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Date: 18.03.2021
To: Centrul pentru Achizitii Publice Centralizate in Sanatate

Tender no.21036633: Realizarea Programului National "Securitatea Transfuzionala si autoasigurarea tarii cu produse sanguine" reactive si consumabile medicale conform necesitatilor pentru anul 2021 (repetat).

Letter of Confirmation

Herewith, we ABBOTT GMBH having its principal of business at Transfusion Medicine in regard to the Tender "Realizarea Programului National "Securitatea Transfuzionala si autoasigurarea tarii cu produse sanguine" reactive si consumabile medicale conorm necesitatilor pentru anul 2021 (repetat), confirm the following:

1. **Requested tests in total – 260 300 tests, including:**

Test for the determination of HBsAg - 65000 tests,
Test for the determination of anti-HCV antibodies - 65000 tests,
Test for the determination of anti-Treponema Pallidum antibodies - 65300 tests,
Test for the simultaneous determination of Ag-HIV-1 P24 and anti-HIV1 / HIV2 antibodies– 65000 tests.

The offer includes one of the technologies:
1) by applied technology of the devices existing in the medical institution, with all components: number of tests, accessories / consumables / reagents / calibrators / solutions and other mandatory products, including related to the activity of the laboratory medical device in the institutional endowment, necessary in the examination process laboratory of donated blood, presenter:
1) HBsAg - 65000 tests;
2) anti HCV antibodies - 65000 tests;
3) antibodies against Treponema Pallidum –65300 tests;
4) Ag-HIV-1 P24 and anti-HIV1 / HIV2 antibodies –65000 tests.

ABBBOTT Confirmation for reagents

Test for the determination of HBsAg – 65000 tests
for the examination of donor blood in markers of hemotransmisible infections - viral hepatitis B.

Destination: for the examination of donor blood in markers hemotransmitter infections - viral hepatitis B.
Method of application in the test reaction:
a) in closed type technology;
b) automated;
c) chemiluminescent, including with various antigen identification options
Duration of the testing process, including the incubation period is 28 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,

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b) qualitative HBsAg,
c) at least 10 genotypes, including at least 3 subtypes characteristic of the European region,
d) antigen in the immunological/serological window until the 21st day;

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

3) Architect HbsAg test specificity is 99,91% (is more than tender spec minimum requirement 99.88%) inclusive, on samples a blood donors;

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.

Form of packing: set delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch number / 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.
1. EC Certificate / Declaration of Conformity Certificate.
2. Abbott Letter confirming each technical requirement of the eligibility criteria for the product offered, issued by the original manufacturer of the product, signed and initialed.
3. Presence of the instruction to use of the product from the manufacturer, in Romanian language.
4. Confirm to present the quality certificate for each lot, in each tranche delivery.
5. Confirm that upon delivery the shelf life of the product will be not less than 80% of its total shelf life.

Test for the determination of Anti HCV – 65000 tests:
Destination: for the examination of donor blood in markers hemotransmissible infections - viral hepatitis C.

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

Duration of the testing process, including the incubation period is 28 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,
c) antibodies in the immunological/serological window until the 14th day;

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

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

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

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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 packaging: the set will be delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch / serial number, validity terms, storage conditions). The identity data displayed on the box must coincide with those on the labels of each component of the set.
1. EC Certificate / Declaration of Conformity Certificate.
2. Letter confirming each technical requirement of the eligibility criteria for the product offered, issued by the original manufacturer of the product, signed and initialed.
3. Presence of the instruction to use of the product from the manufacturer, in Romanian language.
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.

Test for anti-Treponema Pallidum antibodies – 65300 tests
Destination: for the examination of donor blood in markers hemotransmisible infections - anti-Treponema Pallidum antibodies.

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

Duration of the testing process, including the incubation period 28 minutes.

Diagnostic product:
1) Architect Syphilis TP 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% (is more than tender spec minimum requirement 99.88%) inclusive, on samples of blood donors.

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 packaging: the set will be delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch / serial number, validity terms, storage conditions). The identity data displayed on the box will coincide with those on the labels of each component of the set.
1. EC Certificate / Declaration of Conformity Certificate.
2. Letter confirming each technical requirement of the eligibility criteria for the product offered, issued by the original manufacturer of the product, signed and initialed.
3. Presence of the instruction to use of the product from the manufacturer, in Romanian language, initialed 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.

Test for determination of HIV Ab/Ag Combo – 65000 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) Architect HIV Ag/Ab Combo test has a closed type technology;
b) Architect HIV Ag/Ab Combo test is automated;
c) Architect HIV Ag/Ab Combo test is chemiluminescent, including with various identification options a antibodies.

Duration of the testing process, including the incubation period 28 minutes.

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,
c) antigen and antibodies in the immunological/serological window until the 7th day;
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% (is more than tender spec minimum requirement 99.88%) inclusive, on samples of blood donors;
4) **Architect HIV Ag/Ab Combo test 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 packaging: the set will be delivered in secure packaging, marked and labeled by the manufacturer indicating identification data (name, batch / serial number, validity terms, storage conditions). The identity data displayed on the box must coincide with those on the labels of each component of the set.
1. EC Certificate / Declaration of Conformity Certificate.
2. Letter confirming each technical requirement of the eligibility criteria for the product offered, issued by the original manufacturer of the product, signed and initialed.
3. Presence of the instruction to use of the product from the manufacturer, in Romanian language, initialed 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.

The offer includes Architect i2000SR, Abbott devices (2 pieces) located inside the institution, for the offered technology, 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.
Architect i2000SR medical device for examination of donor blood in markers of hemotransmittable infections for the first stage of sorting:
1. Architect i2000SR medical device for identifying markers of blood-borne 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 antibodies, anti-Treponema Pallidum antibodies, HIV Ag / Ac and optionally of other markers, such as: Anti HBc, HTLV, Cov-2IgG.

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;
Test processing speed - 200 tests per hour (summary, for each type of test or separately for each type of test);

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Accessories / consumables / reagents / calibrators / solutions and other mandatory products required in the testing process - provided for the total number of tests required:
Requirements for reagents / calibrators / solutions applied in the offered technology:
a) stability for reagents / calibrators when placed in the medical device for at least 30 days; stability for triger / pre-triger at placement in the medical device for at least 28 days.
b) prepared in "ready-to-use" form and provided with protection against evaporation and leakage of the manufacturer (without any implicit actions / measures of medical staff (excluding the human factor) in the preparation / adjustment of solutions / calibrators / reagents to the form "ready to use".
Requirements for applied consumables:
Unusable;
Ensures a high degree of accuracy and excludes contamination of samples;
Delivered in secure packaging, marked and labeled by the manufacturer with the maintenance of identity data: name, batch / serial number, validity terms, storage conditions).
Requirements for the functionality of the Architect i2000SR device:

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;

8. 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 by 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) 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;
EC certificate / Declaration of Conformity.

1. Letter confirming each technical requirement of the eligibility criteria for the device provided for performing laboratory examinations of the donated blood, issued by the manufacturer of origin of the product, signed and initialed - shall be attached.
2. Confirmation from the manufacturer regarding the insurance with 2 (two) identical units as model and performance, signed and initialed - is attached.
3. We confirm the training of the personnel involved in the operation with medical device, provided by the winning economic operator, within 10 days, including free supply of consumables, calibrators, working

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solutions, controls and tests necessary for 500 examinations, separately for each type of infection (HBsAg, anti-HCV antibodies, anti-Treponema Pallidum antibodies and Ag / AcHIV).

4. We confirm the free assurance of the functionality, maintenance, repair of medical devices, including backup, for the entire period of the number of tests contracted.
5. We confirm the free interconnection with the laboratory data management program in SIA Blood Service.
6. We confirm the insurance by creating free of charge all the components required for the proper functioning of the offered device.

Kind Regards,

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

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