the tender paper.	Page No. / From / To / Yes / No	Details of DD no. & date to be mentioned
3.	EMD Deposited (Yes/ No)	Page No. / From / To / Yes / No	Details of DD no. & date to be mentioned
4.	GST Registration & PAN card (Xerox Copy) submitted or Not	Page No. / From / To / Yes / No	
5	Income Tax Return for last three Years	Page No. / From / To / Yes / No	
6	Audited balance sheet for last three years for Average Annual Turnover of 1.5 crores.	Page No. / From / To / Yes / No	
7.	Manufacturer, ISO 13485 certificate & CE (IVD)/USFDA certificate of the product.	Page No. / From / To / Yes / No	
8.	Affidavit from Notary Public regarding Non-blacklisting of the supplier / agency / firm.	Page No. / From / To / Yes / No	
9	Tender document containing total no of pages.	Page No. / From / To	

Certified that, the above information submitted by me/my firm is true to the best of my knowledge and if any information is found false at any point of time then the whole offer/tender may be cancelled. I have suppressed no facts in the tender which could debar me to participate in the tender. If it is revealed after opening of the tender that any fact is suppressed by me, tendering authority shall have the right to reject my tender along with other punitive action against me as per law. Again I agree & will abide with the terms & conditions fixed by the authority.

Full Signature of the tenderers.
Mobile No & Address

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List of Items (Enclosed in Separate Sheet)

Sl no.	Name of the Item	Pack size	Name of the manufacturer	Rate Quoted (Inclusive all Taxes)	Remarks
1					
2					
3					

Full Signature of the bidder

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List of items		
Sl No	*Name of the Item*	*Pack size*
A	*B*	*D*
1	VDRL Rapid	100 Tests
2	Cover Slip	Pkt of 50
3	Benedicts Reagent	500 ml
4	K3EDTA Vial	Pkt of 100
5	Clot Activator	Pkt of 100
6	ESR Tube	each
7	ESR stand	each
8	ESR Tube (Disposable)	each
9	Capillary Tube	Pkt
10	Glass test Tube for centrifuge (Borosil)	pkt of 100
11	Litmus Paper (Red)	Pkt
12	Litmus Paper (Blue)	Pkt
13	HB Tube	each
14	HB Pippette	each
15	Dispo Needle	No-24
16	Sulphar Powder	100 gm
17	Micro Pipette	0-10 µ
18	Micro Pipette	10-1000 µ
19	Micro Pipette	10-100 µ
20	Micro Pipette	20-200 µ
21	Liquid Parafin	500 ml
22	Methanol	500 ml
23	Leishman Powder	25 gm
24	Micro Tips	0.5-10 ml
25	Micro Tips	20-200 ml
26	Micro Tips	100-1000 ml
27	Lense Cleaning paper	each
28	Tissue paper Roll	each
29	Sulphuric Acid	500 ml
30	Glacial Acetic Acid	500 ml
31	Rectified Spirit	500 ml
32	Fouchet Reagent	100 ml
33	Filter paper	pkt
34	Specimen Container	30 Ml
35	Plastic Wash Bottle	500ml
36	Glass test Tube 16x125mm	Pkt of 100
37	Glass test Tube 12x75mm	Pkt of 100
38	Glass test Tube 12x100mm	Pkt of 100
39	Spirit Lamp (S. S)	each
40	Test Tube Holder	each
41	HBA1C Kit (SD)	Pkt of 20
42	CBC Diluent (Medonic)	20 Ltrs Jar
43	CBC Lyser (Medonic)	5 Ltr jar
44	K2EDTA 20µl Boule (Medonic)	Pkt of 100
45	Glass Slide	Pkt of 50
46	Funnel Plastic	each
47	Plastic Pasture Pipette	each

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48	Staining Rod 2ft	each
49	Barium Chloride powder	500 Gm
50	Barium Chloride 10%	500 ml
51	Hydrogen Pyroxide	100ml
52	Gluco Strip BG03	Pkts of 50
53	Urine alysis Reagent Strip (Uristick)	100 Tests
54	Test Tube Wash Brash	each
55	QBC Tube BD	200Tubes
56	QBC Oil	100 ml
57	Parafin Wax	500 gm
58	Tourniket	each
59	Microscope Bulb	6v 20 W
60	Toxo plasma card	Each
61	Hepatitis C card	
62	X-ray Film (Digital)	10 X 12
63	X-ray Film (Digital)	8 X 10
64	X-ray Film (Digital)	14 x 17
65	BP Blade size-	Pkt of 100
66	BP Blade Holder	each
67	Diamond Marker	each
68	Screw Cap Vial (1.8ml)	each
69	Screw Cap Vial Box	each
70	Conical centrifuge tube(5ml)	each
71	RPR card Test	50
72	HIV rapid whole blood finger test kit	30
73	Rheumatoid Factor	50
74	ASO Kit	35
75	HBsAG	25
76	CRP-C-Reactive Protein (CRP)slide	50
77	Urine complete rapid test reagent strip	100
78	Urine Pregnency Test	40
79	Widal test kit	5 ml
80	Dengue Rapid kit (Dengue NS1 Ag Rapid)	25
81	DenguelagM/IgG Rapid	25
82	Malaria Rapid Kit (Malaria antigen rapid/Pan specific/pf)	25
83	Troponin-I (Card Test)	10
84	Troponin-T	10
85	Hemoglobin Estimation (N/10 HCL)	1000 ml
86	Total Leukocytes counts (WBC diluting fluid)	500 ml
87	Giemsa stain	500ml
88	Leishman Stain	500 ml
89	JSB Stain -I	500 ml
90	JSB Stain -II	500 ml
91	ESR (3.8 % sodium citrate soln.)	500 ml
92	Distilled Water (Laboratory grade DW)	5 Ltr
93	Blood grouping (ABORH typing)	
	Anti-A	10 ml
	Anti-B	10 ml
	Anti-AB	10 ml
	Anti-D	10 Ml

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	Anti-H	10 Ml
	Anti-A1	10 ml
94	Bovine Albumin for grouping & cross matching	10 ml
95	Antigen for red cell panels	4*10 ml
96	Absolute Eosinophil count fluid	100 ml
97	RBC diluting fluid	100 ml
98	Platelet diluting fluid	100 ml
99	Packed cell volume test kit	10 kit
100	Occult blood strip	Each
101	Coombs Reagent (Direct/Indirect)	10 ml
102	Blood Sugar (GOD/POD)	1000 ml
103	Blood Urea (End point)	1000 ml
104	S. Creatinin	1000 ml
105	S. Bilirubin (T)	200 ml
106	Bilirubin (D)	200 ml
107	SGOT	200 ml
108	SGPT	200 ml
109	S. Alkaline Phosphate	200 ml
110	S. Total Protein	50 ml
111	A. Albumin	50 ml
112	S. Calcium/Pottasium /Sodium	100 ml
113	S. LDH	200 ml
114	S. Amaylase	100 ml
115	S. Uric Acid	50 Ml
116	S. Cholesterol	100 Ml
117	S. Triglyceride	100 ml
118	S. VLDL	100 ml
119	S. HDL	50 ml

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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.
- 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.

Sl.No	Name of the Reagent	Pack Size(in ml)	Method	Sensitivity	Linearity
1	Blood Sugar	1000	End point	0.6mg/dl	400mg/dl
2	Blood urea,	1000	End point	2.5mg/dl	300-350mg/dl
3	S. creatinin	1000 R1,R2,R3-Stanard (Vial)	2-point	0.05mg/dl	Upto 30mg/dl
4	S.Bilirubin (T)	200 R1,R2-Direct Nitrite Vial	End Point	0.1mg/dl	20mg/dl
5	Bilirubin (D)	200	End Point	0.2mg/dl	25mg/dl
6	SGOT	200	Kinetic	8u/l	Up to 800U/l
7	SGPT	200	Kinetic	5u/l	Up to 800U/l
8	S.Alkaline Phosphate	200	Kinetic	8.8U/L	Up to 700U/l
9	S.Total Protein	50 R1,R2-Standard(vial)	End point	0.17g/dl	Upto 18g/dl
10	S.Albumin	50 R1,R2-Standard(Vial)	End point	0.1g/dl	.6-.7g/dl

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11	S.Calcium/Potacium/ Sodium	100 R1,R2-Standvial	End point	0.12mg/dl	25mg/dl
12	S.LDH	200	Kinetic	0.13mg/dl	20-1000mg/dl
13	S.Amaylase	100	kinetic	0.03	1300U/l
14	S.Uric Acid	50 R1,R2-Standvial	Endpoint	0.02mg/dl	Up to 25mg/dl
15	S.Cholesterol	100 R1,R2-Standvial	Endpoint	0.3 mg/dL	800-900mg/dL
16	S.Triglyceride	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	50	End Point	3.0 mg/dL	150 mg/dL

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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
- 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

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.

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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**

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.

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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 %

5. 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**

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

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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.
- 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 **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 1minute.
- Accuracy:99%
- Sensitivity:20mIU/mL
- The test strips should have inbuilt quality control to achieve the above accuracy.

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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
- Homologuesantigen antibody reaction with no cross reactivity with other salmonellar groups
- High specificity:98%
- Higher sensitivity:98%
- Self-life 1year

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)

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- 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.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

11.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

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- 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

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:10-15minutes
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.

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 therefrigerator
- 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

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1. **Hemoglobin Estimation**:

Reagent/Chemicals:

- (N/10) Hydrochloride Solutions (HCL)
- Pack Size: **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: **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_2SO_4) 1% : 3 c.c.

iii. Potassium Dichromate ($K_2Cr_2O_7$): 0.5 gm

iv. Disodium Hydrogen Phosphate: 3.5 gm Dehydrate ($Na_2HPO_4 2H_2O$)

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 **500 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: **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 disttle water
0.1 micron filtered
pH value :5-7.5

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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: **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: **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: **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)

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		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** dropper vial. Stability : at 2-80 C Self-life: 24 months. The reagent should contain 0.1% sodium azide as a preservative.

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		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		

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 10nos

12. 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.

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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: **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)

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