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Date: 23.11.2024

To: Centrul Pentru Achizitii Publice Centralizate in Sanatate

Tender no. 21293399/ ocds-b3wdp1-MD-1728632585871

Privind - Achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național „Securitatea transfuzională și autoasigurarea țării cu produse sanguine" conform necesităților pentru anul 2025.

LETTER OF CONFIRMATION

Herewith, we ABBOTT GMBH having its principal of business at Transfusion Medicine in regard to the Achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național „Securitatea transfuzională și autoasigurarea țării cu produse sanguine" conform necesităților pentru anul 2025., confirm the following in regard to the Lot 1: "Teste pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere".

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MOLDOVA SÂNGELUI

DELIVERY TRANCHES:

I. tranche: January.
II. tranche: April.
III. tranche: July.
IV. tranche: October.

Minimum qty to be deliver: 362000 tests.

I. GENERAL REQUIREMENTS; number of tests, accessories / consumables / reagents / calibrators / solutions and needed consumables related to the activity of the laboratory medical device (by technology applied to existing device /by technology applied to another device than the existing one at the customer site).

1.1 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.

1.2 REQUIREMENTS FOR THE CONSUMABLES:
a) Unusable.
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).

REQUIREMENT FOR THE DEVICE TO BE OFFERED ON A LOAN CONTRACT, 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:

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1) HBsAg – 90 000 tests
2) Anti HCV antibodies – 90 000 tests;
3) Antibodies against Treponema Pallidum – 90 000 tests;
4) Ag-HIV-1 P24 and anti-HIV1 / HIV2 antibodies – 92 000 tests.

-We guarantee the technical service/repair of the medical devices provided/offered on loan contract during the entire contract execution period.

Medical Device Requirements.

1. Medical device for screening donor blood for markers of hemotransmissible infections for the first stage of triage.

The offer includes devices ARCHITECT i2000SR, Abbott (2 units), with the year of production 2021 year (SN: ISR64824; ISR 64825) - with all components (number of tests, accessories / consumables / reagents / calibrators / solutions and other mandatory products, including device activity) required in the process laboratory examination of donated blood.

2. Medical device for identifying markers of hemotransmissible infections:

a) Closed type technology analyser;
b) automated technology analyser;
c) analyser with chemiluminescent marker identification technique, including various antibody/antigen identification options;
d) analyser with the technique of concomitant identification of HBsAg markers, Anti-HCV antibodies, Anti-Treponema Pallidum antibodies, HIV Ag / Ab and optionally of other markers, such as: Anti HBc, HTLV, Cov-2 IgG.

3. Accessories/consumables/reagents/calibrators/solutions and other mandatory products required in the testing process - provided for the total number of tests requested – 362 000 tests.

4. The capacity to load at the ARCHITECT i2000SR the samples for testing:
a) 135 samples;
b) the possibility of continuous loading starting from 1 (one) sample;

5. Test processing speed – 200 tests per hour.

6. ARCHITECT i2000SR 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;

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7. 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 analysers, 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;
f) Configuration of the operation of the connected devices.
g) Viewing real-time statistics (production statistics) / statistics generated by the database management system.

8. 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;

TEST FOR DETERMINATION OF HBsAg (2G22-30 ARCHITECT HBsAg Qualitative II Reagent Kit)

Destination: for the examination of donor blood in markers hemotransmissible 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) Architect HBsAg test has 100% sensitivity on samples of blood donors;

3) Architect HBsAg test specificity is 99,91% inclusive, on samples of blood donor (is more than tender spec minimum requirement 99.88%);

4) Architect HBsAg test with analytical sensitivity (detection limit) is between 0.017 and 0.022 IU/ml. (It's much more sensitive than 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.

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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 ANTI HCV (6C37-33 ARCHITECT Anti-HCV Reagent Kit)

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) Architect Anti HCV test has 100% sensitivity on samples of blood donors;

3) Architect Anti HCV test specificity is 99,93% inclusive, on samples a blood donor (is more than tender spec minimum requirement 99.84%).

4) The test detects 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 DETERMINATION OF ANTI-TREPONEMA PALLIDUM ANTIBODIES (8D06-42 ARCHITECT Syphilis TP Reagent Kit).

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.

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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) Architect Syphilis TP test has 100% sensitivity on samples of blood donors;
3) Architect Syphilis TP test with specificity 99,94% inclusive, on samples of blood donors (is more than tender spec minimum requirement 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 (4J27-32 ARCHITECT HIV Ag/Ab Combo Reagent Kit).

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) 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) Architect HIV Ag/Ab Combo test has 100% sensitivity on samples of blood donors;
3) Architect HIV Ag/Ab Combo test with specificity 99.89% inclusive, on samples of blood donors (is more than tender spec minimum requirement 99.87%).
4) Architect HIV Ag/Ab Combo test has 0,87 IU/ml analytical sensitivity test (detection limit) inclusive, for P24 antigen. (It's much more sensitive than tender spec. 2 IU/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.

Documents/certificates of RGT submitted 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.

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3. Presence of the instruction to use of the product from the manufacturer, in Romanian language, signed by the local distributor.

4. Confirm to provide the quality certificate for each lot, in each tranche delivery.

5. Declaration of Conformity certificate for offered devices is 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 provide with 2 (two) identical devices as model and performance (SN: ISR64824; ISR 64825).
- We confirm to present 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.
- We confirm to provide 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.
- We confirm to deliver free of charge consumables, calibrators, working solutions, controls.
- We confirm 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.
- We confirm 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.

Kind regards,
Onur Minare
General Manager
Europe and Region Turkey
Transfusion Medicine

Abbott
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