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Date:04.10.2023

To: CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE

Tender no. ocds-b3wdp1-MD-1695282164898: "Achiziția produselor diagnostice, materiale consumabile, reagenți pentru investigații biochimice și consumabile de laborator, reactivi și dezinfectanți, și alte produse de uz medical conform necesităților Centrul Național de Transfuzie a Sângelui, pentru anul 2024".

LETTER OF CONFIRMATION

Herewith, we ABBOTT GMBH having its principal of business at Transfusion Medicine in regard to the Tender "Achiziția produselor diagnostice, materiale consumabile, reagenți pentru investigații biochimice și consumabile de laborator, reactivi și dezinfectanți, și alte produse de uz medical conform necesităților Centrul Național de Transfuzie a Sângelui, pentru anul 2024", confirm the following technical parameters in regard to the Lots 66, 67, 68, 69:

Delivery terms: within 20 days from the date of request, starting with 01.01.2024

Lot 66. Test for the determination of HBsAg,
ARCHITECT HBSAG QUAL II (500T), 2G22-35 – 1000 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,
c) qualitative HBsAg,
d) at least 10 genotypes, including at least 3 subtypes characteristic of the European region
d) the antigen in the immunological/serological window with the shortest duration in days;
2) Architect HBsAg test has 100% sensitivity on samples of blood donors;
3) Architect HBsAg test specificity is 99,91% inclusive, on samples a blood donor (is more than tender spec minimum requirement 99.88%);

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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 / 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.

Lot 67. Test for the determination of Anti HCV,
ARCHITECT ANTI-HCV (1 x 500Tests), 6C37-37 – 1000 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,
antibodies in the immunological/serological window with the smallest period in days;

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) 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.

Lot 68. Test for anti-Treponema Pallidum antibodies,
ARCHITECT SYPHILIS TP Reagent Kit (1x 500Tests) 08D06-42 – 500 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) 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.

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Lot 73. Test for determination of HIV Ab/Ag Combo,
ARCHITECT HIV Ag/Ab Combo Reagent Kit (1 x 500Tests) 4J27-37 – 1000 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) closed type technology;
b) automated;
c) chemiluminescent test, including with various identification options of antibody.
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 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 99.88%).
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 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 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 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. We confirm to present the quality certificate for each lot, in each tranche delivery.

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5. We confirm that upon delivery the shelf life of the test will be not less than 80% from its total shelf life.
6. We guarantee the delivery of the products to the recipient in compliance with the storage and transportation conditions throughout the transportation chain from the manufacturer to the beneficiary.

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

Abbott
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