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To: Centrul Pentru Achizitii Publice Centralizate In Sanatate

Tender no. 21063611, Achiziționarea dispozitivelor medicale întru realizarea Programului Național „Securitatea transfuzională și autoasigurarea țării cu produse sanguine” conform necesităților pentru anul 2023.

LETTER OF CONFIRMATION

Herewith, we ABBOTT GMBH having its principal of business at Transfusion Medicine in regard to the Tender number 21063611 confirm that Abbott Alinity i analysers meet below specifications for the tender #21063611, Achiziționarea dispozitivelor medicale întru realizarea Programului Național „Securitatea transfuzională și autoasigurarea țării cu produse sanguine” conform necesităților pentru anul 2023.

GENERAL REQUIREMENTS;

1. Alinity i, for examination of donor blood in markers of hemotransmittable infections is:
 - a) a closed type technology analyzer;
 - b) an automated technology analyzer;
 - c) an analyzer with chemiluminescent marker identification technique, including various antibody identification options;
 - d) analyzer with the technique of concomitant identification of HBsAg markers, Anti-HCV (HCV antibodies), Anti-Treponema Pallidum Antibodies, HIV Ag / Ab and optionally of other markers.
2. The capacity to load samples for testing:
 - a) 150 samples;
 - b) the possibility of continuous loading starting from 1 (one) sample.
3. Alinity i test processing speed is 200 tests/hour.
4. Alinity i system functionality:
 - a) automatic loading / removal for racks or other similar components obligatorily required in the testing process;
 - b) automatic pipetting for reagents / calibrators / solutions applied in the offered technology, as well as samples, including sustained software management (permanent inventory of reagents / calibrators / solutions);
 - c) automatic dilutions, including pre- and post-dilutions;
 - d) automatic waste disposal, including sustained software management (permanent inventory of waste (residues));
 - e) permanent monitoring of the status of the samples in the work list;
 - f) built-in quality control (QC) system that will ensure the analysis of the quality of each sample, reagents / calibrators / solutions applied in the offered technology, qualification of the testing stages, with auditory and visual notification of errors during operation;
 - g) provided with the specially designed module for emergency tests;
 - h) provided with database management system;
 - i) provided with built-in laser barcode readers;
 - j) provided with mobile barcode laser readers;
 - k) possible to connect with the laboratory data management program in SIA Blood Service.

Sitz der Gesellschaft: Wiesbaden
Amtsgericht Wiesbaden HRB 31478

Geschäftsführer:
Christian Grapow
Robert Funck, Konstantinos Varlas



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5. Alinity i software database management system and its functionalities:

- a) available software applications with the latest generation accessories, including the Microsoft Windows Operating System;
- b) receiving / monitoring / printing in electronic form or manually entering the results of the analyzes, the results of the quality control, the messages on the devices and events for the maintenance of the devices;
- c) on-line storage of analysis results, quality control results, device messages and device maintenance events, their record and reporting;
- d) user and certificate management;
- e) submission of the results of the analysis / quality control in the computer system, including the notification of the errors appeared during the operation;
- e) configuration of the operation of the connected devices.
- f) viewing real-time statistics (production statistics) / statistics generated by the database management system.

Alinity i accessories related to the device but mandatory for its operating conditions, if necessary:

- a) RS-232C port;
- b) USB 2.0 port;
- c) USB 3.0 port;
- d) Network port (RJ-45);
- e) UPS with the capacity to provide the power supply for at least 60 minutes;
- f) water preparation system, including tank with minimum capacity for 300 samples in testing.

Declaration of Conformity certificate for Alinity i – included with the quotation,

- a) the copy of operations manual and service manual; electronic diagram, technical passport, including description of technical parts and components of the systems, will be submitted at delivery.
- b) the two systems will be shipped in one single tranche: June 2023.
- c) Installation and training of the personnel involved in the operation of the medical device, will be provided by our local distributor.
- d) We confirm to provide free of charge assurance of the functionality, maintenance, repair of 2 (two) medical devices, for the entire period of warranty of 36 months.
- e) We confirm that the two systems we offer – *Alinity i* – will have the production year not older than 2022 year.

Kind regards,
Murat MERDAL
Division Vice President
Europe, Middle East & Africa
Abbott Transfusion Medicine