19.07.2022
National Blood Transfusion Center
Republic of Moldova

Re: **Tender no. ocds-b3wdp1-MD-1656066025719 from 26.07.2022**

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.

Digitally signed by Lazari Cristina
Date: 2022.07.25 14:08:28 EET
Reason: MoldSign Signature
Location: Moldova

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

1.The offer includes:

All needed test/ accessories / consumables / reagents / calibrators / controls / solutions and other mandatory products to perform 24 000 of test on cobas s201 analyzer.

1.1 The set of reagents is for the simultaneous/multiplex qualitative detection of HCV RNA, group M and O HIV-1 RNA, HIV-2 RNA and HBV DNA in human plasma (individual / separate result for each type of infection):

Destination: cobas TaqScreen MPX Test is a qualitative multiplex polymerase chain reaction (PCR) test that enables the simultaneous detection and discrimination of HIV RNA, HCV RNA and HBV DNA in a single test.

1. Method of application in the test reaction:

a) cobas TaqScreen MPX Test is intendent to be use on cobas s 201 system;

b) automated;

c) Multiplex PCR / NAT real-time polymerase chain reaction.

2. Diagnostic product:

1) Multiplex qualitative test for the simultaneous detection of HIV-1 RNA group M and O, HIV-2 RNA, HCV RNA and HBV DNA (individual / separate result for each type of infection);

2) contains internal control for performance monitoring;

3) possesses the enzyme AmpErase, which reduces the potential for contamination;

4) biological specimen - plasma on EDTA;

5) clinical specificity - 99.98%, including for pools of 6 samples;

6) Genotype/subtype inclusivity: variations of the HIV virus known in the world, including for the Eastern European region;

Roche Diagnostics Polska Sp. z o.o.
ul. Bobrowiecka 8, 00-728 Warszawa
Tel. +48 22 481 55 55
Faks +48 22 481 55 99

Sąd Rejonowy dla m.st. Warszawy
w Warszawie, XIII Wydział Gospodarczy
Krajowego Rejestru Sądowego,
nr KRS 0000132695

kapitał zakładowy 8 000 000 PLN
NIP 527-23-22-068

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7) Genotype/subtype inclusivity: variations of the HCV virus in the world, including the Eastern European region;

8) Genotype/subtype inclusivity: variations of HBV virus in the world, including the Eastern European region;

9) Provide with protection against evaporation and leakage from the manufacturer;

10) Ensures a high degree of accuracy and excludes viral contamination: . The test incorporates an Internal Control for monitoring test performance in each individual test as well as the AmpErase enzyme to reduce potential contamination by previously amplified material (amplicon).

3.The offer includes all the necessary components, in sufficient quantities to be applied in the test reaction, according to the instructions for use of the product.

4. Form of packaging: delivered in a secure package, marked and labeled by the manufacturer with the identification of the identity data (name, batch / serial number, terms of validity, storage conditions). The identification data displayed on the box must 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 S201, 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

- Quantity offered for 24,000 examinations, no. controls / calibrators / solutions and other mandatory products, including repeated examinations.

Supplied devices: Model Cobas S201, manufacturer Roche, year of manufacture 2016 - 2 pieces

We remain at your disposal for any further clarifications

Kindest regards

Wojciech Szymanik
Proxy
Roche Diagnostics Polska Sp. z o.o.
Bobrowiecka 8 str.
00-728 Warsaw, Poland

Olga Mulyarchik
Proxy
Roche Diagnostics Polska Sp. z o.o.
Bobrowiecka 8 str.
00-728 Warsaw, Poland