ANNEX - 01

HPLC Variant Mode (HbA1C, F&A2)

Quantity: 01

Specifications;

Device Performance	• The device must represent the most current technology and comply with the latest standards of care. • Fully Automated, compact analyzer for processing of High-Performance Liquid Chromatography (HPLC) with the Ion Exchange Method for the control of HbA1C and Thalassemia & other Hemoglobinopathies.
Analyst	• The system will be specifically used for the automatic, quantitively and clearly separation/determination of hemoglobin's HbA2 and HbF and the qualitative separation of hemoglobin's HbA, HbS, Lepore, HbD, HbC, HbE, HbH, Alpha-chain variants, and other types of hemoglobin's. • Hemoglobin A1 (including all subtypes (i.e., HbA1a, HbA1b, and HbA1c, LA1C, HbF)) • Total GHb (The total value of glycated hemoglobin (GHb), including any hemoglobin variants, in the sample) like HbS, HbD, HbC, HbE, Lepore, Arab etc. • Column and buffer chemistry can separate clearly labile and stable A1C
Sample Type	• Whole blood samples. To accept various types of primary tubes including tubes K3 EDTA - 4.5 ml vacutainers and preform all dilutions required by the method to be given, prior to introduction for analysis.
Technical Specifications	• Have a built-in barcode scanner for sample identification. • Maximum time to complete the B-Thalassemia chromatogram: less than (*by tenderer* ...) minutes per sample. • Maximum time to complete HbA1C chromatogram: less than (*by tenderer* ....) minutes per sample including any haemoglobin variants • Sample Volume - 20 µl or less • ANALYSIS RATE, min: to be stated by the bidder. • System should have STAT option • Sample capacity/Throughput: minimum (to be specified by tenderer ……) tests/hr. • Walk away system for at least 50 samples

	• Alerts for low reagent and high waste, low and high pressure. • The system should have automated cap-piercing of primary tubes and direct dilution samples without manual intervention. • Operating environment - Analyzer operating environment temperature of 18 - 30°C and humidity of 40 - 70% • System cleaning function selected by the user. • Degassing function, either user-selected or automatic. • When all samples have been processed, have the data management system perform an automatic/manual flush and enter standby mode to conserve reagents. • The system should be NGSP (National Glycohemoglobin Standardization Program) Certified, IFCC (International Federation of Clinical Chemistry) standardized. • Shall have ability to connect any Lab Automation system. • Ability to modify the most common parameters of the analysis (Column temperature, elution times) to adapt the operating conditions. • Ability to analyze pre-diluted blood samples (manual dilution), which have been placed either in a random order among other normal samples or in a special rack. In both cases the analyst should give the final result taking into account the dilution. • Machine should be a compact bench top model and less than 60 kg. • Long MTBF (Mean Time between Failure) (to be specified by tenderer … days)
Software	• Capability for LIS interfaces for data transfer. • Provided software should be able to control the chromatography unit, manage and automatically store and export of the results of patient samples, internal & external quality control and chromatography data for future purposes. • Parameter Entry capability. • The analyzer must be connected to a PC on which the patient's data will be registered and on which there is pre-installed software for managing the data extracted by the analyzer as well as a printer for printing the results in the form of a repot. • The operating program of the PC connected to the analyzer must be Windows 10 and higher. • Offering centralised chromatogram interpretation/validation software
Other technical characteristics	• With acoustic notification for operational problems i.e., alarm notifications / settings.

	• Automatic placement of the samples in position to read the barcode • Calibration in 2 points for better linearity of results • The analyzer software has the ability to process the results based on previous calibration values, without repeating the analysis. • System should have capability of automatic bubble flush. • Device must be CE, FDA or CSA approved. • Manufacturer should have ISO certification for quality standards. • IVDR registered products
Power Supply	• Must comply with standard voltage supply; single phase 240V +/- 6% (225V-255V), 50 Hz +/-1 Hz utilizing a three pin British style electrical plug or double insulated AC power supply adaptor (and as applicable, a rechargeable battery source). • UPS (minimum of 30 minutes) must be provided with the analyzer. • If higher voltages are required; the only alternate is a 415V +/- 6% (390V-440) three phase power supply.
Other Specifications	• Autosampler: Required • Reagent life time: to be specified by the bidder. The longer the better. • Must state model year of introduction, spare parts availability after end of sales (in years) and any planned end of manufacturing date. • Easy to use with preferably touch screen technology • Rack Loader: Continuous Samples loading can load minimum 50 samples • Detector: Light Source LED • External and/or built-in printer with graphic capability must be provided • Sample Rack: minimum 10 positions. • All consumables required for installation and standardization of system to be given free of cost.
Documentation	• Operating and detailed service manual (soft and hard copy) with circuit diagrams in English language should be provided along with the instrument. • Certificate of Calibration and inspection. • Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of clearly spelt out.