

28.09.2022 Center for Centralized Public Procurement in Health

Republic of Moldova

Re: Tender no. ocds-b3wdp1-MD-1662133727713 from 18.10.2022

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.

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

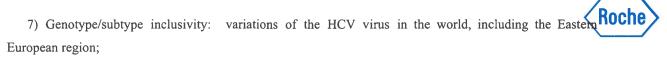
1. The offer for lot 2 includes:

All needed test/ accessories / consumables / reagents / calibrators / controls / solutions and other mandatory products to **perform 15360 of tests 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;



- 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 15360 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

> Olga Mulyarchik Proxy Reche Diagnostics Polska Sp. z o.o.

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