

**Terms and Conditions for Supply of
Lab Reagents & Consumables
For
Puri District**

Chief District Medical & Public Health Officer
(on rate contract basis for one year)

Tel / Fax: 06752-222124/232294

E-Mail-cdspuri@gmail.com

**TENDER DOCUMENT FOR SUPPLY
OF
LAB REAGENTS & CONSUMABLES UNDER NIDAAN**

LAST DATE & TIME FOR SUBMISSION OF TENDER DOCUMENT: 10.09.2018 upto 5 P.M

PRE-BID DISCUSSION : 27.08.2018 at 11 A.M

DATE & TIME FOR OPENING OF TENDER DOCUMENTS : 11.09.2018 at 11.00 A.M

**PLACE OF OPENING OF TENDER
AND**

**OFFICE OF THE CHIEF DISTRICT MEDICAL & PUBLIC HEALTH
OFFICER**

ADDRESS FOR COMMUNICATION

AND

HOSPITAL SQUARE, GRAND ROAD PURI

RECEIPT OF BID DOCUMENT

PURI

OFFICE OF THE CHIEF DISTRICT MEDICAL & PUBLIC HEALTH OFFICER:PURI

Grand Road, Medical Square, Puri. Pin No.-752002
Phone No-06752-222124(O) & 232294(C.S), E-Mail ID-cdspuri@gmail.com
No. 5039 C.S. Puri Dated.18.08.2018

TENDER CALL NOTICE

Sealed Tenders are invited from the Reputed Manufacturers, Authorized Distributors having valid distributor license from principal manufacturer, EPM & GEM Rate contract Firms for supply of the Lab Reagents & Consumables under NIDAAN for Puri District during the year 2018-19. The rate should be quoted including all taxes. The supply should be door delivery & no freight charges should be borne by this Office.

The tender proposals should reach to the undersigned on or before **10.09.2018 upto 5 PM** and the same will be opened on dated **11.09.2018 At 11.00 A.M** in the office chamber of the C.D.M & P.H.O., Puri in presence of the tenderers or their authorized representatives. The authority reserves full rights to accept or reject any or all tenders without assigning any reason thereof.

Receipt of Tender

The sealed tender must be sent through Regd. Post/Speed Post/ Courier Services only.

Tender Cost

The Bidders have to download the Tender Documents directly from the WEBSITE available at www.puri.nic.in. The Tender Paper cost fee of Rs.1000/- by way of separate Bank Draft drawn in favour of CDM & PHO ,Puri payable at Puri

E.M.D

- (i) The tenderer is required to submit the earnest money deposit amounting to Rs.10,000.00 (Ten thousand) only in shape of bank draft from any nationalized bank in favour of C.D.M & P.H.O, Puri.
- (ii) The E.M.D of the unsuccessful bidder will be returned only after finalization of the tender.
- (iii) The E.M.D of the successful bidder will be returned only after submission of the performance security.
- (iv) The E.M.D will be forfeited if the successful bidder will refuse to supply the indented items.

Performance Security

The successful bidder is required to submit the performance security @ 10% of the purchase value in shape of Bank Guarantee within 21 days from the date of issue of purchase order.

Terms & Conditions

- (i) The bidders are to submit their tenders in separate sealed covered envelops for technical bid & price bid by superscribing Cover 'A' (Technical Bid) & Cover 'B' (Price Bid) and both the covers should be put into a third cover , which should be superscribed as **'TENDER FOR SUPPLY OF LAB REAGENTS & CONSUMABLES UNDER NIDAAN FOR PURI DISTRICT'**.
- (ii) Tenders shall be opened on due date and time as mentioned above in case the scheduled date is declared as Govt. holiday then such date shall automatically shifted to next working day.
- (iii) The price bid will be opened only those bidders who have qualified in the technical bid & should be submitted as per format with signature & Seal.

- (iv) The rate will be valid up to one year from the date of approval.
- (v) The price quoted by the bidder must not exceeds the controlled price if any fixed by the Central Govt/State Govt/GEM and MRP.
- (vi) The selection will be made considering the quality & cost of the product as well as the decision of the Purchase committee.
- (vii) Preference will be given to the MSE/SSI units of the state of Odisha as per MSME Development Policy -2009 and IPR-2007.
- (viii) In case of any tender amendment and clarification, responsibility thereon lies with the tenderer to collect the same from the Web site before the last date of submission of tender& purchaser shall have no responsibility for any delay/omission on part of the tender.
- (ix) Order will be given at the time of non-supply from OSMCL and as per the requirement as well as availability of funds.

Documents to be submitted with the Technical Bid

- (i) Attested copy of GST regd Certificate, PAN Card are to be attached in the tender proposal.
- (ii) Manufacturer must be an ISO13485 certified organisation. Xerox copy of valid ISO certificate should be attached & the product should be USFDA/CE (IVD) approved.
- (iii) The Bidder should have 3 Years market standing in supply of items to Govt/corporate/PSU hospitals in India,copy must be submitted with the tender.
- (iv) Incase of authorised distributor the authorisation certificate from the principal manufacturer must be submitted with the tender proposal.
- (v) The Annual turnover of the tendering firm should be Rs.1Crore or more in each financial year and last preceding 3(three) financial years duly certified by a chartered accountant.
- (vi) The bidder is required to provide a self declaration in an affidavit (as per annexure -1) that he has not been black listed by any Govt. organisation & he has gone through the tender document carefully and shall accept all terms and conditions of the document.

Supply

- (i) The supply should be door delivery i.e Central Store, Puri within 30 days from the date of issue of the purchase order to meet the emergency need.
- (ii) All the items should be packed as per the unit pack size as mentioned in the price bid, no loose items should be accepted.
- (iii) The supply should be in less no of batches with remaining shelf life of at least 5/6th of the stipulated shelf life from the date of manufacturing of that product.
- (iv) The Dist. Authority will also do random tasting of the supplied items in approved laboratory for which quality testing, packing, forwarding charges if any will be borne by the supplier.

Payment.

- (i) 100% payment will be released only after completion of the supply.

Chief District Medical & Public Health Officer: Puri.

DECLARATION FORM

I / Wehaving My / our
.....office at.....do declare
that I / We have carefully read all the terms & conditions of tender of the _____, Odisha
for the supply of Lab Reagents and consumables under Nidaan of Puri district. 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 that 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 or
Security Deposit and blacklist me/us for a period of 5 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.

I / We further declare that I / We possess valid manufacturing license / authorised
distributor bearing noValid upto I / We
..... do hereby declare
that I / we will supply the _____ as per the terms, conditions & specifications of
the tender document.

Signature of the bidder :

Date :

Name & Address of the Firm:

Affidavit before Executive Magistrate / Notary Public.

List of the Items

Sl No	Name Of The Reagent Solution & Chemicals	Unit Of Measure
1	N/10 Hydrochloric Solution(Haemoglobin Estimation)	In ml
2	Haematology test reagents for automated haematology analyser(5 part/3 part)	In test
3	Haematology test under microscope	
3.1	WBC Diluting Fluid(TLC)	In ml
3.2	Total Eosinofil count	In ml
3.3	RBC Diluting Fluid(Total Red Blood Cell Count)	In ml
3.4	Platelet Diluting Fluid(platelet count)	In ml
3.5	Distill Water	In ml
4	Blood Grouping(ABO-RH typing)Anti-A,Anti-B,Anti-AB,Anti-D,Anti-H,Anti A1,Bovine Albumin,Antigen for Red cell panel)	In ml
5	JSB Stain-I,JSB Stain-II(Malaria Parasite)	In unit
6	3.8 % Sod Citrate Solution (ESR)	In ml
7	Coombs Reagent(Direct & Indirect)AHG Anti C3d monoclonal)	
8	Laborotory Stain(Giema Stain,Leishman Stain)	In ml
9	Immersion Oil(Microscope)	In ml
10	Occult Blood	In unit
11	PT Reagent(prothombin time)	In ml
Rapid & Packed Kits		
1	RPR Card(Syphilis)	In unit
2	HIV Rapid	In unit
3	Rheumatois Factor(Rh typing)	In unit
4	ASO	In unit
5	HbsAg(Rapid)	In unit
6	CRP	In unit
7	Uri- Stic	In unit
8	Pregnancy Kit	In unit
9	Widal Kit	In unit
10	Malaria Rapid	In unit
11	Dengue	In unit
12	Toxoplsma(Rapid)	In unit
13	Hepatitis B & C card test	In unit
14	Troponin-I	In unit
15	Troponin-T	In unit
16	H2S Strip	In unit

Sl No	Name Of The Reagent Solution & Chemicals	Unit Of Measure
Biochemical Reagents(semiauto/fully auto analyser)		
1.a	Blood Sugar(Lab Method)	In ml
1.b	Blood Sugar(Glucometer strip)	In unit
1.c	Blood Sugar(Glucomter strip with lancet)	In unit
2	Blood Urea	In ml
3	S.creatinin	In ml
4	S.Bilirubin(T)	In ml
5	Bilirubin(D)	In ml
6	SGOT	In ml
7	SGPT	In ml
8	S.Alkaline Phosphate	In ml
9	S.Total Protein	In ml
10	S.Albumin	In ml
11	S.Calcium/Potacium/Sodium	In ml
12	S.LDH	In ml
13	S.Amalyse	In ml
14	S.Uric Acid	In ml
15	S.Cholesterol	In ml
16	S.Triglyceride	In ml
17	S.VLDL	In ml
18	S.HDL	In ml
Other Consumables		
1	Glass Slide	In unit
2	Pipete Tips	In unit
3	Urine Collection bottle	In unit
4	EDTA sample Tube	In unit
5	Plain vial for blood collection	In unit
6	Fluoride vial for blood collection	In unit

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 (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-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 disttle water
0.1 micron filtered
pH value :5-7.5
Packed in transparent

7. Blood Grouping (ABO-RH typing)

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

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
<ul style="list-style-type: none"> ❖ 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.
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. 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)

Technical Specification Rapid test Kits

Quality Standard:

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

- The bidder/manufacture 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.

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 %

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/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.
- 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 mosquito-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 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 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: 10 test 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: 1 month

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.

- 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	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

