ANNEX 01

HPLC Variant Mode (HbA1C, F&A2) System Specification

Device Performance:	1 - Device must represent the most current technology and comply with the latest standards of care. 2 - Fully Automated, compact analyzer for processing of High-Performance Liquid Chromatography (HPLC) with the Ion Exchange Method for the control of Thalassemia and other Hemoglobinopathies.
Analyst:	1- The system will be specifically used for the automatic, quantitively determination of hemoglobin's HbA2 and HbF and the qualitative separation of hemoglobin's HbA, HbS, Lepore, HbD, HbC, HbH, Alpha-chain variants, and other types of hemoglobin's. 2- Hemoglobin A1 (including all subtypes (i.e., HbA1a, HbA1b, and HbA1c, LA1C, HbF)) 3 - Total GHb (The total value of glycated hemoglobin (GHb), including any hemoglobin variants, in the sample) like HbS, HbD, HbC, HbE, Lepore, Arab etc.
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 6 minutes per sample. Sample Volume - 20 µl or less ANALYSIS RATE, min: to be stated by the bidder. STAT option Walk away system for at least 50 samples

	Alerts for low reagent and high waste. Operating environment - Analyzer operating environment temperature of 18 - 30 deg.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 flush and enter standby mode to conserve reagents. 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.
Software:	1 - Capability for LIS interfaces for data transfer. 2 - 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. 3 - Parameter Entry capability. 4 - 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. 5 - The operating program of the PC connected to the analyzer must be Windows 10 and higher.

Other technical characteristics:	1 - With acoustic notification for operational problems i.e., alarm notifications / settings. 2 - Automatic placement of the samples in position to read the barcode 3 - Calibration in 2 points for better linearity of results 4 - The analyzer software has the ability to process the results based on previous calibration values, without repeating the analysis.
International Standards:	Device must be CE, FDA or CSA approved.
Power Supply:	1 - 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). 2 - UPS (minimum of 30 minutes) must be provided with the analyzer. 3 - If higher voltages are required; the only alternate is a 415V +/- 6% (390V-440) three phase power supply.
Other specifications:	Sample capacity: to be specified by the bidder. Autosampler: Required Reagent life time: to be specified by the bidder. 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