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Date: 17.02.2022

To: Centrul pentru Achizitii Publice Centralizate in Sanatate

Tender no. 21051267:

REQUIREMENTS FOR THE REAGENTS:
a) stability when placed in a medical device: stability when placing in the medical device at least for 28 days;
b) provided by the manufacturer with protection elements against evaporation and leakage.

REQUIREMENTS FOR THE CONSUMABLES:
a) single use;
b) ensures a high degree of accuracy and excludes contamination of samples;
c) delivered in secured package, marked and labelled by the manufacturer with the mention of identity data (name, batch / serial number, terms of validity, storage conditions). The identity data displayed on the box must coincide with those on the labels of each component of the set (as appropriate).

TEST FOR THE DETERMINATION OF HBSAG – 70770 TESTS
Destination: for the examination of donor blood in markers hemotransmisible infections - viral hepatitis B.
Method of application in the test reaction:
a) closed type technology;
b) automated;
c) chemiluminescent, including with various antigen identification options
Duration of the testing process, including the incubation period - till 30 minutes.

Diagnostic product:
1) test for the screening of blood donated and intended for transfusion or as a raw material for the production of the human plasma preparation, of a generation that will ensure the detection of:
a) in human serum / plasma,
b) qualitative HBsAg,
c) common characteristics for the genetic variations of HBV virus worldwide known, including for the Eastern European region.
2) 100% sensitivity on samples of blood donors;
3) test specificity is %99,91 inclusive on blood donor samples (better than tender spec %99,88);
4) the analytical sensitivity results for Architect HBsAg Qualitative II, calculated by linear regression, ranged from 0.017 to 0.022 IU/mL (better than the tender spec 0.13 IU/ml)

Components accompanying the diagnostic product: mandatory present all the necessary components, in sufficient quantities for the application of the test in the test reaction, according to the instructions for use of the product.

Form of packing: set delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch number / series, expiry terms, storage conditions). The identity data displayed on the box must coincide with those on the labels of each component of the set.

Digitally signed by Ceaicovschi
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Reason: MoldSign Signature
Location: Moldova

TEST FOR THE DETERMINATION OF ANTI HCV – 70924 TESTS:
Destination: for the examination of donor blood in markers hemotransmissible infections - viral hepatitis C.

Method of application in the test reaction:
a) in closed type technology;
b) automated;
c) chemiluminescent test, including with various antibody identification options.
Duration of the testing process, including the incubation period - till 30 minutes.

Diagnostic product:
1) test for screening blood donated and intended for transfusion or as a raw material for the production of preparations from human plasma generation that will ensure the detection of:
a) in human serum / plasma,
b) quality of antibodies to viral hepatitis C virus,

2) test 100% sensitivity on samples of blood donors;

3) test specificity is %99,93 inclusive on blood donor samples (better than the tender spec 99,84%)

4) test will detect the combination of circulating antibodies to Core viral antigens Core, NS3, NS4 proteins, including at least 3 subtypes characteristic of the European region.

Components delivered together with the diagnostic product: mandatory present all the necessary components, in sufficient quantities for the application of the test in the test reaction, according to the instructions for use of the product.

Form of packing: set delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch number / series, expiry terms, storage conditions). The identity data displayed on the box must coincide with those on the labels of each component of the set.

TEST FOR ANTI-TREPONEMA PALLIDUM ANTIBODIES – 70924 TESTS
Destination: for the examination of donor blood in markers hemotransmisible infections - anti-Treponema Pallidum antibodies.

Method of application in the test reaction:
a) closed type technology;
b) automated;
c) chemiluminescent test, including with various antibody identification options.

Duration of the testing process, including the incubation period - till 30 minutes.

Diagnostic product:
1) test is designed for the qualitative detection of antibodies to Treponema Pallidum in human plasma, used in the screening of donated blood and intended for transfusion or raw material for the production of human plasma preparations;
2) test with 100% sensitivity on samples of blood donors;
3) test with specificity inclusive on blood donor samples are %99,94 (better than tender spec 99,88%)

Components delivered together with the diagnostic product: mandatory present all the necessary components, in sufficient quantities for the application of the test in the test reaction, according to the instructions for use of the product.

Form of packing: set delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch number / series, expiry terms, storage conditions). The identity data displayed on the box must coincide with those on the labels of each component of the set.

TEST FOR DETERMINATION OF HIV AB/AG COMBO – 70560 TESTS
Destination: for the examination of donor blood in markers of hemotransmissible infections - Ag-HIV-1 P24 antigen and anti-HIV1 / HIV2 antibodies.

Method of application in the test reaction:
a) test closed type technology;
b) automated;
c) chemiluminescent test, including with various identification options of antibody.
Diagnostic product:
1) test for screening blood donated and intended for transfusion or as a raw material for the production of human plasma preparations, of a generation that will ensure the detection of:
a) in human serum/plasma,
b) simultaneous qualitative of HIV-1 p24 Ag and anti-HIV1 / HIV2 antibodies,
2) test 100% sensitivity on samples of blood donors;
3) test with specificity inclusive on blood donor samples are %99,89 (better than tender spec 99,88%);
4) test with analytical sensitivity (detection limit) for p24 antigen is 0,87 IU/ml (better than tender spec till 2IU/ml).

Components delivered together with the diagnostic product: mandatory present all the necessary components, in sufficient quantities for the application of the test in the test reaction, according to the instructions for use of the product.

Form of packing: set delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch number / series, expiry terms, storage conditions). The identity data displayed on the box must coincide with those on the labels of each component of the set.

THE OFFER MANDATORY WILL INCLUDE ONE THE FOLLOWING TECHNOLOGIES:

The Abbott Architect i2000SR analyzers with all components: the laboratory medical device, number of tests, accessories / consumables / reagents / calibrators / solutions and other mandatory items, related to the activity of the medical laboratory device, required in the laboratory examination process of the donated blood, corresponding to:
1) HBsAg - 70770 tests;
2) anti HCV antibodies - 70924 tests;
3) antibodies against Treponema Pallidum –70924 tests;
4) Ag-HIV-1 P24 and anti-HIV1 / HIV2 antibodies –70560 tests.

Technical specification for the Architect i2000SR – 2 units, not older than 2016 year:
1.Medical device for examination of donor blood in markers of hemotransmittable infections
a) closed type technology analyzer;
b) automated technology analyzer;
c) analyzer with chemiluminescent marker identification technique, including various antibody identification options;
d) analyzer with the technique of concomitant identification of HBsAg markers, Anti-HCV, Anti-Treponema Pallidum Antibodies, HIV Ag / Ab and optionally of other markers.

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2. Accessories / consumables / reagents / calibrators / solutions and other mandatory products required in the testing process - provided for the total number of tests required: 283178 tests.

3.The capacity to load the samples for testing:
a) minim 50 samples;
b) the possibility of continuous loading starting from 1 (one) sample;

4.Test processing speed – minim 150 tests per hour (summary, for each type of test or separately for each type of test), and more for each device.
5. Requirements for 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) interconnected with the laboratory data management program in SIA Blood Service;
6. Requirements for the software database management system and its functionality:
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;
c) 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.
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)Distributor GBG-MLD Srl provides UPS with the capacity to provide the power supply for at least 60 minutes;
f) Distributor GBG-MLD Srl provides water preparation system, including tank with minimum capacity for 300 samples in testing;

Documents/certificates of RGT to include with the offer:
1. EC Certificate / Declaration of Conformity Certificate for the reagents, consumables, solutions.
2. Manufacturer Letter confirming each technical requirement of the eligibility criteria for the offered product, issued by the original manufacturer of the product, signed and stamped.
3. Presence of the instruction to use of the product from the manufacturer, in Romanian language, signed by the economic operator.
4. Confirmation to present the quality certificate for each lot, in each tranche delivery.
5. Confirmation that upon delivery the shelf life of the product will be not less than 80% of its total shelf life.

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Declaration of Conformity certificate for offered devices included.

-Confirmation letter of each technical requirement from the eligibility criteria for the 2 (two) devices offered for performing laboratory examinations of donated blood.

- We confirm to supply with 2 (two) identical devices as model and performance.
- We confirm to present on delivery and during the activity of the devices, of the copies of the manual service, electronic diagram, technical passports, including description of technical parts and components a device.

-Confirmation regarding the free of charge delivery and installation of 2 (two) identical medical devices, at least with 15 days before the delivery of the first tranche of tests and the signing of the delivery-receipt of the a loan agreement between the beneficiary and the winning economic operator.
- training of the personnel involved in the operation of the free medical device, that will be provided by our local distributor, within 10 days of the device being put into operation.
- Confirmation to deliver free of charge consumables, calibrators, working solutions, controls and reagents required for 500 examinations, for each device, separately for each type of infection, for devices / consumables / reagents / calibrators / solutions, that has not been used by the CNTS.
-Confirmation to provide free of charge assurance of the functionality, maintenance, repair of medical devices 2 (two) units, for the entire period of the number of tests contracted.
-Confirmation to provide free of charge interconnection with the laboratory data management program in SIA Blood service during 10 days from the moment of commissioning and written notification of the beneficiary.
-Confirmation regarding the insurance by creating free of charge all components (energy / water source, etc.) necessary for the proper functioning of the device offered, within 10 working days from the date of notification issued by beneficiary.

17.02.2022

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