

राजेन्द्र आयुर्विज्ञान संस्थान

(झारखण्ड सरकार का एक स्वयत्ताशासी संस्थान)

राँची-834009 (झारखण्ड)

दुरभाष: 0651-2541533, फ़ैक्स: 0651-2540629,

E-mail: rimsranchi@rediffmail.com



RAJENDRA INSTITUTE OF MEDICAL SCIENCES

(An Autonomous Institute under Govt. of Jharkhand)

Ranchi-834009 (Jharkhand)

Phone: 0651-2541533, Fax: 0651-2540629,

Email : rimsranchi@rediffmail.com

Ref. No.

3993

Dated: 12/09/2024

Subject: Purchase of Reagent/Consumables for Cobas 6800 Machine on proprietary Item basis (Inviting comments / offer there on).

The demand/request has been received from the department of Microbiology, Rims, Ranchi for procurement of reagent/ consumables on proprietary basis. The product is the proprietary product of M/S Roche Molecular System Inc. 1080 US Highway 202 South, Branchburg, NJ 08876, United States. The Roche Regional Office is Unit – 1002, Merlin Acropolis, 1858/1, Rajdanga main Road, East Kolkata Township, Kolkata, West Bengal 700107 or 3rd Floor Office Block MGF Corporate Park Metropolitan mall, Plot No. A2 Didtrict Centre, Saket New Delhi - 110017 and Regd. Office is 501 B, Silver Utopia Cardinal Gracious Road Chakala, Andheri (East) Mumbai – 400069. The PAC Certificate, product & price performa, Authorization Certificate to M/S Powermech India Pvt. Ltd, Swastik House, Gandhi Chowk, Upper Bazar, Ranchi - 834001 from the firm forwarded by the end user departments are attached and uploaded on the website. The proposal submitted by M/S Roche Diagnostics India Private Limited and Performa invoice/ price justification and department certificated are attached.

The above documents are being uploaded for open information to all firms to submit the objections/ comments/ offer, with respect to the proprietary nature of the product/item, authorization and prices, if any vendors want to give their offer then they should also inform within 15 days from the date of issue/uploading of the notification, giving reference no. ~~3993~~ /MO(S)/ Cobas 6800 /2024-25. The comments/ offer should be sent to The Director Office, RIMS, Bariatu, Ranchi, PIN – 834009 on or before 28.10.2024 up to 05. : 00. PM, and must be received by email-id - rimsranchi@rediffmail.com, failing which it will be presumed that any other vendor is having no comments to offer/ having no new offer to provide and the case will be decided on merit and the item will be purchased directly on proprietary basis.

Enclosures: **Related Documents**

1. Authorization Certificate from the Principal firm.
2. Not blacklisted undertaking by OEM.
3. PAC Certificate by OEM.
4. Offer Rate by OEM.
5. Undertaking (Annexure I) from the Principal firm.

Sumit

12/09/2024

Medical Superintendent

Rajendra Institute of Medical Sciences, Ranchi

Madhoo Kumar
10/09/24

Sumit
10/09/24
Pro-Chemist



Report ID: GEM/GARPTS/16082024/XFNU0D6NC36I

Report Name: COBAS 6800 HBV VIRAL LOAD KIT

Generated By: Dr. Manoj Kumar , Health Medical Education and Family Welfare Department Jharkhand

Generated On: 16/08/2024

Valid till: 15/09/2024

GeM Availability Report and Past Transaction Summary

GeM Availability Report and past transaction summary report is generated based on the specifications searched by the Buyer. The specification may be modified appropriately for searching relevant categories on GeM. Buyer may navigate to GeM category page by clicking on the category link to view category specifications and products/services available in the category.

Order Count and Order Value displayed is on a cumulative basis since GeM inception.

1. Search String: COBAS 6800 HBV VIRAL LOAD KIT

Search type: Product

1. There are categories available on GeM matching your requirements (as listed here). You can create a bid on GeM with a product closest matching your required specifications and add additional parameters in specifications through Corrigendum using RMS functionality.
2. If you feel that category TP needs updating you can submit category updating request also through RMS.
3. If you do not want to use any of the above option and want to proceed for procurement outside GeM, please suggest the specifications of the required product for creation of new category on GeM for future procurement.

Search Result: Category available/suggested on GeM but marked as "not matching requirements" by the buyer with undertaking as under:

It is certified that I have thoroughly checked all probable categories suggested by GeM and I am satisfied that the product required is not covered / does not fall in any of the suggested categories and can not be procured under any of these categories even after inclusion of List of Values(LOV) wherever possible in category specifications of suggested categories. It is also certified that the technical specification requirement are such that these can not be covered even by adding specification parameters using ATC in any of the GeM suggested categories. This is a one-time requirement hence new category creation is not proposed / or requirement is recurring but request for new category creation will be submitted separately post generation of GeMARPTS.

Category Name	Catalog Count	Order Count			Order Value (in Lakhs)		
		Direct Purchase	Reverse Auction	Bid	Direct Purchase	Reverse Auction	Bid
HBV Viral Load Test Kit	3	8		0 6	15		0 24

 16/08/2024
 16/08/24
 16/08/2024
 16/08/24

61



RDIN/East/RIMS/Micro/2024/07-03
Date: 31/07/2024

To,
The Director
Rajendra Institute of Medical Sciences
Indraprasth Colony, Bariatu,
Ranchi, Jharkhand 834009

Subject: Price Submission for rate contract of Reagents and consumables of cobas 6800 for HBV, HCV, HIV Viral Load Testing.

Dear Sir/Madam

This is with respect to the price submission for rate contract of reagents and consumables of cobas 6800 system in Dept. of Microbiology, RIMS-Ranchi for conducting HBV, HCV, HIV - Viral Load Testing.

We would further like to inform you that the validity of previous submitted price has been expired as well as there is changes in GST of various materials.

Please find the below mentioned revised offered prices with the current applicable GST for rate contract. This new price submission supersedes all the previously submitted prices.

Sl. No.	GMMI NO	Material Description	Pack Size	Unit Price in INR	GST % Extra As Applicable	Unit Price in INR GST Inc.
1	9040820190	KIT COBAS 58/68/8800 HBV 192T IVD	192	141,600.00	12%	158592.00
2	9040765190	KIT COBAS 58/68/8800 HCV 192T IVD	192	147,400.00	12%	165088.00
3	9040803190	KIT COBAS 58/68/8800 HIV 192T IVD	192	133,446.00	12%	149459.52
4	9040773190	KIT COBAS 58/68/8800 HBV/HCV/HIV RMC IVD	8	38,450.00	12%	43064.00
5	9051554190	KIT COBAS 58/68/8800 NHP NEG RMC IVD	16	31,570.00	12%	35358.40
6	6997503190	KIT COBAS 58/68/8800 WASH IVD	4200	4,730.00	18%	5581.40
7	6997511190	KIT COBAS 58/68/8800 SPEC DIL RGNT IVD	3500	10,876.00	12%	12181.12
8	6997538190	KIT COBAS 58/68/8800 LYS REAGENT IVD	3500	27,020.00	12%	30262.40
9	6997546190	KIT COBAS 58/68/8800 MGP IVD	480	8,241.00	12%	9229.92
10	5534941001	cobas omni Amplification Plate	32	23,043.00	18%	27190.74
11	5534925001	cobas omni pipette Tip	16	17,638.00	18%	20812.84
12	5534917001	cobas omni Processing Plate	32	8,181.00	18%	9653.58

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN-U85195MH1988PTC11417

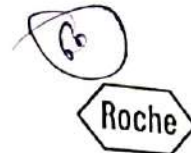
Regd. Office:
501 B, Silver Utopia
Cardinal Garclous Road
Chakala, Andheri (East)
Mumbai - 400069

Tel: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in
info.india@roche.com

[Signature]
12/08/2024

[Signature]
12/08/2024

[Signature]
6/8/24



Terms & Condition:

1. Price Validity : 90 Days.
2. Tax : GST will be extra as applicable as per current HSN.
3. Supplies : Kits & Reagent will be supplied against the confirmed order through authorized supplier.
4. Delivery : 6-8 weeks after receiving the confirmed order.
5. Contract Period: Five Years with exclusive usage of Roche Platform for HCV and HBV Viral Load Testing.
6. Payment : Against delivery of goods.
7. Service & Application Support : will be provided by Roche Diagnostics India.

Looking forward for your considerations.

For Roche Diagnostics India Pvt. Ltd.

Authorised Signatory
Birendra Singh
Regional Manager-East
Ph No-09334255963
Email : Birendra.singh@roche.com



[Handwritten signatures and dates]
12/8/24 12/08/24 12/8/24 06/08/2024 6/8/24

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN-U85195MH1988PTC141417

Regd. Office:
501 B, Silver Utopia
Cardinal Garclous Road
Chakala, Andheri (East)
Mumbai - 400069

Tel.: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in
info.india@roche.com

57

121

Annexure-1

UNDERTAKING

To
The Director
RIMS, Ranchi

Kind Attn : Head of the Department, Microbiology

Sir/Madam,

I, undersigned Birendra Singh – Regional Manager- Molecular Lab duly authorized representative of M/s Roche Diagnostics India Private Limited hereby undertake, affirm, confirm and declare that

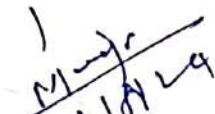
1. Undersigned is fully competent and authorized from Proprietorship/Firm/Company/Agency To make this undertaking to bind Proprietorship/Firm/Company/Agency.
2. All details/information/documents furnished by Proprietorship/Firm/ Company/Agency in provided are true and correct in all are aspects and I/we hold the responsibility for the same.
3. Proprietorship/Firm/Company/Agency is fully solvent and legally/financially competent.
4. Proprietorship/Firm/Company/Agency is duly registered under various relevant government notifications and all dues have been paid as on date.
5. The Undersigned certify that the rates quoted by me/us are valid and binding on me/us for acceptance till the validity. Rate quoted as per requirement/tender pack size.
6. I/We also certify that firm will be supplied the item / consumables/ Equipment as per the specification, requisite quality & quantity given by Rims, Ranchi and also abide all the terms & condition stipulated in supply order.
7. The articles shall be of the best quality and of the kind as per the requirement of the institution. The decision of the Director, RIMS, Ranchi, India (herein after called the said officer and end user department) as regard to the quality and kind of article shall be final and binding on me/us.
8. I/We undertake to arrange for a demonstration of the Equipment/item/ Consumables. Failure to arrange for a demonstration on the given date may lead to cancellation of award. Cost of such demonstration shall be borne by me/us. I/We undertake to supply the all Literature (Log Book/ Maintenance Record/ Troubleshooting / Operation Manuals etc.) supplied with each Equipment/item/ Consumables by Principal Manufacturer in Original to Rims, Ranchi.


12/08/24


12/08/2024


12/08/24


06/08/2024


06/08/24

56

9. I/we undertake to supply the ordered items within stipulated period and if fail to supply during the stipulated period The Director RIMS, Ranchi has full power to imposed patently and take necessary action.

10. I/We declare that no legal/financial irregularities/No criminal case/ Police case are pending against the proprietor Partner/Director of the tendering firm or manufacturer.

11. Proprietorship/Firm/Company/Agency has not quoted price in this Tender higher than one at which goods/services were previously supplied to any government Institute/ Organization/ reputed Private Organization or DGS&D/GEM rate in recent years. If at any stage it is found that the firm (bidder) has quoted lower rates to any Govt. / Private Institute, Bidder shall be liable to payback access value to Rims, Ranchi. Rims, Ranchi further reserves right to impose suitable penalty shall be made by competent authority Rims, Ranchi.

12. I/We undertake that if the rates of any items are lowered due to any reason. I will charge the lower rates.

Undertaking (Fall Clause) I Birendra Singh hereby undertake that if any reduction in ours price or sells or even offers to sell the contracted goods of identical specification and terms and conditions to that of the contract, at a price lower than the contract price, to any person or organization during the currency of the contract the contract price will be automatically reduced with effect from that date for all the subsequent supplies under the contract and the contract amended accordingly. Any excess amount charged will be deposited back.

13. I/We undertake that the items supplied are as per Make/Model/Catalogue/ technical literature description.

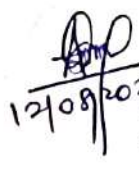
14. I/we here by undertake to provide price justification and authorization whenever asked during the period of contract/validity.

15. I/We further undertake that none of the Proprietor/Partners/Directors of the firm was or is Proprietor or Partner or Director of any firm with whom the Government have banned /suspended business dealings. I/We further undertake to report to the RIMS Ranchi immediately after we are informed but in any case not later 15 days, if any firm in which Proprietor/Partners/Directors are Proprietor or Partner or Director of such a firm which is banned/suspended in future during the currency of the Contract with you.

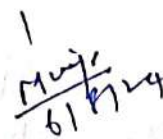
16. I/We also confirm that whenever The Director Rims, Ranchi, India and competent authority ask for any documents and certificate related proprietorship/ Price related etc (on requirement basis) for clarification etc at any time we will provide them.

17. I/We also confirm that we have neither set any terms & condition nor there is any deviation taken from the condition of Rims, Ranchi Reagent's specification either Technical or commercial.

18. I/We also confirm that any expired or unused reagent will be replaced or refunded by us.


12/08/2024


12/08/2024


6/11/24

58

19. I/We also confirm that The Product and Reagent in original packing of the manufacturer and not refilled are provided by us.

20. I/We also confirm that After the supply of the items, I will submit three copies of the bills along with These Certificate:-

(i) **Low rate certificate:** I/We have to give a certificate that I/We are not supplying items below this quoted rate to any other Government Institution. Vendor should be inform in case of price reduction and order copy will be revised accordingly

(ii) I/We have to give a certificate that the rate of GST / Tax is charging in bill is as per the state / central/inter/product/HSN Code / etc. are correct. However in case if it is found that wrong rate of GST / Tax has been charged, I/We will be responsible we will do for it is rectification.

(iii) I/We Roche Diagnostics India Certify that the factory of the manufacturer of the medicine & chemical of supplier is not closed. There is no. legal Investigation going on regarding production and product quality nor it has been found guilty in the past.



(iv) HSN Code of each items should be clearly mentioned (**Performa attach, Kindly submit with bill**).



21. I/We here by certify than item/consumables/Equipment (must meet with technical specification and quality) are offered by us are made in India. If there is any item of foreign origin than the reason is that..... (Kindly submit valid documentary evidence in support)(specify item name). (Declaration for Local Content). – **clause Not Applicable, as Roche Diagnostics India, item/consumables/Equipment are of foreign origin.**

22. We have read (GFR 2017 Rule 144 (XI)) & the clause regarding restrictions on procurement from a bidder of a county which shares a land border with India and on sub-contracting to contractors from such a country; and solemnly certify that we are not from such a county, we have no Business dealing with these countries. It is to declare that if, our bid/offer is accepted by the purchaser, as per undertaking given by us as per aforementioned points on the basis of certificate are found to be false, in such case this would be a ground for immediate termination of our bid/offer and further legal action in accordance with the law to be initiating on us by the procuring entity i.e. RIMS, Ranchi.

23. We also hereby certify that we are the authorized distributor ..(Roche Diagnostics India Pvt. Ltd.). And authorization is valid upto a period of one year from the date of issuance of letter. (Authorization Attached)

24. I/We here declare that we must follow order instruction which is given in purchase order.


12/8/2024

12/8/24


12/8/2024

06/08/2024


6/8/24

58

(B) Part B:

General Terms & Condition of the Contract Agreement.

1. If your rate approved by Purchase Committee, initially the rate contract with approved supplier will be valid for one year and subjected to receipt of satisfactory performance report of the supplier from the end user department and approval of competent authority will be extended further one year.
2. **Delivery:** - The successful bidder should strictly adhere to the following delivery schedule i.e. within 45 days from the date of purchase order. In short expiry items like control delivery period will be 20 days. Free delivery on consigning site. All the safe delivery & installation shall be the exclusive responsibility of the supplier. Goods/ items must be securely and adequately packed and protected in order to prevent damage, otherwise all losses/ damage resulting from inadequate packed shall be borne by seller.
3. **Delivery Instruction:** - Kit/ Reagents should be supplied in staggered manner as per the requirement, (If applicable/ according to purchase order). All approved item on order must be made available in sufficient quantity to cater the whole need of the institute lead time for replenishment of such stock will be 24 to 48 hours it will be communicated by telephone and email to authorized distributor.
4. **Discrepancy:** - Discrepancy if any in Purchase order should be reported within 10 days from the date of issue. In case nothing is heard within the schedule time. It will assume that the order has been accepted in full.
5. **Penalty:** - If the seller fails to deliver and install any or all of the Goods/Services within the original re-fixed delivery period(s) specified in the Purchase order. Rims, Ranchi will be entailed to deduct/ recover the Liquidated Damages for the delay. Penalty @0.50% per week will levied on supply order value and will be deducted from the payment bill. The maximum penalty will be 10% against any of purchase/supply order total values.
6. **Performance Security:** - Performance security @ 50,000.00 Rs. (Calculated approx 5% of the orders value as per approximate 01 years consumption) the performance security will be in shape of bank guarantee. Drawn in favour of director in Rims, Ranchi A/C from any nationalize bank/scheduled bank the performance security will have the minimum validity for 24 months from the date of issuance of a rate contract approval and it should be submitted within week before placement of supply order. Failing which the above mentioned amount may be deducted from the bill amount against performance bank guarantee. Performance security shall be returned to the agency without any interest after completion of period (subjected to satisfactory performance certificate given by end user department).
7. Force majeure will be accepted on adequate proof thereof.
8. **Material Life/ Expiry:** Supply material should have ordinarily minimum 2/3rd of shelf life. (Minimum of the 2/3rd of the expiry period remaining on the date of receipt of items in concerned department of Microbiology). Long-expiry items should be given, Short-expiry items will be rejected and those will be replaced by the supplier free of cost and supply back the fresh items within the given time. Also, unused reagents should be replaced Qr Incase if the supplier is unable to supply the required shelf life Or supplies short expiry items (shelf life less than 06 months) and the end user Department is unable to consume) those materials will be replace by the supplier at free of cost and supply back the fresh items within a Months time.
9. **Inspection of Goods/Materials:** - The End user department or authorized representative shall carry out the inspection of the supplied material at Store/concern department in case. The material is not found in accordance with the prescribed specification or otherwise defective/ found expiry/ damage/ poor/ substandard in quality. It will be rejected and will have to be replaced by the supplier at their own risk and cost.

12/09/2024

06/08/2024

12/09/24

12/09/24

12/09/24

3

10. **Transit Insurance:** - Shall be arranged by the supplier/vender at its own cost.
11. All goods/ stores supplied to the hospital shall have to be stamped "Rims supplies" and printed "NOT FOR SALE" in bold letter will indelible inks.
12. If the Principle Manufacturer (OEM) withdraws its distributorship from the bidder during the validity of rate contract by issuing authorization letter to another firm, The Director has full right to accept candidature of new coming distributor subject to the new firm fulfilling all other terms and conditions of contract. No claim whatsoever will be entertained from. The previous bidder (However, if any supply order is pending with the previous bidder, same will be executed by the new bidder). Bidder should also inform within 10 days about distributorship change.
13. The new acceptable bidder will have to deposit full Performance Security money deposit in the document by the hospital in favour of Director, Rims, Ranchi. In case any dispute regarding authorization from principle manufacturer occurs, the same will directly be confirmed through direct correspondence with principle manufacturer (OEM).

14. Terms & Conditions of Payment:-

- (a) The Vendor/Supplier is requested to submit the GST invoice in triplicate and mandate form duly signed by concerned bank along with a proof of cancelled cheque/bank details in case of NEFT/RTGS/PFMS/Online payment transfer with the invoice.
- (b) 100% Payment shall be made after successful, satisfactory and complete supply of ordered items) at respective site and subject to availability of funds.
- (c) No Payment shall be made for rejected/expired items. Rejected items must be picked up by the supplier within one week of the date of issue of rejection at their own cost &, replace immediately. In case these are not removed these will be auctioned at the risk and responsibility of the suppliers without notice.
- (d) Batch number and expiry date must be mentioned on face of the bill.

15. I pledge and solemnly affirm that the information submitted by us is true to the best of my knowledge and belief. I further pledge and solemnly affirm that nothing has been concealed by me and if anything adverse comes to the notice of purchaser during the validity period The Director, Rims, Ranchi (India) will have full authority to take appropriate action as he/she may deem fit.

Note: - Please acknowledge receipt of these Annexure I Terms & Condition (considering this as an agreement) by sending a copy of the same duly signed as a token of acceptance to The Director, Rims, Ranchi/ Head of the Department.



(Signature of the Authorized person of firm)

Name: Birendra Singh
Phone no: 9334255963
Email: Birendra.singh@roche.com
Designation with Seal of the Firm: Regional Manager

1
mwp
6/8/2024

12/08/2024

12/8/2024

06/08/2024

35

Roche

RDIN/East/RIMS/Micro/2024/06-01
Date: 12/06/2024

To,

The Director
Rajendra Institute of Medical Sciences
Indraprasth Colony, Bariatu,
Ranchi, Jharkhand 834009

Subject: Authorization Certificate for supply of cobas 6800 HBV, HCV, HIV Viral Load reagent & consumables.

Dear Sir

This is with respect to the distributor authorization for supply of cobas 6800 HBV, HCV, HIV Viral Load reagents kits & Consumables in Dept. of Microbiology, RIMS-Ranchi, Jharkhand.

We hereby authorize M/S Powermech India Pvt. Ltd, Address: Swastik House, Gandhi Chowk, Upper Bazar, Ranchi-834001, Jharkhand. Mob No: +919431100311 to supply and collect payment on behalf of Roche Diagnostics India Pvt. Ltd.

Authorization certificate is valid for the period of One Year from the date of issue.

Thanking you

For Roche Diagnostics India Pvt. Ltd.

Birendra Singh



Authorized Signatory

Birendra Singh
Regional Manager
Roche Molecular Diagnostics
Ph No- 09334255963
E-mail - Birendra.singh@roche.com

[Signature]
22/06/2024
[Signature]

[Signature]
22/6/20

[Signature]
22/6/2024

[Signature]
22/6/2024
Head of Microbiology Dept.
RIMS, RANCHI

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH11988P1C141417

Regional office :
3rd Floor Office Block
MGF Corporate Park
Metropolitan mall, Plot No. A2
District Centre, Saket
New Delhi - 110017

Tel: +91 (11) 40034500
Fax: +91 (11) 40034520

Regd. Office :
501 B, Silver Utopia
Cardinal Gracias Road
Chalata, Andheri (East)
Mumbai - 400069

Tel: +01 (22) 60974900
Fax: +01 (22) 60974909
www.roche-diagnostics.co.in

31



TO WHOM SO IT MAY CONCERN

Ref no : RIMS/Micro/Viraload/c6800/24-25/01 Date : 21/06/2024

This is to certify that the prices offered in this tender are the lowest considering the commercial/technical terms and conditions of this tender.

Yours sincerely,
For Roche Diagnostics India Pvt. Ltd.

Binendra Singh
Authorised Signatory



[Signature]
22/06/2024
[Signature]
22/6/2024

[Signature]
22/06/2024

[Signature]
22/6/24

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN-U85195MH1988PTC141417

Regd. Office :
501 B, Silver Utopia
Cardinal Garcious Road
Chakala, Andheri (East)
Mumbai - 400069

Head of Microbiology Deptt.
RIMS, RANCHI
Tel: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in
info.india@roche.com

30



NON BLACKLISTING UNDERTAKING

To,
The Director,
Rajendra Institute of Medical Sciences (RIMS),
Bariatu, Ranchi- 834 009.

We M/s Roche Diagnostics India Pvt. Ltd. having registered office at 501B, Silver Utopia, Cardinal Gracious Road, Andheri, Mumbai – 400069 (INDIA) and Regional Office at Unit - 1002, Merlin Acropolis, 1858/1, Rajdanga Main Road, East Kolkata Township, Kolkata, West Bengal 700107 hereby certify that our company is not debarred/blacklisted or no legal case pending by any Government/Semi Government Organizations/Institutions on any account.

For Roche Diagnostics India Private Limited

Birendra Singh



Birendra Singh

Regional Manager-Molecular Lab

SA
22/06/2024
[Signature]
22/6/20
[Signature]
22/6/2024

[Signature]
22/6/24
Head of Microbiology Deptt.
RIMS, RANCHI

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN-U85195MH1988PTC141417

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN-U85195MH1988PTC141417

Regd. Office:
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400069

Tel.: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in
info.india@roche.com

29



PROPRIETARY CERTIFICATE

This is to certify, we, M/s. Roche Molecular Systems Inc., 1080 US Highway 202 South, Branchburg, NJ 08876, Country: United States is the legal manufacturer for the reagents and Instruments listed in Annexure I and are proprietary products of Roche.

Roche Diagnostics India Pvt. Ltd., having its registered office in 501 B, Silver Utopia, Cardinal Gracious Road, Andheri (Est), Mumbai-400069, India, is 100% subsidiary of M/s. Roche Molecular Systems Inc.,.

19 April 2024

Sincerely,

Roche Molecular Systems Inc.

DocuSigned by:
Mariana Roldan
CA259B3D9AFD470...

Mariana Roldan Ocampo
Regulatory Specialist Diagnostics
International Regulatory Operations

[Signature]
22/06/2024
[Signature]
22/6/2024
[Signature]
22/6/2024

[Signature]
22/06/2024

[Signature]
22/6/24

Head of Microbiology Deptt.
RIMS, RANCHI



Annexure I

5524245001	cobas® 6800 System
9175431190	Cobas® SARS-CoV-2
9446109190	Cobas® SARS-CoV-2
9448870190	Cobas® SARS-CoV-2
9343733190	Cobas® SARS-CoV-2
9175440190	Cobas® SARS-CoV-2 Control Kit
9446117190	Cobas® SARS-CoV-2 Control Kit
9233474190	Cobas SARS-CoV-2 & Influenza A/B
9446125190	Cobas SARS-CoV-2 & Influenza A/B
9233482190	Cobas SARS-CoV-2 & Influenza A/B Control Kit
9446133190	Cobas SARS-CoV-2 & Influenza A/B Control Kit
7460155190	cobas® HPV
9040544190	cobas® HPV
7460171190	cobas® HPV Positive Control Kit
9040552190	cobas® HPV Positive Control Kit
7002238190	cobas® Buffer Negative Control Kit
9051953190	cobas® Buffer Negative Control Kit
7862113190	cobas® HIV-1/HIV-2 Qualitative
9040528190	cobas® HIV-1/HIV-2 Qualitative
7862091190	cobas® HIV-1/HIV-2 Qualitative Control Kit
9040536190	cobas® HIV-1/HIV-2 Qualitative Control Kit
9051554190	cobas® NHP Negative Control Kit
8064695190	cobas® Specimen Pre-Extraction Reagent
8688206190	cobas® EBV
9040943190	cobas® EBV
8688249190	cobas® BKV
9040960190	cobas® BKV
8688214190	cobas® EBV/BKV Control Kit
9040951190	cobas® EBV/BKV Control Kit
9040897190	cobas® CMV (192 Tests)
9040919190	cobas® CMV Control Kit
6997546190	cobas omni MGP Reagent (MGP)
6997511190	cobas omni Specimen Diluent (SPEC DIL)
6997538190	cobas omni Lysis Reagent (LYS)
6997503190	cobas omni Wash Reagent (WASH)
9040820190	cobas® HBV
9040773190	cobas® HBV/HCV/HIV-1 Control Kit
9040765190	cobas® HCV
9040803190	cobas® HIV-1
6998917190	cobas® MPX
9040862190	cobas® MPX
6999069190	cobas® MPX Control Kit
9040846190	cobas® MPX Control Kit
7460066190	Cobas CT/NG

22/06/2024
 [Signature]
 22/6/24

22/6/2024
 [Signature]

22/6/24
 [Signature]

Head of Microbiology Deptt.
 RIMS, RANCHI

27



9040501190	Cobas CT/NG
7460082190	Cobas® CT/NG Positive Control Kit
9040510190	Cobas® CT/NG Positive Control Kit
9040633190	cobas® TV/MG
9040641190	cobas® TV/MG Positive Control Kit
9500111190	cobas® SARS-CoV-2 Duo
9500120190	Cobas SARS-CoV-2 Duo Control Kit

Deepak Sharma

22/06/2024
22/6/20
22/6/2024

Moujir
22/6/24
22/6/2024

Head of Microbiology Deptt.
RIMS, RANCHI

Memorandum of Understanding

BETWEEN

Mission Director,
National Health Mission
Jharkhand

And

Roche Diagnostic India Pvt. Ltd.
Unit-1002, Merlin Acropolis
1858/1, Rajdanga Main Road, East Kolkkata Township
Kolkata- 700107

Towards, supply and installation of 2 Nos. Cobas 6800 and 50,000 reagents.

This MOU is made and executed at Ranchi on 20th day of JUNE 2022.

By and between

Mission Director, National Health Mission, Jharkhand hereinafter referred to as the "1st Party", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include any successors-in - office

And

Roche Diagnostic India Pvt. Ltd, Unit-1002, Merlin Acropolis, 1858/1, Rajdanga Main Road, East Kolkata Township, Kolkata- 700107 hereinafter referred to as "2nd party", which expression unless repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns.

1. Background

Whereas, Covid-19 has taken the dimensions of a pandemic and affected most of the states In India including Jharkhand, there is an urgent need for ramping up testing. Whereas, Roche Diagnostc Is manufacturer of Cobas-6800 which has a capacity to test 1344 samples In 24 Hrs.

2. Scope of MOU

The current scope of MOU Is to engage Roche for supply and installation of 2 nos. Cobas 6800 - one each at Ranchi and Dumka and supply of reagents (initially 50,000).

3. Role and Responsibility of NHM

- a) To provide BSL-2 + Lab Infrastructure as per Annexure- A for Installation of Cobas 6800 at both places.




[Handwritten signatures and initials]

- b) To advance 75% of total amount of equipment and balance 25% within 10 days of installation of equipment as per Annexure-B
- 4. An advance for purchase of reagents as per requirement to AUTHORISED DISTRIBUTOR.
- 5. Role and Responsibility of Roche
 - a) M/s Roche will ensure supply and Installation of equipment within 15 days of readiness of sight at Dumka and Ranchi.
 - b) M/s Roche will provide a warranty for 5 years.
 - c) M/s Roche will ensure timely supply of reagents through its authorized distributor.
- 6. Mediation and Dispute Resolution:
 - a) Any dispute arising out of this agreement will be referred to the Mission Director, NHM, Government of Jharkhand or person nominated by him, and the provision of Article-12 of Arbitration and Conciliation Act, 1996 will be followed.
 - b) No legal proceeding shall lie against the 1st party or any person for anything that is done in good faith or intended to be done in pursuance of this agreement.
 - c) The agreement shall be governed by the applicable laws in force in India. In the event of any dispute arising out of the agreement, the dispute would be subject to the jurisdiction of the Court within the state of Jharkhand only.
- 7. The MOU will come into force from the date of 17th APRIL 2021.

Second Party

Roche Diagnostics India Pvt Ltd

Sutanu De
 Shri Sutanu De 20/06/2022
 Zonal Manger



First Party

National Rural Health Mission Jharkhand

Anil Kumar
 20/6/2022
 Shri Anil Kumar
 State Nodal Officer Procurement Cell
 (ON BEHALF OF MISSION DIRECTOR)

Witness:

1. *Pradyuman*
 20-06-22
 MAHARSHI RAMAN

2. *Aditya Sarangi*
 ADITYA SARANGI

Witness:

1. *Pulakesh*
 20/6/22
 SE, IOSP.

A. S. De

(C)



PROPRIETARY CERTIFICATE

This is to certify, we, M/s. Roche Molecular Systems, Inc., 1080 US Highway 202 South, Branchburg, NJ 08876, USA, are the legal manufacturer for the reagents and instrument listed below and are proprietary products of Roche :-

1	9175431190	Cobas® SARS-CoV-2
2	9343733190	Cobas® SARS-CoV-2
3	9175440190	Cobas® SARS-CoV-2 Control Kit
4	9233474190	Cobas SARS-CoV-2 & Influenza A/B
5	9233482190	Cobas SARS-CoV-2 & Influenza A/B Control Kit
6	6997767190	cobas® HBV/HCV/HIV-1 Control Kit
7	7460155190	cobas® HPV
8	7460171190	cobas® HPV Positive Control Kit
9	7002238190	cobas® Buffer Negative Control Kit
10	7862113190	cobas® HIV-1/HIV-2 Qualitative
11	9040528190	cobas® HIV-1/HIV-2 Qualitative
12	7862091190	cobas® HIV-1/HIV-2 Qualitative Control Kit
13	9040536190	cobas® HIV-1/HIV-2 Qualitative Control Kit
14	9051554190	cobas® NHP Negative Control Kit
15	7002220190	cobas® NHP Negative Control Kit
16	8064695190	cobas® Specimen Pre-Extraction Reagent
17	8688206190	cobas® EBV
18	8688249190	cobas® BKV
19	8688214190	cobas® EBV/BKV Control Kit
20	9040897190	cobas® CMV (192 Tests)
21	9040919190	cobas® CMV Control Kit
22	6997546190	cobas omni MGP Reagent (MGP)
23	6997511190	cobas omni Specimen Diluent (SPEC DIL)
24	6997538190	cobas omni Lysis Reagent (LYS)
25	6997503190	cobas omni Wash Reagent (WASH)
26	9040820190	cobas® HBV
27	9040773190	cobas® HBV/HCV/HIV-1 Control Kit
28	9040765190	cobas® HCV
29	9040803190	cobas® HIV-1
30	9040862190	cobas® MPX
31	9040846190	cobas® MPX Control Kit
32	7460066190	Cobas CT/NG
33	7460082190	Cobas® CT/NG Positive Control Kit

Roche Diagnostics India Pvt. Ltd., having its registered office in 501 B, Silver Utopia, Cardinal Gracious Road, Andheri (Est), Mumbai-400069, India, is 100% subsidiary of M/s. Roche Molecular Systems, Inc., USA.

Sincerely,
21 April 2022

Deborah Liu

Deborah Liu
Sr. Regulatory Affairs Specialist II
International Regulatory Affairs

Roche Molecular
Systems, Inc.

Aradhana
21/4/22
22/06/2022
[Signature]
21/6/22

1080 US Highway 202 South
Branchburg, NJ 08876
USA

Moujeer
[Signature]
Head of Microbiology Dept.
PIMS, RANCHI

5



75
आज़ादी का
अमृत महोत्सव



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011

Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011

रोली सिंह, भा.प्र.से.

Roli Singh, I.A.S.

अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Additional Secretary & Mission Director (NHM)

D. O. No. M.11034/02/2018-Hep (NCDC) (CCD)

Dated 13th June, 2022

Dear Colleagues

As you are aware, under the National Viral Hepatitis Control Program (NVHCP), viral load testing for HBV DNA and HCV RNA is a critical diagnostic molecular test. The outcome of this test is important for the clinical decision of initiation of the treatment and monitoring. An erroneous result can lead to progression of the patient to develop life-threatening complications of cirrhosis and hepatocellular carcinoma.

During the COVID-19 pandemic, the availability of infrastructure for molecular testing has increased in the country. Most of these platforms were for qualitative SARS-CoV-2 testing on open platforms. However, viral load tests for HCV RNA and HBV DNA, being quantitative, need to be validated before being used on these platforms.

In view of above, the Technical Resource Group (TRG) on Laboratory Services under NVHCP has recommended use of closed integrated system with IVD approval for viral load testing of HBV DNA and HCV RNA under the program for the next year. Meanwhile, protocols will be established using the competence of ICMR for validation of kits to avoid compromise on quality.

A detailed guidance note as per the recommendations of TRG is annexed alongside for consideration by the States/UTs with regards to estimation of viral load in patients for viral hepatitis.

with best wishes,

Yours sincerely,

Roli Singh
(Roli Singh)

To

1. Mission Director (NHM) of all States/UTs
2. Nodal Officers of all States/UTs
3. Hepatitis Cell

Monye
21-2-24
Asish Ran
21/2/24

ASMD of Microbiology **देश में भारत - स्वास्थ्य भारत**

Tele : 011-2306 3693, Telefax : 011-2306 3687, E-mail : asmd-mohfw@nic.in

②

Subject: Guidance Note for estimation of viral load in patients screened positive for viral hepatitis under the National Viral Hepatitis Control Program (NVHCP)

Consequent upon meeting of the Technical Resource Group (TRG) on Laboratory Services under NVHCP held on 28th April, 2018 and the recommendations thereafter, the following guidance note is issued by NVHCP for consideration by the States/UTs with regards to estimation of viral load in patients screened positive for viral hepatitis under NVHCP.

Viral Load testing for HCV RNA and HBV DNA is a critical diagnostic molecular test. The outcome of this test is important for the clinical decision to determine whether the patient requires treatment, monitoring of HBV and determining cure of HCV infected patients. Thus, the tests and machines/platforms need to be IVD approved as every individual/ patient report generated by a laboratory holds the doctor responsible and accountable for the same and directly affects patient lives.

There are two types of machines available in the market viz. open and closed depending on the use of kits and reagents by any manufacturer or specifically by the manufacturer of the machine respectively. Open systems require infrastructure, are technique intensive requiring highly trained manpower and failure of batch runs is more probable. Monitoring of quality is difficult due to multiple variable factors e.g. equipment, batch/lot variation of kits and reagents, optimum designing of the laboratory and requirement of trained human resource. Also due to no clarity of limit of detection, availability of sufficient standards in terms of the range and volume in the kits, the results (quantity of DNA/RNA) may not be reliable and jeopardise the life of a patient if he is falsely declared as cured. The patient may in such situations develop the life-threatening complications of cirrhosis and hepatocellular carcinoma.

The availability of infrastructure for open platforms for molecular testing has increased in the country during the COVID-19 pandemic. The molecular test for SARS-CoV-2 during the COVID-19 pandemic was **qualitative** in nature. The available infrastructure could be considered for a variety of pathogens without compromising the quality.

However, the molecular testing for viral hepatitis B & C infection requires **quantification i.e measurement of quantity of virus present in the plasma/serum sample in IU/mL**. The assessment of critical parameter of Limit of detection (LOD) (i.e. the ability of the machine and test kit to detect the lowest quantity of virus in IU/mL in plasma/serum) determined the efficiency of the test result, which is essential to ascertain whether the patient infected with HCV infection has cleared the virus and also for continuous monitoring of HBV infection. Moreover, most of the approvals accorded for SARS-Cov-2 molecular tests were through "emergency authorization use" only which may have overlooked certain critical parameters of validation in view of the unprecedented crisis faced by the world.

An open system comprised of two machines with separate processes and objectives viz. an extraction platform and an RT-PCR platform. Testing on these machines requires compatibility of kits and reagents with the platforms. Some kits give sub-optimal yield on the automated extraction platform and may require manual extraction (highly technique intensive and prone to contamination).

The yield of extraction decides the outcome on the RT-PCR platform. The result is thus dependent on multiple variables. There is often compromise in synergy between the reagents and machine leading to erroneous results which can compromise on patient care. The regulator (CDSCO) confirmed that IVD approval for kits and reagents were being given without keeping in mind the machine on which they were to be used.

Certain kits used on open system often compromise on quality by reducing the range and volume of standards. The same is often not validated during procurement and L1 is calculated discounting the fact that more such standards will have to be procured if the kits have to be utilised fully in multiple runs. This increases the per patient tested cost immensely which is unaccounted, compromising on financial efficiencies.

In view of above, the recommendations of the TRG on Laboratory Services are as follows

1. Use of closed integrated system with IVD approval to be used for roll out of the program for the next year.
2. A group of laboratories shall be identified to develop protocols/SOPs for validation of kits on open systems for all kits procured in the country to be validated across all batch/lot on specified machines. This will ensure quality testing, reproducibility of accurate and standardized results.

Arsha Ram
2/2/24

Mony
21-1-24
Head Microbiology Dept
RMA, Patna