



Ref No of GeM Bid No. GEM/2025/B/6871631

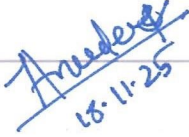
Issue Date of Bid : 11-11-2025


Name of the Bid: New Born Screening set up

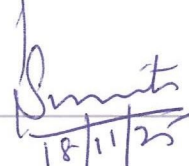
The clarifications and amendments on the representation received during Prebid Meet

Trivitron Healthcare

S. No.	Title	Tender Technical Specification	To be amended/modified (Representation)	Amendment
1.	Point No.6: Computer and interfacing	A computer and certified software (IVD-certified) necessary for handling instrument and patient data and relevant disease risk calculation as applicable should be provided by the company.	Suggestion- A computer and Certified software (well tested and quality Certified) necessary for handling Instrument and patient data and relevant disease risk calculation as applicable should be provided by the company.	A computer and Certified software (IVD-certified/ well tested and quality Certified) necessary for handling Instrument and patient data and relevant disease risk calculation as applicable should be provided by the company.
2.	Point No.11: Others	The system must have at least three currently operational installations in Institutes of National Importance in India.	Suggestion- The system must have at least three currently operational installations in Institute of National Importance/ NABL accredited Lab/ Institute	None

  
18-11-25  
(DR. ANUDEEP P.P.)

  
(DR. ANURAG SANKHYAN)

  
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**Department of Biochemistry**  
**All India Institute of Medical Sciences, Bilaspur (H. P.)**  
**Technical Specifications of**  
**Semi-automated Newborn Screening System**

Sr No.	Title	Details of Specifications
1.	General information	The instrument set up should be capable of carrying out Newborn screening (NBS) of various parameters from dried blood spot sample.
2.	Type of automation	Semi-Automated
3.	System/ Equipment requirements	<ul style="list-style-type: none"> <li>The system should be capable of carrying out the following assays under Newborn screening i.e., TSH, T4, G6PD, Phenylalanine, Biotinidase, Total Galactose, GALT, 17-OHP etc. (Annexure-1)</li> <li>The system should have all the accessories required for processing the dried blood spot samples through 'Punch and Elute' methodology including Dried Blood Spot Puncher, Disc Remover, 96-Well Plate Shaker, Plate washer, and Microplate Incubator Shaker.</li> <li>The system should have the capability to include additional parameters as per the requirement.</li> <li>All the devices should work at ambient temperature (18-24 degree Celsius) and relative humidity (30-50%) condition at user site.</li> <li>At the time of installation, dried blood spot collection filter paper card, reagents, calibrators and controls for the process of validation should be provided by the company.</li> </ul>
4.	Methodology	The system should work on the principle of Fluorometry/Fluoro-Enzymatic Assays/ Fluoro Enzymatic immunoassay/Time resolved fluorescence.
5.	Reagents, calibrators, controls and other Accessories	<ul style="list-style-type: none"> <li>The system should be capable of multipoint calibration.</li> <li>The system should have built in alarm/ warning (audio/visual/audiovisual) for any error in the process.</li> <li>The company shall quote rates of consumables (minimum 75% shelf life) viz reagent kits, calibrators and controls in Indian Rupees. The price of kits, accessories, accessories reagents, calibrators and controls shall be frozen on rate contract basis for the period of 10 years. The company shall quote on the following format: <ul style="list-style-type: none"> <li>Equipment name</li> <li>Reagent kits as per Annexure 1 (Yearly price X 10 years)</li> <li>Accessories and accessories reagents (Yearly price X 10 years)</li> <li>Calibrators and controls (Yearly price X 10 years)</li> <li>CMC charges</li> <li>Total cost</li> </ul> </li> <li>The price of all consumables for 10 years period shall be considered for price comparison. Any consumable or accessory component required for the maintenance of the equipment should be supplied free of cost by the company.</li> </ul>

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		<ul style="list-style-type: none"> <li>Quality control should be available for all the test parameters. (Annexure 1)</li> <li>The system should be able to perform and analyse Quality control data.</li> <li>The bidder should provide option to enrol the instrument for participation in EQAS or provide third party controls for EQAS.</li> </ul>
6.	Computer and interfacing	<ul style="list-style-type: none"> <li>A computer and certified software (IVD-certified) necessary for handling instrument and patient data and relevant disease risk calculation as applicable should be provided by the company.</li> <li>The company should provide the computer (Latest Windows, i-7 processor 13<sup>th</sup> generation or above, RAM 16 GB or above, SSD- 1TB, Standard graphics card, MS office or equivalent configuration for optimal instrument functioning) and laser printer. The vendor should provide support for upgradation of the system. Software should provide facility to enter and track patient and contact information, create and maintain rules related to patient reports and statistical information to monitor performance of the program.</li> <li>The software should allow the user to enter additional information about a patient/ specimen.</li> <li>The information entered must be viewable, and modifiable, if required throughout the application. i.e., from sample entry to report generation.</li> <li>The system should be capable of bidirectional interfacing with LIS/HIMS and bidder should provide necessary IT related consumables for integration in consultation with LIS/HMIS team.</li> <li>The system should be barcode enabled.</li> <li>There should be option to take backup of data or store the data to external storage device. (Min. 1TB)</li> </ul>
7.	Certification	<ul style="list-style-type: none"> <li>The system should be certified by US FDA/CE IVD/ EU/BIS.</li> <li>All the assays should be certified by US FDA/CE-IVD/BIS.</li> <li>The reagents to be supplied should have the traceability certificate.</li> </ul>
8.	Training and support	Complete and detailed set of operation and service manual must be supplied with the system. The company should provide onsite training to user department as and when required.
9.	Power supply	Power requirements: Main voltage 200-240V, 50/60Hz. The system should be provided with 1.5-3 KVA online UPS. (30 min back-up)
10.	Warranty and CMC	<ul style="list-style-type: none"> <li>Five years on-site warranty for the complete set up and comprehensive warranty for subsequent five years shall be part of specifications/ tender document.</li> <li>The CMC as per conditions of contract of the tender document for the complete equipment including batteries for UPS, other parts wherever applicable.</li> </ul>

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		<ul style="list-style-type: none"> <li>• The warranty period will be 5 years from the date of installation of the equipment.</li> <li>• 95% up time warranty of complete equipment with extension of warranty period by double the downtime period on 24(hrs) x 7(days) x 365 (days) basis. Alternatively, round the clock technical support may be deputed at the site for operation and maintenance of the equipment.</li> <li>• All software updates should be provided free of cost during warranty and CMC period.</li> </ul>
11.	Others	<ul style="list-style-type: none"> <li>• The instrument breakdown time should not exceed 24 hours.</li> <li>• The system must have at least three currently operational installations in Institutes of National Importance in India. The vendor should submit satisfactory performance certificates from these users and the contact details must be shared for feedback/user experience.</li> <li>• The bidder must visit/ inspect the lab site before installation of the system and check for any construction or fabrication that need to be done at the site with institute's engineering section. The cost for the same will be borne by the bidder. The institute will only provide space, water and electricity.</li> </ul>

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Annexure 1

**List of parameters**  
 (Minimum required parameters but not limited to)

Sr No	Parameter	No. of tests per year (Approx.)	Cost per test	Total cost for 1 year	Total cost for 10 years
1.	TSH	5000			
2.	T4	5000			
3.	G6PD assay	5000			
4.	Phenylalanine	5000			
5.	Biotinidase	5000			
6.	Total Galactose	5000			
7.	17-OHP(17-Hydroxy Progesterone)	1000			
8.	GALT assay	1000			
9.	Immunoreactive Trypsinogen	1000			

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