Ref: AIIMS/MG/Micro/Non DPR/CSR-CLIA-Consumables/2023-24/03
FTS: 3328 **Date**: 20-01-2024

Call for Objection

Subject: Inviting comments/objection, if any before declaring proprietary article for procurement of "**Consumables for CSR-CLIA Machine**" for the Department of Clinical Microbiology AIIMS Mangalagiri.

Clinical Microbiology Department, AIIMS Mangalaigiri has to procure "**Consumables for CSR-CLIA Machine**" through Proprietary Article basis.

The proposal submitted by M/s. Beckman Coulter India Pvt ltd, Mumbai who is sole manufactures and M/s. Sridevi Medical and Allied products, Vijayawada who is authorized Sole Dealer/agents of the sole manufacturer of this item along with Proprietary Article Certificate are attached & uploaded on Institute website.

The above documents are being uploaded for open information to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment/items to be procured, within 10 days i.e., (30-01-2024) from the date of issuance/uploading of the notification.

The objection should be raised in the technical compliance sheet as enclosed in Annexure -I, if any Firm claiming suitability of their product with respect to specification mentioned.

The comments should be sent to the office of Procurement Cell, 2nd floor, Admin cum Library building at AIIMS Mangalagiri in a sealed envelope with above reference on or before (30-01-2024) up to 05:00 PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacture/vendor is having no comment to offer and case will be decided on merits.

-sd-
F I/C Procurement
AIIMS Mangalagiri

PAC CERTIFICATE

P-3 Form

(To be attached with P-2 form for Proprietary items)

AIIMS, Mangalagiri

PROPRIETORY ARTICLE CERTIFICATE

It is certified that the **CONSUMABLES AND REAGENTS** for **Chemilumiscence Immuno Analyzer (Model: Unicel Dxi600)** should be purchased from **M/s Sridevi Medical and Allied Products, 1st Floor, 30-7-2, Anaparthi Vari Street, Durga Agraharam, Vijayawada – 520002, Andhra Pradesh.** To the best of my knowledge **M/s Sridevi Medical and Allied Products, 1st Floor, 30-7-2, Anaparthi Vari Street, Durga Agraharam, Vijayawada – 520002, Andhra Pradesh.** are the sole Dealer/agents of the sole manufacturer of **BECKMAN COULTER INDIA PVT. LTD.**

Similar items manufactured by other firm(s) shall not be suitable for our purpose as it is a closed system. The consumables and reagents of same company has to be used to provide appropriate reliable results.

(Signature indenter)

Dr. Vasudha C L
MD (Microbiology)
Associate Professor
Department of Clinical Microbiology
All India Institute of Medical Sciences
Mangalagiri (Andhra Pradesh)

Date: 27/9/2023

Designation: Associate Professor

Department: Clinical Microbiology

27/9/23.

Dr. SUMIT RAI
MD(Gold Medalist),PDCC(Infectious Diseases)
Professor & Head
Department of Clinical Microbiology
All India Institute of Medical Sciences
Mangalagiri (Andhra Pradesh)

Signature of Head of Department /Section

N.B.: The indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.

Beckman Coulter India

Regional Office:
Building 6A, 5th Floor,
Unit No.401,402 & 501 & 502
RMZ Ecoworld Sarjapur,
Marathalli Outer Ring road
Bengaluru - 560103
Tel: 080-67515700
Email: dxtendersindia@beckman.com

Ref.: BCIPL/GEN/053/2023
Dated: March 30, 2023

To,
The Director,
AIIMS-Mangalagiri,
Guntur, A.P.

Ref: Fully Automated CLIA analyser (Model: Unicel DxI 600)

Sub: Authorisation letter.

Dear Sir,

We, Beckman Coulter India Private Limited, a subsidiary of Beckman Coulter Inc., USA the OEM, hereby authorize M/s Sridevi Medical and Allied Products, 1st Floor, 30-7-2, Anaparthi Vari Street, Durga Agraharam, Vijayawada-520002, Andhra Pradesh as the authorized distributor for the supply of reagents and consumables for the High throughput Fully Automated Chemiluminescence Immunoassay Analyzer (Model: UniCel DxI 600) installed at Department of Microbiology Lab in AIIMS-Mangalagiri.

This authorization letter is valid until revoked by us and informed to your office in writing, The contact details of the distributor are as follows:

M/s Sridevi Medical and Allied Products,
1st Floor, 30-7-2, Anaparthi Vari Street,
Durga Agraharam,
Vijayawada-520002, Andhra Pradesh

Contact Person: Mr. Ganesh Babu.
Mobile: 09676456798
Email: ganesh3798@gmail.com

Thanking you,

For Beckman Coulter India Private Limited

DocuSigned by:
Raghavendra SR
Signer Name: Raghavendra SR
Signing Reason: I approve this document
Signing Time: 31-Mar-2023 | 2:27:02 PM IST
63150BE214E19ADE2DE7228A78477

(Raghavendra S.R)
Sales Head - Government Business, India
Clinical Diagnostics

Dr. Vasudha C L
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MD(Gold Medalist),PDCC(Infectious Diseases)
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All India Institute of Medical Sciences
Mangalagiri (Andhra Pradesh)

All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh – 522503
Department of Clinical Microbiology

Technical Specification for CLIA – Kits, Consumables & Reagents

S.No	Name of the test	Description	Method
1.	Access HCV Ab V3	Kit should detect antibodies against Hepatitis C virus in patient serum/plasma qualitatively.	CLIA (Chemiluminescence Immunoassay)
2.	Access HCV Ab V3 Calibrators	To calculate cut-off values using calibration curve.	
3.	Access HCV Ab V3 QC	Positive and Negative Controls for quality control purpose.	
4.	HAV IgM	Kit should detect IgM antibodies against Hepatitis A virus in patient serum/plasma.	CLIA (Chemiluminescence Immunoassay)
5.	HAV IgM Cals	To calculate cut-off values using calibration curve.	
6.	HAV IgM QC	Positive and Negative Controls for quality control purpose.	
7.	HBs Ag	Kit should detect Hepatitis B virus surface antigen in patient serum/plasma qualitatively.	CLIA (Chemiluminescence Immunoassay)
8.	HBs Ag Cals	To calculate cut-off values using calibration curve.	
9.	HBs Ag QC	Positive and Negative Controls for quality control purpose.	
10.	HIV Combo	Kit should detect antibodies against HIV 1 / 2 virus or P24 Antigen in patient serum/plasma qualitatively.	CLIA (Chemiluminescence Immunoassay)
11.	HIV Combo Cals	To calculate cut-off values using calibration curve.	
12.	HIV Combo QC	Positive and Negative Controls for quality control purpose.	
13.	Access HAV Ab Kit	Kit should detect total antibodies against Hepatitis A virus in patient serum/plasma quantitatively.	CLIA (Chemiluminescence Immunoassay)
14.	Access HAV Ab Cals	To calculate cut-off values using calibration curve.	
15.	Access HAV Ab QC	Positive and Negative Controls for quality control purpose.	
16.	Access Toxo IGM II Kit	Kit should detect IgM antibodies against Toxoplasma in patient serum/plasma qualitatively.	CLIA (Chemiluminescence Immunoassay)
17.	Access Toxo IGM II Cals	To calculate cut-off values using calibration curve.	
18.	Access Toxo IGM II QC	Positive and Negative Controls for quality control purpose.	
19.	Toxo IgG	Kit should detect IgG antibodies against Toxoplasma in patient serum/plasma qualitatively & quantitatively.	CLIA (Chemiluminescence Immunoassay)
20.	Toxo IgG Cals S0-S5	To calculate cut-off values using calibration curve.	
21.	Toxo IgG QC	Positive and Negative Controls for quality control purpose.	
22.	Rubella IgM	Kit should detect IgM antibodies against Rubella virus in patient serum/plasma qualitatively.	CLIA (Chemiluminescence Immunoassay)
23.	Rubella IgM Cals	To calculate cut-off values using calibration curve.	
24.	Rubella IgM QC	Positive and Negative Controls for quality control purpose.	
25.	Rubella IgG	Kit should detect IgG antibodies against Rubella virus in patient serum/plasma qualitatively & quantitatively.	CLIA (Chemiluminescence Immunoassay)
26.	Rubella IgG Cals	To calculate cut-off values using calibration curve.	

Associate Professor
Department of Clinical Microbiology
All India Institute of Medical Sciences
Mangalagiri (Andhra Pradesh)

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Professor & Head
Department of Clinical Microbiology

27.	Rubella IgG QC	Positive and Negative Controls for quality control purpose.	
28.	CMV IgM	Kit should detect IgM antibodies against Cytomegalovirus in patient serum/plasma qualitatively.	CLIA (Chemiluminescence Immunoassay)
29.	CMV IgM Cals	To calculate cut-off values using calibration curve.	
30.	CMV IgM QC	Positive and Negative Controls for quality control purpose.	
31.	CMV IgG	Kit should detect IgG antibodies against Cytomegalovirus in patient serum/plasma qualitatively & quantitatively.	CLIA (Chemiluminescence Immunoassay)
32.	CMV IgG Cals	To calculate cut-off values using calibration curve.	
33.	CMV IgG QC	Positive and Negative Controls for quality control purpose.	
34.	ACCESS PCT 2X50 DET	Kit should detect Procalcitonin levels in patient serum/plasma quantitatively.	CLIA (Chemiluminescence Immunoassay)
35.	ACCESS PCT CALIBRATOR KIT	To calculate cut-off values using calibration curve.	
36.	IL-6	Kit should detect Interleukin - 6 levels in patient serum/plasma quantitatively.	CLIA (Chemiluminescence Immunoassay)
37.	IL-6 Cals S0-S5	To calculate cut-off values using calibration curve.	
38.	IL-6 QC	Positive and Negative Controls for quality control purpose.	
39.	Substrate (Access / DxI)	Accessory Reagents	CLIA (Chemiluminescence Immunoassay)
40.	Ringed Reaction Vessels (DxI)	Accessory Reagents	
41.	Wash Buffer II, (DxI)	Accessory Reagents	
42.	Contrad 70,	Accessory Reagents	
43.	Citranox,	Accessory Reagents	
44.	System Check Solution,	Accessory Reagents	
45.	UniCel Dxl Waste Bags,	Accessory Consumables	
46.	Sample Cup (2mL)	Accessory Consumables	
47.	Sample Cup (5mL)	Accessory Consumables	

***All kits, Calibrators, Controls, Consumables & Reagents should be compatible with Beckman Coulter Unicel Dxi 600 Equipment.**

1. Test should be performed in Human Serum, Plasma or Whole Blood.
2. Sensitivity should be ≥ 98%, Specificity should be ≥ 98%.
3. Cold chain indicator to be provided with the kits.
4. A cumulative time/temperature indicator prequalified by WHO which indicates the exposure to temperature in the range of 2–8 degree C is to be provided on every pack of kits.
5. The supplier should ensure maintenance of cold chain during transportation of kits at 2° C to 8° C.

Dr. Vasudha C L
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All India Institute of Medical Sciences

Dr. S[illegible]
MD(Gold Medalist, Infectious Diseases)
Professor & Head
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All India Institute of Medical Sciences

6. Original kit literature in English/Hindi (not photocopy) provided with each kit in English mentioning the principle, components, methodologies, validity, criteria, performance characteristics, bio-safety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal provided.
7. Kit should be approved from the statutory in its country of origin.
8. Kit should be **CE-IVD** approved
9. Manufacture shall submit all necessary certifications, license and test reports to the buyer along with supplies.
10. Kit should have 3/4th of shelf life from the mentioned date of expiry when received by the department.
11. Supplier should agree to provide advance sample of the kit for buyer's approval before commencement of bulk supply.

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Ma[illegible]desh)

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Mangalagiri (Andhra Pradesh)

ANNEXURE – I

SPECIFICATIONS

Objection should be submitted in following format:

S. no	Item specification as given	Specification offered by firm	Deviation if any	Remarks