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Date: 10.02.2021
To: Centrul pentru Achizitii Publice Centralizate in Sanatate

Tender no.21033728: Realizarea Programului National "Securitatea Transfuzionala si autoasigurarea tarii cu produse sanguine" reactive si consumabile medicale conform necesitatilor pentru anul 2021.

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

2.The offer includes also the device for the offered technology with all the components (number of tests, accessories / consumables / reagents / calibrators / solutions and other obligatory products, including related to the activity of the device) necessary in the laboratory examination process of the donated blood.

3. Medical device for the examination of donor blood at markers of hemotransmittable infections for the first stage of sorting:

I) Technical requirements for each unit:
Destination: for performing examinations of donated blood in the presence of markers of hemotransmisible infections (HBsAg, Anti-HCV, Treponema Pallidum antibodies and HIV Ag / Ab).
1. Medical device identification markers hemotransmisibile infections:
Instruments characteristics declaration and confirmation;
a) Architect i2000SR is a closed type technology analyzer;
b) Architect i2000SR is an automated analyzer;

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Reason: MoldSign Signature
Location: Moldova

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c) Architect i2000SR is an analyzer with chemiluminescence marker identification technique, including with various antibody identification options;
d) Architect i2000SR is an analyzer with the technique of concomitant identification of markers HBsAg, Anti-HCV, Treponema Pallidum antibodies, HIV Ag / Ab and optionally other markers like Anti HBc, HTLV and Cov-2 IgG for screening blood products .
e) offer includes a back up system.

Accessories / consumables / reagents / calibrators / solutions and other products required in the testing process - provided for the number testing, accordingly:
1) HBsAg - 65000 tests;
2) antibodies against HCV-65000 tests;
3) antibodies against Treponema Pallidum - 65300 tests;
4) Ag-HIV-1 P24 and anti-HIV1 / HIV2 antibodies –65000 tests
5) Delivered in a secure package, marked and labeled by the manufacturer with the identification of identity data (name, batch / serial number, terms of validity, storage conditions). The identity data displayed on the box will coincide with those on the labels of each component of the set (as appropriate).

3. Requirements for reagents / calibrators / solutions applied in the offered technology:
a) The stability of reagents when placed in the medical device for at least 30 days and the stability of accessories like trigger and pre-trigger for at least 28 days;
b) prepared in a "ready to use" form and provided with protection against evaporation and leakage from the manufacturer (without any implicit actions / measures of the medical staff (excluding human factor) in the preparation / adjustment of solutions / calibrators / reagents in the form "ready to use".

4. Requirements for consumables applied in the technology offered:
a) non-reusable;
b) ensures a high degree of accuracy and excludes contamination of samples;
c) delivered in secure packaging, marked and labeled by the manufacturer with mention of identity data (name, batch / serial number, terms 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).

5. Load capacity of samples for testing:
a) Architect i2000SR has 135 sample loading capacity;
b) the possibility of continuous loading starting from 1 (one) sample;

6. Test processing speed is 200 per hour (summary of each type of test or separately on each type of test);

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7. Requirements for device functionality:
a) Architect i2000SR is able to automatic loading / removal for racks or other components similar mandatory required in the testing process;
b) Architect i2000SR is able to automatic pipetting for reagents / calibrators / applied solutions in the technology provided, as well as evidence, including management supported by software (permanent inventory of reagents / calibrators / solutions);
c) Architect i2000SR is able to do automatic dilutions, including pre- and post-dilutions;
d) Architect i2000SR is able to do automatic waste disposal, including management supported by software (permanent inventory of waste);
e) Architect i2000SR is able to do permanent monitoring of the status of the samples in the work list;
f) Architect i2000SR is 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, the qualification of the testing stages, with the auditory and visual notification of the errors occurred during operation;
g) Architect i2000SR is provided with the specially designed module for emergency tests, the users can load 35 stat samples in case of need to run emergency samples,
h) Architect i2000SR is provided with database management system;
i) Architect i2000SR is provided with built-in laser barcode readers;
k) Architect i2000SR is provided with mobile barcode laser readers;
l) Architect i2000SR is able to interconnect with the laboratory data management program in SIA Blood Service;

8. Requirements for the database management system software and its functionality:
a) Architect i2000SR has software applications with state-of-the-art accessories available, including the Microsoft Windows operating system;
b) receiving / monitoring / printing in electronic form or by manually entering test results, quality control results, messages and events from devices for maintaining devices;
d) Architect i2000SR has user and certificate management;
c) online storage of analysis results, quality control results, device messages and device maintenance events, their records and reporting;
c) Architect i2000SR has submission of the results of the analysis / quality control in the computer system, including the notification of the errors appeared during the operation;
e) Architect i2000SR has configuration for the operation of the connected devices.
f) Architect i2000SR is able to view real-time statistics (production statistics) / statistics generated by the database management system.

9. Accessories related to the device mandatory to supply:
a) Architect i2000SR has RS-232C port
b) Architect i2000SR has USB 2.0 port
c) Architect i2000SR has USB 3.0 port
d) Architect i2000SR has network port (RJ-45)

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e) Architect i2000SR will be installed with an UPS with the capacity to provide the power supply electric for at least 60 minutes;
f) Architect i2000SR will be installed with a water preparation system, including tank with minimum capacity for 300 samples in testing;

There will be a backup insurance for instruments (availability of 2 identical systems in terms of model and performance).
The systems will include at delivery: sn, year of production, the service manual, electronic diagram of the technical passport, including the description of the technical parts and components of the device, authorized by the manufacturer for each device.
2 systems will be delivered at site and installed within 10 working days from Beneficiary notification.
- Confirm that will be provided training of the personnel involved in the operation of the medical devices free of charge, provided by the our distributor "GBG-MLD" SRL company, within 10 days from the moment of putting into operation of the device, including the free supply of consumables, calibrators, working solutions, controls and tests necessary for the functionality of the devices and the performance of 500 examinations, separately for each type of infection.
- We confirm the free assurance of the functionality, maintenance, repair of medical devices, for the entire period of performing the number of contracted tests.
Free interconnection with laboratory data management program in SIA Blood service within 10 days after systems installation.
- We confirm the insurance by creating free of charge all components (energy / water source, etc.) required for the proper functioning of the devices offered, within 10 working days from the date of notification issued by the beneficiary.

ABBBOTT Confirmation for reagents

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

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

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

3. 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:

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a) in human serum / plasma,
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.)

4. 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.

5. 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.
II) Certification:
1. EC / MS Declaration of Conformity and / or EC / MS Certificate of Conformity.
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.

Anti HCV – 65000 tests:
I) technical requirements:
Destination: for the examination of donor blood in markers hemotransmissible infections - viral hepatitis C.

1. 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.

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

3. 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.

4. 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.

5. 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.
II) Certification:
1. EC / MS Declaration of Conformity and / or EC / MS Certificate of Conformity.
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.

Anti Treponema Pallidum–44800 tests
I) Technical requirements:
Destination: for the examination of donor blood in markers hemotransmisible infections - anti-Treponema Pallidum antibodies.

1. Method of application in the test reaction:
a) Architect Syphilis TP has a closed type technology;
b) Architect Syphilis TP is automated;

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c) Architect Syphilis TP test is chemiluminescent, including with various antibody identification options.

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

3. 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.

4. 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.

5. 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.
II) Certification:
1. EC / MS Declaration of Conformity and / or EC / MS Certificate of Conformity.
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.

HIV Ab/Ag Combo – 65000 tests
I) Technical requirements:
Destination: for the examination of donor blood in markers of hemotransmissible infections - Ag-HIV-1 P24 antigen and anti-HIV1 / HIV2 antibodies.

1. 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.

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

3. 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)

4. 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.

5. 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.
II) Certification:
1. EC / MS Declaration of Conformity and / or EC / MS Certificate of Conformity.
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.

Kind Regards,

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Murat MERDAL
Division Vice President
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