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Reply to Objections raised by different companies in response to "Call for Objection- AIIMS Deoghar, published Letter AIIMS/DEO/Bio/2026/AUG/451, dated 17/08/2026

A] General: This process of procurement was followed to facilitate patient care and smooth laboratory services in this remote area:

- During the first half of the summer vacation the biochemistry lab was closed for nearly two weeks creating a crisis for the institute and patient care. As there was an existing rate of tests approved by SFC for the previous lab run by HLL on Vitros 5600 platform (Ortho Clinical Diagnostics), the competent authority asked the HLL representatives to reinstate their old dry VITROS integrated machine present in AYUSH block and therefore RC for consumables of this machine were called for. But the HLL authorities refused to let their old integrated system to be used. In the prebid meeting for establishing rate contracts [held as per **Order no. AIIMS/Deo/lab consumables/ Pre-Bid query/2025-26/01 (1/C)]** calling all the qualified participants in January 2026, few of the qualified companies participated and in that meeting, in the immunochemistry section, only Ortho Clinical Diagnostics participated and developed a fresh Rate Contract with the institute as L1) To mitigate the crisis in the lab and presence of readily available RC and the SFC approved rates along with interest showed by the OCD representatives to install an instrument free of cost, the department in discussion with the competent authority asked the vendor to keep its demo machine till further official procedures are being done and online call for web objection is done. <u>This complies with **GFR Rule 166 clause (ii) (Single Tender enquiry attached as 6/C).**</u>
- Three auto-analysers for clinical chemistry and one for immunochemistry in a remote area with poor water quality (silt deposition) should ideally have an integrated **dry chemistry platform** as a backup. As AIIMS is a premier educational institute having undergraduate and postgraduate courses in medical, nursing and paramedical courses, this backup option is also needed in a teaching institution for teaching the usage, calibration, maintenance and testing methodologies of different leading platforms.

B] Specific reply to Objections:

Published specification	Objection	Justification for published specification
Integrated System/Analyzer to be based on "Dry Chemistry" technology	No immunoassay system in the market operates on dry-chemistry technology, and not all photometric (biochemistry) assays are dry chemistry based either. The clause as worded , is technology specific and matches one manufacturer's product line	AIIMS Deoghar, is an institute of National importance, and as a premier institution for medical sciences, needs to equip its biochemistry department and laboratory service by providing different technology based analyzers to enhance the patient service, teaching facility and research work. Dry chemistry based integrated system has been mentioned for not only for meeting the above mentioned purposes but it also considered as parallel /back up technology for existing wet chemistry based analyzers. Majority of the assays applicable to the dry chemistry based integrated system are dry microslide based and the institution/department has the expertise to use best suitable technology for desired parameter as per the diagnostic need of the patient. Immunoassay part of the dry chemistry based integrated system is beneficial for the laboratory as a backup of existing immunoassay system, for cross checking the doubtful results, for getting hemolysis, icteric and turbidity interference free test report for critical samples without splitting the sample which will minimize human error, man-hour and improves the TAT.
Immunoassay module requires to be dry chemistry /slide based	Immunoassay technology is inherently wet-chemistry based across all global manufacturer; a dry chemistry qualifier for this module is not technically meaningful and eliminates every other OEM	
Procurement proposed to be finalized on proprietary Article Certificate (PAC)/Single - Tender basis	PAC /Single source procurement is permissible only where goods are manufactured exclusively by one source and no equivalent alternative exists. Multiple US-FDA approved , six-sigma certified manufacturers supply technically equivalent or superior wet-chemistry analyzers and reagents, the item is therefore not proprietary in nature	Considering the nation wise initiative for minimizing the water wastage and maximizing the water saving, dry chemistry technology based system has been considered as the most suitable solution for the institution. Generally wet chemistry based system used approximately 25 liter of DW water / hour and to produce such volume of DW, approximately 100 liter raw water is used / Hr. So considering 24 hr x 7 functioning laboratory, dry chemistry based system, which does not require any external water resources, can save approximately 8,50,000 liter of water in a year. There is no equivalent technology available with such environmental sustainability. Further, there are many unique advantages of dry chemistry technology- such as use of fresh electrode for every electrolyte test, interference (water impurities, hemolysis, icteric, turbidity) free test results by not consuming any extra reagents and without hampering TAT, minimum dead volume for pediatric sample to do test without dilution, zero carry over & contamination etc.

		85% of the parameters in dry chemistry based integrated system are six-sigma complied which is highest across the available technologies. "Call for objection' has been published for checking the proprietary nature of the dry chemistry based integrated system, so if any manufacturer have the proprietary for the same, they should provide the proprietary certificate for the same.
	More than 90% of diagnostics market are using wet chemistry systems .So make the specification wet/dry	The biochemistry department/laboratory of AIIMS Deoghar is using wet chemistry systems and planning to adopt dry chemistry system also to provide multiple resources to the faculties and laboratory personnel to deliver best possible patient service , research and academic requirements.
	The dry chemistry system (slide/cartridge) waste is non-biodegradable impacting the environment	Slides, Reagent cartridge do not meet the criteria of hazardous waste as defined by the Resource Conservation Recovery Act (RCRA). This determination has been made through a combination of analytical Toxicity Characteristic Leaching Procedure (TCLP) tests on representative product samples and constituent knowledge of the product. The Environmental Protection Agency recognizes TCLP as the procedure to determine if a substance exhibits a toxicity characteristic to classify the waste as hazardous. Slides, Reagents cartridges falls under RCRA hazardous waste classification categories including the following lists: F, P, U, K, and D (40 CFR 261, Subparts C and D). Slides, cartridge and other disposables that are unused do not contain any human components that would normally be associated with biological/regulated medical waste. As such, special waste disposal or labeling requirements are not required. Slides, cartridge and other disposables that have been in contact with body fluids should be handled as biological/regulated medical waste in accordance with the local regulations. Therefore, storage and disposal should be in accordance with the procedures defined by the National Biohazard Safety Guideline or local regulations for the disposal of biological/regulated medical waste. The quantity of solid waste, generated from dry chemistry system will be very minimal when compared to the solid waste (medical waste) generated in the Hospital.

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