10.10.2023
Center for Centralized Public Procurement in Health

Republic of Moldova

Re: **Tender no.** ocds-b3wdp1-MD-1695305626407 **from 24.10.2023**

Lot.I Letter of Confirmation

Herewith, we Roche Diagnostics express our respect and thankfulness for your interest in Roche's high-quality diagnostic equipment in the blood safety area.

Following to the tender request, we would like confirm the following:

1.The offer for lot I includes:

All needed test/ accessories / consumables / reagents / calibrators / controls / solutions and other mandatory products to perform **328255 of tests, on cobas e601 analyzer** :

1.Test for determination of HBsAg – 82100;

2. Test for determination of HCV Ab – 82275;

3. Test for determination of Treponema Pallidum Ab – 82275;

4.Test for determination of Ag-HIV-1 P24 and HIV1/HIV2 Ab – 81575;

1.1 Requirements for Regents:

a) stability when placed in the medical device for at least 28 days;

b) provided by the manufacturer with protection elements against evaporation and leakage.

1.2 Consumables Requirements:

a) non-reusable;

b) ensures a high degree of accuracy and excludes sample contamination;

c) delivered in safe packaging, marked and labeled by the manufacturer with identification data (name, batch/serial number, validity terms, storage conditions).

1.3 HBsAg G2 Elecsys cobas e 100 V2 08814856190 - 70 200 tests;

Purpose: Immunoassay for the in vitro qualitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma, including for screening of blood donations;

Application method in the test reaction:

a) closed type technology; For cobas e 601

Digitally signed by Lazari Cristi
Date: 2023.10.20 11:56:25 EES
Reason: MoldSign Signature
Location: Moldova

b) automated;

c) The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers;

The duration of the test process, including the incubation period - 18 minutes.

Diagnostic product:

1) test for the screening of blood donated and intended for transfusion or as raw material for production preparations from human plasma, of a generation that will ensure the detection of:

a) in human serum/plasma;

b) qualitative of HBsAg;

c) mutations: detection of genetic variations of the HBV virus known in the world, including for Eastern Europe region

2) test with 100% sensitivity on blood donor samples (performance panels);

3) test with specificity not less than 99.98% on blood donor samples;

4) test with analytical sensitivity (detection limit) - up to 0.04 IU/ml.

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

Form of packaging: delivered in safe packaging, marked and labeled by the manufacturer with identification data (name, batch/serial number, validity terms, storage conditions).

Identity data displayed on the box will coincide with those on the labels of each component of the set.

1.4 Anti-HCV G2 Elecsys cobas E 100T 08836981190 - 82275 tests:

Purpose: in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma including the screening of blood donations.

Application method in the test reaction:

a) in closed type technology; for cobas e 601;

b) automated;

c) ECLIA;.

The duration of the test process, including the incubation period – 18 minutes.

Diagnostic product:

1) test for the screening of blood donated and intended for transfusion or as raw material for production preparations from human plasma, of a generation that will ensure the detection of:

a) in human serum/plasma;

b) qualitative detection of antibodies to hepatitis C virus (HCV)

2) test with 100% sensitivity on blood donor samples;

3) test with specificity not less than 99.84% inclusive, on blood donor samples;

4) uses peptides and recombinant proteins representing HCV core, NS3 and NS4 antigens for the determination of anti-HCV antibodies, including at least 3 subtypes characteristic of the European region.

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

Form of packaging: delivered in safe packaging, marked and labeled by the manufacturer with identification data (name, batch/serial number, validity terms, storage conditions).

Identity data displayed on the box will coincide with those on the labels of each component of the set.

1.5 Syphilis Elecsys cobas e 100 09014977190 -Test for the determination of antibodies against Treponema Pallidum – 82275 tests:

Purpose: in vitro qualitative determination of total antibodies to Treponema pallidum in human serum and plasma including the screening of blood donations.

Application method in the test reaction:

a) in closed type technology; for cobas e 601;

b) automated;

c) ECLIA;

The duration of the test process, including the incubation period - up to 18 minutes.

Diagnostic product:

1) test designed for the qualitative detection of antibodies to Treponema Pallidum in human plasma, used in screening of blood donated and intended for transfusion or raw material for the production of preparations from

human plasma;

2) test with 100% sensitivity on blood donor samples;

3) test with specificity not less than 99.88% inclusive, on blood donor samples.

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

Form of packaging: the set delivered in secure packaging, marked and labeled by the manufacturer with the mention of data of identity (name, batch/serial number, validity terms, storage conditions). Identity data displayed on the box will necessarily coincide with those on the labels of each component of the set.

1.6 HIV combi PT Elecsys cobas e 100 V2 08924163190 — 81575 tests;

Purpose: Immunoassay for the in vitro qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma, for screening of blood donations;

Application method in the test reaction:

a) in closed type technology; for cobas e 601;

b) automated;

c) ECLIA

Diagnostic product:

1) test for the screening of blood donated and intended for transfusion or as raw material for production preparations from human plasma, of a generation that will ensure the detection of:

a) in human serum/plasma;

b) simultaneous qualitative HIV-1 p24 Ag and anti-HIV1/HIV2 antibodies.

2) test with 100% sensitivity on blood donor samples;

3) test with specificity not less than 99.88% inclusive, on blood donor samples;

4) test with analytical sensitivity (detection limit) – up to and including 2IU/ml, for the P24 antigen.

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

Form of packaging: the set delivered in secure packaging, marked and labeled by the manufacturer with the mention of data

of identity (name, batch/serial number, validity terms, storage conditions). Identity data

displayed on the box will necessarily coincide with those on the labels of each component of the set.

II. The offer is for:

2.1 the technology applied to the devices provided by the institution: model Cobas e601, manufacturer Roche, year of manufacture 2016 - 2 pieces;

- with all components: number of tests, accessories / consumables / reagents / calibrators / controls / solutions and other mandatory products, including the activity of the laboratory medical device provided by the institution, required in the process laboratory examination of donated blood

We remain at your disposal for any further clarifications

Kindest regards

Jacek Jopek
Prokurent
Roche Diagnostics Polska Sp. z o.o.

Karen Vroonhof
Prokurent
Roche Diagnostics Polska Sp. z o.o.