

**Response To Pre-Bid Queries (Pre-Bid date: 11.10.2018)**

**NIB Ref:HITES/PCD/NCI-AIIMS/34/18-19**

<b>S.No:- 1. ABG Analyser (Rfx 3000003412)</b>				
<b>Ref. to the Bidding document</b>	<b>Specification/Clau ses in the Bidding document</b>	<b>Name of Firms</b>	<b>Queries/clarifications asked by Bidders</b>	<b>Recommendations/ replies by the Committee</b>
Point 2, Page 46	Essential Measured parameters; pH, pCO <sub>2</sub> , pO <sub>2</sub> , SaO <sub>2</sub> with co-oximetry, tHb, Lactates, BUN, Glucose, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> . All these parameters should be measured simultaneously.	CL Micromed Pvt. Ltd.	Essential Measured parameters; pH, pCO <sub>2</sub> , pO <sub>2</sub> , tHb/ Hb, Lactates, Glucose, Na <sup>+</sup> , K <sup>+</sup> , g <sub>2</sub> <sup>++</sup> , Cl <sup>-</sup> . All these parameters should be measured simultaneously. Calculated parameters should include BE, BE ecf, HCO <sub>3</sub> , Anion Gap , SaO <sub>2</sub> etc. <b>Remarks:</b> SaO <sub>2</sub> with co-oximetry is not an essential measured parameter of ABG Analyser . BUN is not an critical Care parameter & can be analyzed in any Biochemistry analyser at much cheaper cost. In case of emergency also it can be measured as a stat sample in same analvzer.	<b>To be Amended as:-</b> Essential Measured parameters; pH, pCO <sub>2</sub> , pO <sub>2</sub> , SaO <sub>2</sub> with co-oximetry, tHb, Lactates, <b>BUN or creatinine</b> , Glucose, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> . All these parameters should be measured simultaneously.
		Hospimax	Essential Measured parameters; pH, pCO <sub>2</sub> , pO <sub>2</sub> , SaO <sub>2</sub> with co-oximetry, tHb, Lactates, Glucose, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> . All these parameters should be measured simultaneously.	
		Deep Meditech Pvt Ltd	Optional or calculated parameter : SaO <sub>2</sub> with co-oximetry, tHb, Lactates, BUN, Glucose. Remarks : Esential measured parameters : pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> or Cl <sup>-</sup>	
		Edif	The BUN should be deleted from the above; the	

		Medical Systems	specification should be as : Essential Measured parameters; pH, pCO <sub>2</sub> , pO <sub>2</sub> , SaO <sub>2</sub> with co-oximetry, tHb, Lactates, Glucose, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> . All these parameters should be measured simultaneously.	
		Radiometer	You have mentioned BUN as essential parameter. We request you to remove it and add Creatinine as "BUN" parameter is available only with one company but "Creatinine" is available with most of the companies.	
Point 3, Page 46	Calculated parameters should include BE, BE ecf, HCO <sub>3</sub> , Anion Gap etc.	CL Micromed Pvt. Ltd.	Essential Measured parameters; pH, pCO <sub>2</sub> , pO <sub>2</sub> , tHb/ Hb, Lactates, Glucose, Na <sup>+</sup> , K <sup>+</sup> , g <sup>2++</sup> , Cl <sup>-</sup> . All these parameters should be measured simultaneously. Calculated parameters should include BE, BE ecf, HCO <sub>3</sub> , Anion Gap , SaO <sub>2</sub> etc. <b>Remarks:</b> SaO <sub>2</sub> with co-oximetry is not an essential measured parameter of ABG Analyzer . BUN is not an critical Care parameter & can be analyzed in any Biochemistry analyser at much cheaper cost. In case of emergency also it can be measured as a stat sample in same analyzer.	No change considered
Point 4, Page 46	Sample volume-less than 150 micro liter.	Edif Medical Systems	It should be modified as Sample Volume - less than 200 micro litre	<b>To be Amended as:-</b> Sample volume should be - less than <b>150 -200 micro liter.</b>
		Radiometer	We request you to please amend it "Sample volume - less than 200 micro litre" As the required volume of sample depends on the number of test parameters.	
Point 6, Page 46	Maintenance free electrodes with	CL Micromed	Low Maintenance /Maintenance free electrodes with individual replaceable facility whichever	No change considered

	individual electrodes ON/OFF facility.	Pvt. Ltd.	need to be replaced Remarks: ON/ OFF facility comes as default in every blood gas. If individual replaceable electrode is asked this will help in saving the wastage.	
Point 11, Page 46	Built in auto Quality control facility	CL Micromed Pvt. Ltd.	Built in Quality control software facility. Remarks : It enables to run third party controls as and when needed.	No change considered
		Deep Meditech Pvt Ltd	Auto/Manual QC facility should be available. Remarks : Built in Quality control facility.	
Point 17, Page 46	It must be UF-FDA /European CE with four digit notified body number approved and certificate to be submitted.	Edif Medical Systems	Sir, as our instrument falls under Class-I MDD and Self Declaration of Conformity is sufficient to mark CE product along with notified body ISO 13485 Certificate. The specification should be as ; should be USFDA / Self Declaration of Conformity for CE Marking along with ISO 13485 Certificate from notified body.	No change considered
		Radiometer	We request you to please amend "It must be USFDA & European CE approved with four Digit notified body number. As these equipments are used in critical patients so the system must be USFDA approved. As once USFDA is given for any product the FDA organisation keeps on monitor equipments continuously to ensure safe working of machine.	

**S.No:- 2. ESR Analyser (Rfx 300003413)**

<b>Ref. to the Bidding document</b>	<b>Specification/Clauses in the Bidding document</b>	<b>Name of Firms</b>	<b>Queries/clarifications asked by Bidders</b>	<b>Recommendations/ replies by the Committee</b>
Point 2, page 47	Should be able to accept EDTA blood samples in closed tubes with continuous loading possibilities	Suyog Diagnostics Pvt Ltd	The words continuous loading to be deleted. Reasons for desired changes : The existing specifications are favoring single company.	<b>To be Amended as:-</b> Should be able to accept EDTA blood samples in closed tubes with <b>either</b> continuous loading possibilities <b>or should have 2 to 4 racks with minimum samples loading per rack .</b>
Point 3, page 47	System preferably should not involve costly disposables, and offer very low running cost employing 100 or more precision bore Westergren glass tubes, with automatic wash and reuse.	Suyog Diagnostics Pvt Ltd	These words to be deleted. Reasons for desired changes : Now a day's no model is coming for glass tube and automated washing.	<b>To be amended as:- DELETED</b>
Point 4, page 47	Test can be performed within up to 24 Hours from Blood Collection.	Suyog Diagnostics Pvt Ltd	Tests to be performed with 4 hours of blood collection if exceeds 4 hours should be stored in 2-8 degs C Reasons for desired changes : ESR test to be performed within 4 hours from the time of collection.	<b>To be amended as:- DELETED</b>
Point 5, page 47	System should have ability to have up to two racks at one location, each rack	Suyog Diagnostics Pvt Ltd	Should have 2 to 4 racks with minimum 15 samples samples on average Reasons for desired changes : The existing specifications are favoring single	<b>To be amended as:- DELETED</b>

	with a capacity to hold minimum of 30 samples on an average.		company.	
Point 8, page 47	Automatic temperature correction to 18.-20 deg C should be available.	Suyog Diagnostics Pvt Ltd	Automatic temp correction to 37 degs C	<b>To be Amended as:-</b> Automatic temperature correction <b>to 37 deg c should be available.</b>
Point 10, page 47	Whole blood sample volume should not exceed 2.0 ml with total automation.	Suyog Diagnostics Pvt Ltd	EDTA blood minimum sample volume 1ml Reasons for desired changes : The existing specifications are favoring single company. However there should be minimum volume condition rather maximum volume while EDTA tubes are coming with 3.0 ml capacity.	No change considered
Point 11, page 47	The tubes should be automatically cleaned on board, followed by drying cycle with automatic waste control, for low cost runs.	Suyog Diagnostics Pvt Ltd	To be deleted since not available in most of the existing ESR analysers.	<b>To be amended as:-</b> <b>DELETED</b>
Point 12 , Page 47	Should have the ability to detect and measure the position of the meniscus accurately, and consistently always for precise results.	Suyog Diagnostics Pvt Ltd	Should have ability to detect & measure red cell aggregation accurately. Reason for desired changes:- The existing specifications are favoring single company.	<b>To be amended as:-</b> <b>DELETED</b>
BOQ - 3	All consumables (including reagents, Cartridge, paper,	Suyog Diagnostics Pvt Ltd	Quality control frequency to be mentioned to calculate control consumption cost.	<b>To be Amended as:-</b> All consumables (including reagents, <b>Cartridge/</b>

	electrode if applicable) per samples for all tests for first five years (365X200X5)			<b>Labware</b> , paper, electrode if applicable) per samples for all tests for first five years (365X200X5). <b>Clarified as:-</b> 3 levels controls every 12 hours.
BOQ	ESR vaccum tubes for 25000 cases	Suyog Diagnostics Pvt Ltd	To be deleted since samples are collected in EDTA vaccunators vials for blood cell counter and same tubes can be used for ESR systems.	<b>To be amended as:- DELETED</b>

**S.No:- 3. Urine Analyser (Rfx 300003414)**

<b>Ref. to the Bidding document</b>	<b>Specification/Clau ses in the Bidding document</b>	<b>Name of Firms</b>	<b>Queries/clarifications asked by Bidders</b>	<b>Recommendations/ replies by the Committee</b>
Point 2 , Page 48	It should analyze Glucose, Bilirubin, Ketone, Blood, pH, Protein, Urobilinogen, Nitrite, Leucocytes, Specific Gravity, Albumin, Creatinine, Albumin-Creatinine Ratio, Protein Creatinine Ratio.	Suyog Diagnostics	Albumin, Creatinine ratio, Protein- Creatinine ratio to be deleted. <b>Reason for desired changes:-</b> These words are favoring single manufacturer.	No change considered
		Aspen Diagnostics Pvt Ltd	It should analyze glucose, bilirubin, ketones, blood pH, protein, urobilinogen, nitrite, leucocytes, specific gravity. <b>Remarks:-</b> These parameter are not commonly used for every urine sample, albumin , cretinine, albumin-cretinine ratio, protein-cretinine ratio.	
Point 3, Page 48	The analyser should be based on fluorescence flow cytometry/ reflectance photometry principle for accurate measurement of urine parameters such as rbc, wbc, epithelial cells, cast and bacteria.	Suyog Diagnostics	Auto Image evaluation module to be added. <b>Reason for desired changes:-</b> There two technologies available for urine sediment analysis one if fluorescence flow cytometry and second is auto image evaluation module.	No change considered
		Aspen Diagnostics Pvt Ltd	The analyser should be based on fluorescence flow cytometry or digital image capturing/ reflectance photometry principle for accurate measurement of urine parameters such as rbc, wbc, epithelial cells, cast and bacteria. <b>Remarks:-</b> Flowcytometry+ Digital image capturing artificiaal particle reorganization software, all three principle combined makes more accurate testing, the real images of elements is more accurate then staining dye.	
		SPSS Mediline	The analyser should be based on fluorescence flow cytometry principle for accurate	

			<p>measurement of urine parameters such as rbc, wbc, epithelial cells, cast and bacteria.</p> <p><b>REASON:</b> Flow cytometry is the most Advanced technology available in the market in which there is no need to sit in front of the machine or no need of the technician to view the digital image and analyse sample. Flow cytometry provides scattergrams and histograms for easy interpretation. Flow cytometry and Digital imaging technology are two different technologies in which Flow cytometry is far more superior and time saving, these two technologies cannot be compared with each other in terms of technology and price.</p>	
		Medex India Pvt Ltd	The analyser should be based on fluorescence flow cytometry for accurate measurement of urine parameters such as rbc, wbc, epithelial cells, cast and bacteria.	
Point 4, Page 48	The instrument should provide scatter grams and histograms and/or real time images with neighbor for easy interpretation.	SPSS Mediline	<p>The instrument should provide scatter grams and histograms for easy interpretations.</p> <p><b>REASON:</b> Scattergrams and Histograms are the best for interpretation where as real time images are again time consuming and does not give the result and you have to interpret the result yourself after analysing the image. Real time Image does not solve the actual purpose of easy interpretation.</p>	No change considered
		Medex India Pvt Ltd	The instrument should provide scatter grams and histograms for easy interpretations.	
Point 5, Page 48	Software should be user friendly with and data storage of minimum blood	Suyog Diagnostics	<p>7500 to changed 5000 samples &amp; facility to take back up from system.</p> <p><b>Reason for desired changes:-</b> These words are favoring single manufacturer.</p>	<b>To be Amended as:-</b> Software should be user friendly with and data storage of minimum blood



	information of 7500 samples.			information of <b>5000 samples.</b>
Point 12, Page 48	12. Equipment should have US FDA or European CE with 4 digit notified body no certified.	Aspen Diagnostics Pvt Ltd	CE & USFDA are equivalent certification, asking both certificate will restrict the participation of many bidders who are having good quality instruments. <b>Remarks:-</b> Should be CE approved from notified body or USFDA approved.	No change considered
BOQ- 3	All consumables (All calibration reagents and controls if applicable) for first 5 (five) Years.	Suyog Diagnostics	Quality control frequency to be defined to calculate cost of controls.	<b>Clarified as:-</b> 3 level controls every 12 hours.