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

Tender call notice no. 2654 /C.D.M. & P.H.O, Cuttack dated 23 / 02 / 2019

SHORT TENDER CALL NOTICE

Sealed tenders superscribing **"TENDER FOR SUPPLY OF CHEMICALS, REAGENTS, DIAGNOSTIC TEST KITS AND LAB. CONSUMABLES FOR NIDAAN 2018-19"** are invited from the registered manufacturers/importers/ authorized distributers for supply of chemicals, reagents, diagnostic test kits & lab. consumables to the undersigned. The details terms & conditions, product list and specifications are available in the official website of Cuttack district i.e. **www.cuttack.nic.in.** The tender paper can only be obtained from the Sub Store, City Hospital, Cuttack during the office hours from dt.01/03/2019 to 23/03/2019 on payment of Rs.2500/- (Rupees Two thousand Five hundred only) Plus GST @ 18% extra, which is not refundable. The bidders are allowed to submit their tender within dt.25/03/2019 up to 2 PM through Regd. Post/ Courier Service/ Speed Post only in the office of the undersigned and the tender (Technical Bid) will be opened at 4PM on the same day. If the event date being declared as a holiday by the Govt. of Odisha, the due date of submission of bids and opening of bids will be the following working day at the appointed place & time. The authority reserves right to reject any or all the tenders without assigning any reason(s) there off. Any dispute is subject to Cuttack jurisdiction only.

23/2/19

Chief District Medical &
Public Health Officer,
Cuttack

TERMS & CONDITIONS FOR RATE CONTRACT OF LAB. CHEMICALS, REAGENTS, DIAGNOSTIC TEST KITS AND CONSUMABLES

CHIEF DISTRICT MEDICAL & PUBLIC HEALTH OFFICER, CUTTACK
(Health & F.W Department, Govt. of Odisha)
Tel No.0671-2301007/ Fax-0671-2301007

Bid reference No. C.D.M. & P.H.O(2655)/LAB/2018-2019

TENDER DOCUMENT FOR SUPPLY OF CHEMICALS, REAGENTS, DIAGNOSTIC TEST KITS AND CONSUMABLES ON RATE CONTRACT BASIS FOR A PERIOD OF ONE YEAR FROM THE DATE OF APPROVAL OF TENDER

DATE OF COMMENCEMENT OF SALE OF THE TENDER DOCUMENTS:- 01-03-2019

PRE-BID CONFERENCE:- 11-03-2019 (4PM)

LAST DATE & TIME FOR RECEIPT OF TENDER:- 25-03-2019 (2PM)

DATE &TIME OF OPENING OF TENDER (COVER-A) 25-03-2019 (4PM)

DATE & TIME OF OPENING OF TENDER (COVER-B) will be intimated later.

ADDRESS OF COMMUNICATION FOR RECEIPT & OPENING OF TENDER

Zilla Swasthya Bhawan
O/O Chief District Medical & Public Health Officer, Ctc
At-Old Secretariate Campus, Near Banijyakar Bhawan,
Po-Buxibazar, Cantonment Road, Cuttack -753001

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

SALE OF TENDER / BID DOCUMENT

A complete set of bidding documents may be purchased by prospective bidders on payment of a non-refundable fee as indicated below in the form of a Demand Draft in favour of Chief District Medical & Public Health Officer, Cuttack payable at Cuttack from any Nationalised /Scheduled Bank at Sub-Store, O/o the District Medical Officer (Medical Services) Cum Superintendent, DHH, Cuttack during office hours from 11 A.M. to 4 P.M. on all working days.

The Original money receipt against bidding documents cost should be enclosed along with the Technical Bid. The Bidder should specifically superscribe **"TENDER FOR SUPPLY OF LAB. CHEMICALS, REAGENTS, DIAGNOSTIC TEST KITS AND CONSUMABLES FOR NIDAAN 2018-19"** on the top left corner of the outer envelope containing Technical Bid and Price Bid separately. In case of any bid amendment and clarification, responsibility lies with the bidders to collect the same from the website or the office notice board before last date of purchase of tender documents and the CDM & PHO, Cuttack shall have no responsibility for any delay/omission on part of the bidder.

a) Price of bidding document Rs.2500/-plus GST @18%

(Non refundable) (Not Applicable for SSI UNITS)

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

C.D.M & P.H.O, Cuttack

TERMS AND CONDITIONS FOR ACCEPTANCE OF TENDER FOR SUPPLY OF SUPPLY OF LAB. CHEMICALS, REAGENTS, DIAGNOSTIC TEST KITS AND CONSUMABLES TO THE C.D.M&P.H.O, CUTTACK ON RATE CONTRACT BASIS FOR A PERIOD OF ONE YEAR FROM THE DATE OF APPROVAL BY THE COMPETENT AUTHORITY.

1.1 Sealed tenders for the purchase of Lab. chemicals, reagents, diagnostic test kits & consumables will be received in the office of the C.D.M.& P.H.O, Cuttack, Zilla Swasthya Bhawan, At-Old Secretariate Campus, Near Banijyakar Bhawan, Po-Buxibazar, Cantonment Road, Cuttack -753001 within due date and time for submission of tender document as specified therein i.e. 2.00 PM of / /2019. Any tender received after the due date and time will be rejected and returned unopened to the sender. The Tenders will be received through Regd. Post / Courier Service / Speed Post only.

1.2 The sealed tender 'Cover A'(Technical Bid) submitted by the tenderer will be opened by the Purchase Committee at the Officer Chamber of the Chief District Medial & Public Health Officer, Cuttack at 3.00 PM on Dt. / /2019 the tenderers or their duly authorized representative is allowed to be present during the opening of the tenders if they so like.

ELIGIBILITY CRITERIA:-

2.1 Tenderers shall be a Manufacturer/ Importer having valid up-to-date manufacturing License with product endorsement copy, Import License (if bidder is an Importer) , ISO Certificate, GMP Certificate / valid CE as per IVD directive Certificate /USFDA Certificate manufacturing firm, Products should be DCGI approved if the products are imported from abroad. The manufacturer should have PAN card, Last 3 years IT return (2015-16, 2016-17 &2017-18), GST Registration Certificate, Valid GST clearance certificate/ GSTR 3B & GSTR-1(final summery copy) on monthly basis for last quarter.

Note: All above mentioned documents are applicable for Lab. Chemicals, Reagents &Diagnostic Test kits except Consumables.

2.2 Authorized distributer can participate in the bidding process. If so, he/she has to submit Authorization letter from Manufacturer(s)/ Importer, Notarized Xerox copy of Valid Drug License, PAN card, Last 3 years IT return (2015-16, 2016-17 &2017-18), GST Registration Certificate, Valid GST clearance certificate/ GSTR 3B &GSTR-1 on monthly basis for last quarter along with Valid manufacturing License with product endorsement copy, Import License (if products are imported), Valid ISO Certificate, valid GMP certificate / valid CE as per IVD directive certificate/ USFDA certificate of manufacturer, Product should be DCGI approved if the products are imported from abroad.

2.3 The Annual Average Turnover of the Manufacturer should be Rs. 5 Crorers or more during the last three financial years (2015-16, 2016-17 &2017-18) duly certified by the Charted Accountant as per the prescribed format (Annexure –VII). If the tenderer is an Authorized distributor, he/she has to submit the Annual Average Turnover statement of Rs.2 Crorers or more with annual audited statement / Annual Report of his/her firm in prescribed format along with Annual Average Turnover statement of the Manufacturer of Rs.5 Crorers or more. ***The approved authorized distributor (tenderer) shall have the direct responsibility for supply of stock and who shall only be entitled to raise the bills against such supply.***

Payments will be made only in favour of the approved authorized distributor (tenderer).

2.4 Tenderer/manufacturing unit which has been blacklisted for any item either by the Tender inviting authority or by any State Govt. or Central Govt. Organization cannot participate in the Tender for that item during the period of blacklisting supporting to court affidavit (Annexure- I).

2.5 The Tenderer should have typically not less than 3 (three) years of marketing experience in Lab. chemicals, reagents, diagnostic test kits & consumables products supplying to the Government Organization/ Corporate Hospital/PSU Hospital/UN agencies in India duly supported documentary evidence ((05 (five) no's of Purchase Order copy for each financial year duly attested by Notary Public) from minimum 3 (three) or more competent Authorities & End User Certificate from same 3 (three) or more competent authorities for last 3 year i.e. 2015-16, 2016-17, 2017-18) (Annexure- VIII).

2.6 Third party manufacturing units i.e. Lab. chemicals, reagents, diagnostic test kits & consumables manufactured by one unit and marketed by another unit / firm will not be allowed to participate in the tender.

2.7 Tenderer /firm/manufacturing unit is not eligible to participate in the present tender who will have history of supply of four(4) or more NSQ items & four (4) batches of one item during 2015-16, 2016-17 & 2017-18 (all financial years added together) supporting to court affidavit (Annexure-I).

Note:-

A.**"Tenderer"** means the Manufacturer/Importer/Authorized Distributer participating in this tender.

B. Valid up-to-date means the certificate should be valid on the date or beyond the opening of Tender (Cover-A) as per Tender conditions. In case the validity of GMP / manufacturing license has expired within six months on the date of opening of tender and the firm / tenderer has applied for renewal of the same, a letter from the competent authority with treasury challan has to be attached along with the tender submitted mentioning that the renewal is under process consideration as per D & C Act.

Sealed cover containing the tender in the prescribed form should be submitted in two sealed covers, Cover "A"(Technical Bid) & Cover "B"(Price Bid) as indicated below. Both the covers should be put into a third Cover, which should be superscribed as **"TENDER FOR SUPPLY OF LAB. CHEMICALS, REAGENTS, DIAGNOSTIC TEST KITS AND CONSUMABLES FOR NIDAAN 2018-19"**. Reference No C.D.M. & P.H.O(2655)/LAB/2018-2019.

DOCUMENTS TO BE SUBMITTED IN TECHNICAL BID (COVER- 'A'):

3.1 Earnest Money Deposit of Rs. 100000/-(Rupees one lakh) only.

3.2 Checklist with detail of the documents enclosed in Cover 'A' with page number. The documents should be serially arranged as per this format and should be securely tied or bound.

3.3 Particulars of the tenderer (Company, Firm and Individual) and its authorized representative (Director/Managing Partner/Proprietor) like; name, address, telephone no., mobile no., fax, e-mail, etc. (Annexure-IV)

3.4 Address, Telephone No., mobile No., e-mail, Fax of the Branch Office /Contact Person in Odisha. (Annexure-IV)

3.5 List of items quoted with strength / specification and packing. (Annexure-III)

3.6 Valid up-to-date Manufacturing License with product endorsement (i.e. the list of approved items issued at the time of grant / renewal of the license and it should be a single list) of the items quoted / copy of Import license along with registration Certificate with DCGI approval if items quoted are imported wherever applicable. If the validity of Manufacturing License has expired within six months on the date of bid opening, then letter from the competent authority with treasury challan is to be attached along with the tender submitted mentioning that the tenderer has applied for renewal as per D&C Act. 1940 and this will be retained for a period of dt_____ to dt_____

Note: Valid up-to-date Manufacturing License with product endorsement is applicable for all products except consumables).

3.6.1 In case of manufacturer, the copy of the valid manufacturing license issued by the competent authority with product endorsement of each item quoted, has to be submitted along with the tender.

3.6.2 In case of importers, copy of the Import license with approval certificate issued by Drugs Controller General of India will have to be submitted by the tenderer. The importer shall also submit the **Authorization certificate from the manufacturer** to deal business in India.

3.7 Valid up-to-date Good Manufacturing Practice (GMP) certificate/USFDA certificate/ CE as per IVD directive.

3.8 Certificate duly filled by the Auditor / Chartered Accountant that the Annual average turnover of pharmaceutical products of the tendering Manufacturer is Rs. 5 crores or more for preceding 3 (three) financial years i.e. 2015-16, 2016-17 &2017-18 (Annexure-VII). If the tenderer is an authorized distributor, he/she has to submit the Annual Average Turnover of 2 crorers or more in prescribed format with annual audited statement / Annual Report duly filled by the Chartered Accountant of his/her firm along with manufacturer(s) Turnover statement for preceding 3 (three) financial years i.e. 2015-16, 2016-17 & 2017-18. (Annexure-VII).

3.9 Tenderer has to submit Market Experience (Performance Statement (Annexure-VIII)) towards supply of the Lab. chemicals, reagents, diagnostic test kits and lab. consumable products to Govt./ Corporate Hospitals/ PSU Hospitals in India during the last 3 financial years. Notarized copies of ((05(five) no's of Purchase Order copy for each financial year duly attested by Notary Public) from minimum 3 (three) or more competent Authorities & End User Certificate from same 3 (three) or more competent authorities for last 3 year i.e. 2015-16, 2016-17, 2017-18) (Annexure- VIII)

3.10 The Tenderer has to submit Court Affidavit or Affidavit from Notary Public in respect to not been convicted under the provision of D&C Act 1940 by any court of law in contravention to the above Act & Rules & has not been blacklisted for any item either by the tender inviting authority or by any state Govt. or Central Govt. Organization participate in the tender for that items during the period of blacklisting. (Annexure- I)

3.11 The Original Tender Book duly signed and sealed by the bidder in each page with Original Money Receipt.

3.12 Valid & up-to-date ISO Certificate of the Manufacturer. (applicable as per product which are mentioned in Technical Specification attached in Annexure IX).

3.13 Valid CE as per IVD directives/ USFDA certificate/ GMP certificate of the manufacturer (applicable as per products which are mentioned in Technical Specification attached in Annexure IX).

3.14.1 Authorization letter from the Manufacturer if the tenderer is an authorized distributer (The purchase order may be placed to the authorized distributer & bills can be raised by the authorized distributer on behalf of the manufacturer if specially authorized by the manufacturer.)

3.14.2 If the tenderer is an authorized distributer, he/she has to submit Valid Drug license, GST Registration Certificate, GST Clearance Certificate/ GSTR 3B &GSTR-1 on monthly basis for last quarter, PAN Card, Last 3 years IT return (2015-16, 2016-17 &2017-18), Annual Average Turnover with annual audited statement / Annual Report duly certified by Chartered Accountant of his/her firm/agency along with all the above documents of the manufacturer.

N.B: - All the photo copies are to be attested by Notary Public.

DOCUMENTS TO BE SUBMITTED IN PRICE BID (COVER- 'B'):

4.1 The rates offered or quoted by the tenderer for various Lab. chemicals, reagents, diagnostic kits & consumables (item-wise) should be submitted in a separate sealed cover hereafter-called Cover 'B' (Price Bid). The lists of items with specifications for which tenders are invited are in Annexure – II.

4.2 The Price Bid (price schedule) in the prescribed form (as per Format) should be submitted inclusive of excise duty, insurance, packing, forwarding and freight (except SSI units registered under OSIC & NSIC (i.e. door delivery) but exclusive of GST. The rate should be quoted for each bottle/kit/ tube etc. i.e. only absolute rate (both in figures and words). But supply will be made in unit pack. The hard copy of price schedule must be signed and sealed in each page by the tenderer.

4.3 The Cover 'B' should contain the price schedule duly signed and stamped properly filled in price column both in figures and words. If any discrepancy found between figure and words, the price mentioned in form of word will be considered as final price.

4.4 The "Cover 'B'" of only those tenderers who qualify in technical bid evaluation will be opened at the Office chamber of the C.D.M. & P.H.O, Cuttack in the presence of the tenderers or their authorised representatives. The date & time to this effect will be intimated later on.

4.5 Any overwriting/ correction which shall be signed by the tenderer.

NON RESPONSIVE/ REJECTION CRITERIA

5. The tender paper will be rejected if any of the following documents are wanting:-
   i. Earnest money deposit (EMD) of Rs. 100000/-(Rupees one lakh)only (Not applicable for SSI UNITS)
   ii. Original Money receipt against cost of Bid Documents & Original bid Document signed and sealed by tenderer.

iii. Attested photocopies of up-to-date valid manufacturing license with Product endorsement copy/ Import License with approval certificate from DCGI if products are imported from abroad.

iv. Price Bid/quoted rates (hard copy) without signature and seal of the tenderer.(Annexure – II)

v. GST Registration Certificate issued by competent authority of the manufacturer.

vi. Proof of Annual Average turnover of Rs.5 Crorers or more during last three financial years i.e. 2015-16, 2016-17 &2017-18 with respect to Lab. chemicals, reagents, diagnostic kits & consumables products only in India being certified by Chartered Accountant of the Manufacturer (Notarized copy) .(Annexure –VII)

vii. Copy of last 3 years IT return (2015-16, 2016-17 &2017-18) & PAN Card of the manufacturer if the bidder is a manufacturer.

viii. Valid GST Clearance certificate of the manufacturer/ GSTR 3B & GSTR-1 on monthly basis for last quarter.

ix. 05 (five) no's of Purchase Order copy for each financial year duly attested by Notary Public) from 3 (three) or more competent authorities & End user certificate from same 03 (three) or more competent authorities for last 3 years i.e. 2015-16, 2016-17, 2017-18 as mentioned in the performance Statement Annexure VIII.

x. Court Affidavit in respect to not been convicted under the provision of D&C Act 1940 by any court of law in contravention to the above Act & Rules & has not been blacklisted for any item either by the tender inviting authority or by any state Govt. or Central Govt. Organization participate in the tender for that items during the period of blacklisting (Annexure-1)

xi. Documents as per Category of Products

I. Rapid Diagnostic Test kit.
   1. ISO Certificate from competent Authority.
   2. Approval Certificate from DCGI/competent Authority if products are imported from abroad.
   3. CE as per IVD directive/ USFDA/GMP Certificate.

II. Biochemical Reagents
   1. CE as per IVD directive/ USFDA Certificate
   2. ISO Certificate from competent Authority.
   3. Approval Certificate from DCGI/ competent Authority if products are imported from abroad.

III. Lab. chemicals, Reagent Solution & Other Lab. chemicals
   1. CE certificate as per IVD directive.
   2. ISO Certificate from competent Authority.

xii. If the tenderer is an authorized distributer, bidder has to submit Authorization letter from the Manufacturer (Annexure - VI), valid Drug License, PAN Card, IT Return for last 3 financial Year (2015-16, 2016-17 &2017-18), last 3 years Annual Average Turnover of Rs.2 Crorers duly certified by a Chartered Accountant with annual audited statement / Annual Report & GST Registration Certificate issued by competent authority, Valid GST Clearance Certificate/ GSTR 3B &GSTR-1 on

monthly basis for last quarter of his/her firm along with documents mentioned in Sl. No. "III, VI, & XI" of the Manufacturer.

EARNEST MONEY DEPOSITED (BID SECURITY)

6.1 The EMD is deposited to safeguard against a bidder withdrawing or altering its bid during the bid validity period. The earnest money deposit Rs. 100000/- (Rupees one lakh) only for tender will be submitted by the tenderer. The earnest money deposit must be paid in the shape of **demand draft** in favour of the Chief District Medical & Public Health Officer, Cuttack from any Nationalized /Schedules Bank payable at Cuttack which will be deposited in the ZSS account of the CDM & PHO, Cuttack. This should be submitted with the tender in Cover "A" E.M.D **in shape of Cheque/Cash/Postal Order/Bank Guaranty will not be accepted.**

6.2 The local micro, small & medium enterprises registered with respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC & NSIC shall be exempted from payment of EMD.

6.3 The EMD will be forfeited by the CDM & PHO, Cuttack if the tenderer withdraws the tender in any respect within the validity of the bid or does not accept the approved rates by the bidder & Fails to furnish the required performance security within the specified period.

6.4 The E.M.D of the unsuccessful bidders only returned back from the ZSS account of the CDM & PHO, Cuttack without interest latest by 30th days after the award of the contract & the E.M.D will be refunded to the successful bidder on receipt of Performance Security.

PERFORMANCE SECURITY

7.1 To ensure due performance of the contract, performance security is to be deposited by the successful bidders awarded the contract.

7.2 5% of the Purchase Order value will be deposited by the successful bidder as performance security in shape of account payee Demand draft in favour the Chief District Medical & Public Health Officer, Cuttack payable at Cuttack after within 30 days of issue of the purchase Order & will be deposited in the ZSS Account of the CDM & PHO, Cuttack. **If the tenderer is local Micro & Small Enterprises** registered with respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC & NSIC **shall be liable to pay 25% of the prescribed Performance security deposit**.

7.3 The performance security will be returned without interest after expiry of approved list (Contract period)/extended period if any/ completion of the supply against the respective purchase order or completion of the quality testing or expiry of the last batch of Lab. chemicals, reagents, diagnostic kits and consumables supplied whichever is later.

TENDER CONDITION

8.1 The quoted rate shall not vary with the quantum of order placed for destination points.

8.2 A copy of the original tender condition and the schedules should be signed by tenderer at the bottom of each page with the office seal duly affixed and returned along with the tender in cover "A".

8.3 Tenders should be type-written or Computerized and every correction/over writing in the tender should invariable be attested with signature of the tenderer with date before submission of the tenders to the authorities concerned. No

revision of price (upward or downward) will be allowed once the tender is opened (Cover B).

8.4 Each tender format (price schedule) must contain the rate of each item which includes Excise Duty, Transportation (i.e door delivery), Insurance and all other charges etc. and excludes GST. The absolute rate should be quoted both in figure and word.

8.5 If there is a discrepancy between word and figure, the amount mentioned in word will prevail.

8.6 If there is discrepancy in absolute and unit rate (which is obtained by multiplying the absolute rate with the total number in a unit pack) **the absolute price will prevail and the unit price will be corrected accordingly.**

8.7 To ensure sustained supply without any interruption the C.D.M. & P.H.O, Cuttack reserves the right to split orders for supplying the requirement among more than one tenderer provided that, the rates and other conditions of supply are equal. In case of non-supply of any item by any approved lowest quoted firm, the C.D.M. & P.H.O, Cuttack can ask for willingness to L2/L3/L4/L5 etc. firm for supply at L1 rate (lowest approved rate) and procure the same item in L1 rate. The unit packing should be uniform as prescribed for each item.

8.8 **The rates quoted and accepted will be binding with the tenderer for a period of one year from the date of publication of the approved list (Opening date of Price Bid) and that of publication of the next approved list whichever is earlier and on no account any increase in the price will be entertained till the completion of this tender period.**

8.9 No tenderer shall be allowed at any time on any ground whatsoever to claim revision or modification of the bid document including price quoted by him. Clerical error, typographical error etc. committed by the tenderers in the tender forms will not be considered after opening of the tenders. Conditions such as **"SUBJECT TO AVAILABLITY , SUPPLY WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED"** etc. will not be considered under any circumstance and the tenders of those who have given such condition shall be treated as incomplete and for that reason, shall be summarily rejected.

8.10 If at any time during the period of contract, the price of the tendered items is reduced or brought down by any law or act of the Central or State Govt. or by the tenderer himself, the tenderer shall be morally and statutorily bound to inform the C.D.M. & P.H.O, Cuttack immediately about such reduction in the contracted prices. The C.D.M. & P.H.O, Cuttack is empowered to unilaterally effect such reduction as is necessary in rates in case the tenderer fails to notify or fails to agree for such reduction of rates. In case of any enhancement in Tax due to statutory Act of the Govt. after the date of submission of the tenders and during the tender period, the additional Tax so levied will be allowed to be charged extra as separate item without any change in price structure of the drugs approved under the tender. For claiming the additional cost on account of the increase in Tax, the tenderer should produce letter from the concerned Tax authorities indicating his commitment for the supply made to the C.D.M. & P.H.O, Cuttack on account of the increase in Tax.

8.11 The Tax will be charged as per the guideline given by the Finance Deptt. from time to time. GST component should be shown separately in the cost price (Price Schedule) **(Annexure-II).**

8.12 If the C.D.M. & P.H.O, Cuttack desires, he can extend the period of validity of approved list by mutual consent with due approval from Purchase Committee with sufficient ground.

8.13 In the event of the date being declared as a holiday for Govt. of Odisha, the due date of submission of bids and opening of bids will be the following working day at the appointed place & time.

8.14 The C.D.M. & P.H.O, Cuttack reserves the rights to reject the tenders or to accept the tenders for the supplies to all items or any one or more of the items tendered for without assigning any reason.

8.15 The C.D.M. & P.H.O, Cuttack will at liberty to terminate without assigning any reason there of the contract either wholly or in part. The tenderer will not be entitled for any compensation what so ever in respect of such termination.

8.16 If the L1 firm fails to execute the supply within the stipulated time, the C.D.M. & P.H.O, Cuttack is empowered to purchase from L2,L3,L4,&L5 firm at L1 rate or make emergency purchase from local market as per financial guideline to meet crisis .

8.17 The quantity of procurement may increase or decrease depending on the budget provisions, new scheme, natural calamities and epidemics etc.

8.18 The tenderer has to accept all the terms and conditions mentioned in the tender documents.

8.19 **The tender document is not transferable.**

SUPPLY CONDITIONS

9.1 The supplier/firm will supply as per the technical specification and print the generic name in bold letters and brand name if approved by the licensing authority may be printed in small front in bottle/ Test kits/ packing/ carton/ packet/ box etc.

9.2 The tenderer should deliver the Lab. chemicals, reagents, diagnostic test kits, lab. Consumables at the consignee (Door Delivery) at Sub-store, DHH, Cuttack. The insurance, storage & transport charges/courier charges if any will be borne by the supplier. The short supply, damage if any at the time of delivery of consignment shall be replaced by the supplier within seven days of the first supply on indented items.

9.3 In all the cases the responsibility of the purchaser will start only after delivery and due verification of goods.

9.4 The Composition & strength of each item tendered should be as per the specification given in (Technical Specification) item list.

9.5 The supply should be started immediately & completed within 60 days from the date of issue of the purchase order. If supply is not completed within 60 days from the date of issue of purchase order, the CDM & PHO, Cuttack may cancel the order or allow extension. The CDM & PHO, Cuttack has also liberty to cancel those orders and purchase the same items from L2, L3, L4 & L5 firms as the case may be if the other firms agree to supply at L1 rate.

9.6 Each instalment and batch of supply of Lab. chemicals, reagents, diagnostic test kits must be accompanied with an analytical test certificate (applicable as per product which are mentioned in Technical Specification attached in Annexure-IX) that the supplied Lab. chemicals, reagents, diagnostic test kits is of standard quality.

9.7 The Lab. chemicals, reagents, diagnostic test kits should arrive at the destination (Sub-Store) with remaining shelf-life as mentioned in Technical Specification of the products attached in Annexure IX.

QUALITY TESTING

10.1 All the suppliers/ manufacturers must submit Analytical test report from In-house /any approved laboratory of the batches being supplied to the consignee (applicable as per product which are mentioned in Technical Specification attached in Annexure IX).

Note: Analytical Test report of each batch of products must be submitted at the time of delivery (not applicable for Consumables)

10.2 The district will do random testing of the supplied items if required for which quality testing, packing and forwarding charges if any will be borne by the supplier.

10.3 If the Lab. chemicals, reagents, diagnostic test kits as per report is found not of standard quality in first test, the supplier will be required to replace the entire quality of the batch declared NSQ or the cost of it in shape of bank draft in favour of CDM& PHO, Cuttack to be deposited in ZSS account & take back the available stock (unused) in different health institutions of Cuttack district in his own cost within a period of 30 days of receipt of letter from CDM & PHO, Cuttack.

10.4 If the supplier does not take back the NSQ stocks or does not challenge the 1st test report within 30 days of issue of letter by the CDM & PHO, Cuttack, the concerned health institution can destroy the NSQ stocks with intimation to the CDM& PHO, Cuttack following criteria mentioned in the Notification No.25061/H dt.22.09.2012 of Health & FW Dpett. Govt. of Odisha.

10.5 If the items have been tested by the D.I & the CDM&PHO, Cuttack, the NSQ report of either of the authority will be accepted & action will be taken accordingly, if the supplier challenges the test report in the above circumstances then it will go for testing to Central Drugs Testing Laboratory, whose report will be final. The packaging, transportation and testing charges etc. will be borne by the supplier.

10.6 The supplier shall be responsible for the full replacement in his own cost for any product, if the same is found on visual inspection to have deteriorated/ not of standard quality before the expiry date.

TERMS OF PAYMENT

11 No advance payment towards cost of Lab. chemicals, reagents, diagnostic test kits consumables etc. will be made to the supplier. The supplier has to submit 3 (three) copies of the bills/ invoices with a photocopy of the purchase order at the time & place of supply for stock entry. No claims shall be made against the CDM & PHO, Cuttack in respect of interest on EMD, Performance Security or delayed payment.

PENALITIES

12.1 If the tenderer withdraw or alters its bid or unwilling to accept the terms and conditions of the tender after submission of bid & during the bid validity period, the EMD deposited by the said bidder will stand forfeited.

12.2 If the successful tenderer fails to execute the work order/ replacement of NSQ stock within the time specified/unable to undertake the contract or supply as per purchase order, his purchase order will be cancelled. He will also be liable for the

damages sustained by the CDM&PHO, Cuttack, Such damages shall be assessed by the CDM&PHO, Cuttack, whose decision will be final in the matter. The CDM& PHO, Cuttack can forfeit the performance security of the defaulting firms and de-recognise / black list the said firm for 2 (two) years from the date of issue of letter. The entire forfeited amount may be deposited in the ZSS Account of the CDM&PHO, Cuttack and can be utilized for procurement of essential Lab. chemicals, reagents, diagnostic test kits consumables etc., medicines & Medical consumables.

12.3 If any Lab. chemicals, reagents, diagnostic test kits consumables etc supplied by the tenderer being partially used or consumed after supply and are subsequently found to be in bad order, unsound, inferior in quality or description or otherwise faulty or unfit for consumption, the supplier will be required to replace the entire quantity of that item or the cost of it in shape of bank draft in favour of CDM&PHO, Cuttack to be deposited in ZSS account & take back the available stock (unused) from different health institutions of Cuttack district in his own cost within a period of 30 days of receipt of letter from CDM&PHO, Cuttack and if any deviation made by the firm will be de-recognized for 2 (two) years for that item from the date of issue of letter.

12.4 The tenderer can be blacklisted for a period of 3 years by the tender inviting authority in case it is found at the time of evaluation/ verification/ inspection that the tenderer has furnished forged documents/false information alongwith the tender.

12.5 In the event of any litigation arising out of tender such matters would be subject to the jurisdiction of the Hon'ble High Court, Odisha or Civil Courts, Cuttack

LIQUIDATED DAMAGE:

13 The Chief District Medical & Public Health Officer, Cuttack may allow extension on request of the firm for a maximum period of 28 days, after the stipulated date of supply, i.e.60 days from the issue of purchase order, with the penalty of 1% of purchase order value as "Liquidated Damage", for each week upto a maximum of 4% on the value of the goods. So, the firm has to supply Lab. chemicals, reagents, diagnostic test kits consumables etc without penalty upto 60 days and with penalty of 1% each week for the delayed supplies upto a maximum of 4%.

CONDITIONS APPLICABLE TO SSI UNITS OF THE STATE:

14. The SSI Units of the State of Odisha will be eligible to participate in the tenders and get the price preference provided they produce the attested photocopy of the following documents:
15. Copy of valid manufacturing license of the quoted products with product endorsement.
16. Valid up-to-date Good Manufacturing Practice (GMP) certificate /USFDA certificate/CE as per IVD directive (applicable as per products which are mentioned in Technical Specification attached in Annexure IX).
17. Valid ISO certificate of the Manufacturing unit.

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18. P.M.T Certificate from the Director of Industries, Odisha or General Manager District Industries Centre that it is a SSI Units of the State of Odisha, provided that SSI units has not been derecognised by the Govt. for that specified period.

I. Local Micro, Small & Medium Enterprises and Khadi & Village industrial units including coir, handloom and handicrafts will be entitled for a price preference of 10% in comparison with local Medium and Large Industries and Industries outside the State (Odisha).

II. Any local micro & small enterprises having valid ISO certificate / ISI certification for their product will get an additional price preference of 3%.

III. The local micro, Small & Medium Enterprises and khadi & village industrial units including coir, handloom and handicrafts can obtain the Tender Book free of cost at Sub-Store, O/o the District Medical Officer (Medical Services) Cum Superintendent, DHH, Cuttack.

IV. The local micro, small & medium enterprises registered with respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC & NSIC shall be exempted from payment of EMD and shall pay 25% of the prescribed performance security.

V. Fright Charges will be paid to the Local SSI units registered under Director of Industries, Odisha or General Manager District Industries Centre after production of cash memo/bill.

18. The supplies will be delivered by the approved SSI Units at the destination points as mentioned.

19. All the criteria mentioned under Eligibility Criteria except 2.2 & 2.3 are applicable for SSI Units.

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ANNEXURE-I

I/We M/s_____ represented by its Proprietor/ Managing Partner/ Managing Director having its Registered Office at _____ and its Factory Premises at _____ do hereby declare that I/We have carefully read all the conditions of tender in Ref. No_____ for supply of Lab. chemicals, reagents, diagnostic test kits, consumables to C.D.M.& P.H.O, Cuttack for a period of one year on rate contract basis from the date of publication of approved list (Opening of Price Bid) and will abide by with all the terms conditions of the Tender.

I/We declare that we possess the valid Manufacturing /Import License /Drug License & GMP /USFDA/CE as per IVD directive Certificate, ISO Certificate of the manufacturer issued by the Competent Authority. I/We furnish the particulars in this regard in enclosure to this declaration.

I/We do hereby declare that I/We have not been convicted under the provision of D&C Act 1940 by any court of law in contravention to the above Act /Rules & not been derecognized/ blacklisted by any State Govt./Govt of India/ Union Territory/Govt. organization /Govt. Health Institutions for supply of Not of Standard Quality Lab. chemicals, reagents, diagnostic test kits consumables etc (as per 2.7, Eligibility criteria).

I/We agree that the Tender Inviting Authority can forfeit the Earnest Money Deposit/ Performance Security 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 conditions as per the revised Schedule M of the said Act/not abiding by the tender terms and conditions.

I/We do hereby declare that I will supply the Lab. chemicals, reagents, diagnostic test kits & consumables as per the terms & conditions of the tender document.

Signature of the bidder:-

Date:-

Name & Address of the Firm:-

Affidavit in Rs.20/- Non-Judicial Stamp Paper

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TENDER FORMAT (PRICE SCHEDULE)

Whether SSI Unit, of Odisha: - Yes/No

Sl. No	Name of the Lab. chemicals, reagents, diagnostic test kits & consumables	Strength & Composition /Specification	Rates will be quoted for absolute only which includes excise duty, packing, forwarding/transportation & (door delivery) excluding GST & Entry Tax but supply will made in unit pack. Rate for each Tab./Cap/Amp/ Vial/Bottle/Roll etc. (Absolute rate) in Rs. Both in words and figures		GST in Percentage (%)	Remarks
1	2	3	4(Figure)	5(words)	6	7

Signature of the bidder :-

Name :-

Address :-

Place:-
Date:-

Note:-

1. This price format which is also be filled up & submitted in Cover –"B" only.
2. Quoted Price
   a. If there is difference in figure & words, the words will taken into consideration.
   b. The rates should be quoted for absolute only both in figures and words but all supplies will be made in unit pack only
   c. If there are discrepancies in absolute & unit rate the absolute price will prevail and the unit price will be corrected accordingly.

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Annexure -III

SCHEDULE OF REQUIREMENTS WITH TECHNICAL SPECIFICATION FOR

Lab. chemicals, reagents, diagnostic test kits & consumables

Sl. No	Name of the Lab. chemicals, reagents, diagnostic test kits & consumables	Specification / Strength	Unit Pack	Name of the manufacturer	Remarks
1					
2					
3					
4					
5					
6					
7					
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35					

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Annexure –IV

DETAILS OF THE TENDERER & LOCAL CONTACT PERSON

	Corporate Office (The address in which the purchase orders and payment details will be communicated.	Local Contact Person/Branch Office /Zonal Office/ Liaisoning Agent/ if any
Name and full address		
Telephone Nos. Landline		
Mobile		
Fax		
E-mail		
Manufacturing License/Drug License Nos. & Date		
Name of the Issuing Authority		
License valid up to		

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CHECK LIST

Please put √ in the respective box

DOCUMENTS:-SUBMITTED OR NOT

Sl. No	Details	Provided or not	
		Yes	No
1	Earnest Money Deposit (Not applicable for SSI UNITS)		
2	List of items being quoted with specification and strength		
3	Duly attested Valid up to date Photocopy of Manufacturing License with product endorsement copy		
4	Duly attested Valid up to date Photocopy of Drug License (in case bidder is an authorized distributor)		
5	Details of Manufacturing Unit/ contact person for liaisoning /local office in Odisha		
6	Valid up-to-date GMP/CE as per IVD directive/USFDA Certificate Manufacturer		
7	Valid up-to-date ISO Certificate of the manufacturer		
8	DCGI approval certificate from competent authority if the products are imported from abroad.		
9	Notarized copy of the Purchase orders (05 nos for each financial year i.e. 2015-16,2016-17,2017-18) from 3 (three) or more competent authorities (annexure-VIII)		
10	End user certificate from 3 (Three) or more competent authorities for supplying Lab. chemicals, reagents, diagnostic test kits consumables etc from Govt./ Corporate/PSU Hospitals in India in support of marketing experience for last 3 years i.e. (2015-16,2016-17,2017-18) (annexure-VIII)		
11	Average Annual Turnover of Rs.5 Crorer or more during last three financial years (2015-16, 2016-17 &2017-18) duly certified by a Charted accountant of the manufacturer		
12	Authorization letter of the Manufacturer(s) if the bidder is an authorized distributer specifically to participate in the tender.		
13	Average Annual Turnover of Rs.2 Crorer or more during last three financial years (2015-16, 2016-17 &2017-18) duly certified by a Charted accountant for Authorized Distributor with annual audited		

	statement / Annual Report		
14	Attested photocopy of GST Registration Certificate of the Bidder		
15	Valid GST Clearance Certificate of the bidder/ GSTR 3B &GSTR-1 on monthly basis for last quarter.		
16	Declaration form(Annexure-I) signed by the Tenderer and affidavit before Notary public in Rs.20/- non-judicial paper		
17	Copy of Original Tender booklet, duly signed & Sealed by the Tenderer with Original Money receipt.		
18	Cover –"B" with price schedule(Annexure-II)		
19	Photocopy of last 3years IT return (2015-16, 2016-17 &2017-18) of the bidder		
20	Attested copy of PAN Card of the bidder.		

Documents to be arranged as per Manufacturer wise.

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Annexure –VI

(To be submitted on Cover A-Technical Bid)

MANUFACTURER'S AUTHORISATION FORMAT

To

The CDM & PHO, Cuttack
Deptt. of Health & Family Welfare,
Govt. of Odisha.

Ref:- Tender No._____ Dated _____for _____.

Dear Sir,

We_____ _____are the manufacturers of _____having factories at _____

_____.

1. Messrs _____(name and address of the agent) is our authorized agent for sale and services of _____
2. We confirm that Messrs _____ (name of the above agent) is authorized to submit a tender, raise bills & receive payment on behalf of me/us.

Yours faithfully

_____

_____

(Signature with date, name and designation)

For and on behalf of Messrs _____
(Name and 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.
2. Original letter/ True copy attested by Notary Public and also by the Bidder shall be attached to the Technical bid.

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Annexure –VII

(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 Lab. chemicals, reagents, diagnostic test kits & consumables products of M/S_____

_____ **Who is a manufacturing unit/ Distributor** for the last _____ years are given below and certified that the statement is true and correct.

Sl. No	Year	Turnover in (Rs.)	Average Annual Turn over
1	2015-16		
2	2016-17		
3	2017-18		

Date
Place

Signature of
Chartered Accountant
(Name in Capital)

Seal

Membership No.

Registration No. of Firm

Note:-

a) To be issued in the letter head of the Chartered Accountant

b) Separate Certificates should be submitted for different manufacturer in case the bidder is quoting products of different manufacturers.

Annexure –VIII

(To be submitted in *Part – I Technical Bid*)

PERFORMANCE STATEMENT (Lab. chemicals, reagents, diagnostic test kits & consumables)

(For the period of last Three years)

(Pl. Furnish order copies of the clients serially, the names of which are mentioned below)

Name of Bidder:

Name of Manufacturer/Authorised Distributor:_____

Sl.	Order placed by (Address of purchaser) (attach documentary proof)*	Order no. & Date	Qty	Have the items supplied satisfactorily (attach documentary proof)**

Signature and seal of the Bidder

*The documentary proof will be 05 nos of purchase order copies for each year from minimum 3 competent authorities indicating P.O. No. and date. (during the last 3 years i.e. 2015-16,2016-17, 2017-18.)

** The documentary proof will be certificate from the consignee/end user from the same competent authorities during 2015-16, 2016-17 and 2017-18.

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Annexure – IX

(To be submitted in *Part – I Technical Bid*)

Product List with Technical Specification

Sl. NO	Name of the Reagent Solutions & Chemicals
1	(N/10) Hydrochloride Solution (Haemoglobin Estimation)
2	Haematology test Reagent for Automated haematology Analyzer(5part/3part)
3	Haematology test under microscope
3.1	WBC Diluting Fluid(TLC)
3.2	Total Eosinophil Count Fluid
3.3	RBC Diluting Fluid(Total Red Blood cell Count)
3.4	Platelete Diluting Fluid(Platelet Count)
3.5	Distilled Water
4	Blood Grouping (ABO-RH typing)(ANTI-A,ANTI-B,ANTI-A,B,ANTI-D,ANTI-H,ANTI-A1,BOVINE ALBUMIN, Antigen for Red Cell Pannel)
5	JSB Stain-I,JSB Stain-II(Malaria Parasite)
6	3.8% Sodium Citrate Solution(ESR)
7	Coombs Reagent (Direct & Indirect)(AHG Anti C3d monoclonal)
8	Laboratory Stain(Giema Stain,leishman Stain)
9	Immersion Oil(Microscope)
10	Occult Blood
11	PT Reagent(Prothombin Time)
Rapid & Packed Kits	
1	RPR Card (Syphilis)
2	HIV Rapid
3	Rheumatois Factor(Rh Typing)
4	ASO
5	HbsAg (Rapid)
6	CRP
7	Uri-Stick
8	Pregnancy Kit
9	Widal Kit
10	Malaria Rapid
11	Dengue
12	Toxoplasma(Rapid)
13	Hepatitis B&C card test
14	Troponin-I
15	H2S Strip
Biochemical Reagents(Semi-auto /Fully-auto analyzer)	

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1.a	Blood Sugar (Lab method)
1.b	Blood Sugar(Glucometer Strip)
1 c	Blood Sugar(Glucometer Strip with lancet)
2	Blood urea,
3	S. creatinin
4	S.Bilirubin (T)
5	Bilirubin (D)
6	SGOT
7	SGPT
8	S.Alkaline Phosphate
9	S.Total Protein
10	S.Albumin
11	S.Calcium/Potacium/Sodium
12	S.LDH
13	S.Amaylase
14	S.Uric Acid
15	S.Cholesterol
16	S.Triglyceride
17	S.VLDL
18	S.HDL
Consumables	
1	Glass Slide
2	Pipate Tips
3	Urine Collection bottle
4	EDTA sample Tube

Other Chemicals

1.	Sulphur Powder	500gm/ bottle
2.	Immersion oil	30/bottle
3.	Auramine –O	Molecular wt.321.85, Potency. 85.0%, Absorbance-435, 30 Gm bottle
4.	Ethanol (absolute)	Molecular wt.46.7, 500ml bottle
5.	Hydrochloric Acid	Molecular wt.36.46 G/Mol, 500ml bottle
6.	Potassium permanganate	Molecular wt.156.04, Potency .99%, 50gm bottle
7.	Basic Fuschin	Pararosaniline hydrochloride, mol. Wt. 323.8, dye content 85%, 25gm bottle
8.	Methylene Blue	Mol wt. 319.9 dye content approximate 82%, 25gm bottle
9.	Sulphuric Acid	Mol. Wt.98.08 Purity 95 % to 97% Clear, 500ml bottle
10.	Phenol	Carbolic Acid, Mol wt. 94.11. Purity.99.5%, 500ml bottle
11.	Benedict Solution	500ml bottle
12.	EDTA Powder	500gm bottle
13.	Sodium Flouride powder	500gm bottle
14.	Benzidine Powder	100 gm bottle
15.	Hydrogen peroxide	500ml bottle

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Consumables

Sl. No.	Name of the consumable	Specification
1.	Glass Slide	25x75 mm, 1.1 mm- 1.3 mm thick
2.	Urine collection Bottle (sterilized)	Each
3.	EDTA Sample Tube	5 ml/ each
4.	Flouride Sample Tube	5 ml/ each
5.	Plane Sample Tube	5 ml/ each
6.	Dental X-ray Film	150 nos /pack
7.	Ultra Sound Jelly	5 ltrs/jar
8.	X-ray Developer	14 ltrs
9.	X-ray Developer	9 ltrs
10.	X-ray Fixture	14 ltrs
11.	X-ray Fixture	9 ltrs
12.	Capillary Tube	100 nos /pack
13.	Cover Slips	50 nos/pack
14.	Lanse Cleaning Paper	50 nos/pack
15.	Tissue Paper Roll	Each roll
16.	Glass Marking Pencil	Each
17.	Test tube Cleaning Brush	Each
18.	Tourniquate	Each
19.	ESR Tube	Each
20.	Hemoglobin Pipette	Each
21.	Glass Rod	Big size
22.	Dropping Bottle Plastic	100ml/bottle
23.	Pasture Pipette	Each
24.	Filter Paper	100/pack
25.	Plastic Apron	Each
26.	Test tube 12x75	Each
27.	Test tube 12x100	Each
28.	Test Tube 15x150	Each
29.	Spirit lamp	Each
30.	Sputum Container	50 ml plastic, wide mouth, transparent
31.	Conical Flask	1 ltr, glass
32.	Jelly Pack	500ml capacity
33.	Thermo cool Box	10"x10"
34.	Falcon Tube	Conical Bottom, sterilized 50ml
35.	Para film	Each
36.	Diamond Marker Pencil	Each
37.	Paper Sticker	500 nos/ each
38.	Staining Dropping Bottle	200ml capacity, plastic
39.	Glass funnel	500ml, capacity
40.	Foot operated bucket	Plastic, 10 ltrs capacity
41.	Sahil's Heamoglobino Meter	Each
42.	Heamoglobin tube	each
43.	E.S.R stand	6 stage type
44.	Micro Pipette Tips	10 u/L
45.	Micro Pipette Tips	1000 u/L

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Technical Specification

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 ISO certified.
- 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.

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	Up to 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

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

- 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.

Technical Specification Rapid test Kits

Quality Standard:

The following standards and criteria's are applicable to all the following 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 certified
- All the kits should approved by CE(IVD) /USFDA/GMP
- All the Kit should be DCGI approved if the products are imported from abroad.
- 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 %

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

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

Kit Configuration:

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

7.URINE Complete rapid test reagent strips :

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

- 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

  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 certified.
- The strips should be USFDA/CE (IVD) approved.
- The strips should be DCGI approved if the products are imported from abroad.

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

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 certified.
- The strips should be USFDA/CE (IVD) approved.
- The strips should be DCGI approved if the products are imported from abroad.

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

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- 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)
- 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 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, plasmaor whole blood
- The test should be able to differentially detect IgG and IgM antibodies against all 4 serotypes of Dengue virus
- Results should be available in 15-20min.
- Test should be able to give a presumptive differentiation between primary & secondary dengue infections
- Test should have no cross reactivity with other Flavivirus group mediated and mosquitoes-borne disease
- Dengue IgG/IgM (Plasma Serum WB) : Sensitivity 94%, Specificity ≥ 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

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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 non-permeable 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:10-15minutes
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 ISO 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:

Pack Size:

1. Disposable test strips (individually sealed)
2. 5 pipettes (150 µL)

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3. Disposable labels

4.1 package insert

5.1 vial of negative control solution (lyophilized) for 6 determinations

Chemicals and reagent solution

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 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 ISO 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 ISO 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 ISO certified
- Product should be CE certified as per IVD directive

6. **Distilled water.**

Laboratory grade distilled water

0.1 micron filtered

pH value :5-7.5

Packed in transparent

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7. Blood Grouping (ABO-RH typing)

ANTI-A	Monoclonal IgM reagent for forward grouping	Anti A consists of blood grouping reagent for slide and tube tests. The reagent is murine monoclonal IgM for forward grouping. Ready to use solution containing IgM (murine monoclonal) class antibodies specific to the 'A' antigen on the R.B.C Specificity: ANTI-A-100% to A , and A antigens Pack Size:5ml/10ml **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 ISO 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 ISO certified
❖Product should be CE certified as per IVD directive

Packet of 10nos

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

KIT COMPONENTS

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

Laboratory Stains

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

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