12.07.2024

To: Center for Centralized Public Procurement in Health

Re: **Tender no.** ocds-b3wdp1-MD-1717759541261 **from 31.07.2024**

Lot.II 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:

The offer is for:

2.2 similar technology applied to a device other than the provided one: laboratory medical device, the number of tests, accessories / consumables / reagents / controls / solutions and other mandatory products, including related to the activity of the laboratory medical device, necessary in the process of laboratory examination of donated blood, corresponding – the amount required for subsequent examinations according to the contracts, no. controls/calibrators/solutions and other mandatory products, including repeated examinations.

2.3 The technical service/repair of the medical devices offered, during the whole period of execution of the contract, by personnel authorized by the manufacturer will be assured.

1. Medical device – 2 pieces, cobas® 5800 System, year of production 2023
Provided with X800 Data Manager and cobas® Synergy software for connection to **Hamilton MICROLAB ® STAR IVD (pooler).**

1.a) The cobas® 5800 System supports an automated and integrated workflow to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT). The cobas® MPX test is intended for use to screen donor samples for HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA in plasma and serum samples for use on **cobas® 5800 System**;
b) is based on real time PCR technology on a fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection on the cobas® 5800 system;
c) The cobas® MPX test enables the simultaneous detection and discrimination of HIV RNA, HCV RNA, HBV DNA, and the internal control in a single test of an infected, individual donation or pooled plasma from individual donations;

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Date: 2024.07.30 11:32:07 EEST
Reason: MoldSign Signature
Location: Moldova

- The **cobas® 5800 System** is able to test samples in pools and the time to first results is 2 hours 45 minutes; If one pool is reactive, cobas 5800 will indicate the virus right away and will create an order for testing all samples from reactive pool. Testing 6 (up to 24) samples from reactive pool will take less than 3h. In total the final result will be obtained in max. in 6 h;

2. Accessories/supplies/reagents//solutions and other mandatory products required in the process testing - provided for the appropriate number of tests:

- Stabilised real-time PCR reagents do not require calibration;

a) Assay targets: HIV-1 Group M, HIV-1 Group O, HIV-2, HCV and HBV;
b) delivered in secure "ready to use" packaging, marked and labelled by the manufacturer with the identification data (name, batch/serial number, shelf life, storage conditions).
The identity data displayed on the box will be similar with those on the labels of each component of the kit; RFID identification.
3. Ready-to-use reagents do not require thawing, mixing or pouring; RFID tagged reagents and consumables are traceable throughout the whole process and validity (expiry date, cumulative time on board, number of runs);
4. Sample loading capacity: 128 samples in standard racks. Throughput of the analyzer is 144 samples per 8h - per device, (1 (one) sample equivalent to three examinations concurrently (HBV, HCV, HIV); 120 tests in max 7 h;

5. Requirements to the functionality of the device:
a) assure automatic loading/unloading for racks or other similar components required in the testing process;
b) assure automatic pipetting for reagents/solutions applied in the technology offered, as well as samples, including software-supported management (permanent inventory reagents/solutions); When supplies are running low or are missing for the next scheduled run, or there is not enough waste capacity, notifications are displayed:
c) assure automatic dilution, including pre- and post-dilutions;
d) assure automatic disposal of waste, including software-supported management (permanent waste inventory);
e) assure permanent monitoring of the status of the samples in the work list: The Orders overview table provides the following information: • Sample ID. • The test name, the sample type, and the pipetting volume. • If the sample is loaded on the instrument: • Location of the sample: track, carrier ID, position in the carrier • Run ID • Instrument • Estimated end time of the run • The status of the order. • Creation date and time of the order. • If the target is from a high-target test.
f) When supplies are missing or there is an error in the system, the instrument informs you on various levels: • Status light • Audible alarm • User interface indicator • Notification badge • Information inbox notifications • Status indicator at the liquid waste container, wash reagent container, lysis reagent bottle, and diluent bottle.
h) provided with a database management system - **x800 Data Manager;**
i) the reading technology is based on build-in digital cameras;
k) provided with mobile barcode laser readers if it will be necessary;
l) The data manager provides interconnectivity with analyzers and host systems/LIS that communicate with standard protocols and references for implementing connections from external laboratory information systems (LIS) to the product.

6. The software database management system x800 Data Manager:
a) available software applications with latest generation accessories - To maintain the good operation of the system the security, system, and software are updates regularly by Roche.

b) Manages orders; Generates final results based on the technical validation of preliminary results. The system automatically archives audit trail entries, messages, test results, and control results at a configured time. If necessary, in the Administration app, 4 you can manually archive at any time.
c) Stores measurement data, result reports, and other information logged by the system; In the *Results overview table*, flags indicate if a test order result is valid, invalid, not available, or if additional information is provided in the result;
d) user and certificate management - to work on the system, you must be logged on;
c) submission of analysis/quality control results in the IT system, including notification of errors occurring during operation;
e) configuring the operation of connected devices - The data manager can be linked to several instruments. If an instrument is not used anymore, you can unregister it.
f) The following apps of the data manager are a available on the touch screen monitor of the instrument: • Orders • Results • Controls • Reports
For each test order result and each control result, you can track how the result was generated.
the cobas® Synergy generating a variety of reports to manage and analyze results and performance; The data manager allows you to generate a predefined result report with a report summary and information on sample and control results, used consumables, and assays;

7. Accessories related to the device but mandatory for its operating conditions:
The instrument allows you to export reports to an external storage device via:
b,c) 4 USB ports
d) network port – LAN;
e) UPS with the capacity to ensure the electricity supply source for at least 60 minutes is offered - Smart UPS Online 6000VA/5400W;
8. Location and conditions for installment:
a) Line voltage: 100-240 VAC +/- 10%, Line frequency:50/60Hz +/- 10%;
b) Does not require a water source;
c) Instrument dimensions: 1,34 x 1,75 x 0,79 m (W x H x D);

2. Reagents: cobas® MPX test

The cobas® MPX test – is a qualitative in vitro test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA, and Hepatitis B Virus (HBV) DNA in human plasma and serum. Highly sensitive and specific test with dual target approach for HIV-1 Group M and dual probes for HCV; Increased safety with detection of occult and low viremic HBV infection: 1.4 IU/ml per single donation and 8.4 IU in pool of 6;
Destination: This test is intended for use to screen donor samples for HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA in plasma and serum samples, results are simultaneously detected and discriminated for HIV, HCV, and HBV;

1. Method of application in the test reaction:
a) The cobas® MPX test is a qualitative multiplex test that is run on the cobas® 5800 System.
b,c) The cobas® MPX test is based on real time PCR technology on a fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection system. The cobas® 5800 System consists of a single, integrated instrument;

2. Diagnostic product:
1,2) This test is intended for use to screen donor samples for HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA in plasma and serum samples.
The cobas® MPX test enables the simultaneous detection and discrimination of HIV RNA, HCV RNA, HBV DNA, and the internal control in a single test of an infected, individual donation or pooled plasma from individual donations.
3) Any contaminating amplicons from previous PCR runs are eliminated by the AmpErase enzyme [uracil-N-glycosylase], which is included in the PCR master mix, when heated in the first thermal cycling step.
4) biological specimen - Plasma collected in EDTA, CPD, CPDA1, CP2D and 4% Sodium Citrate anticoagulant and serum collected in serum clot tubes may be used with the cobas® MPX test.
5) The clinical specificity of cobas® MPX for source plasma pools was determined by the analysis of 108,306 evaluable donations from 24,514 unique donors. Of these 108,306 evaluable donations, 108,297 were assigned a donation status of negative, of which 108,291 were cobas® MPX non-reactive, for a clinical specificity of 99.994%, Confidence Interval (95% CI: 99.988% to 99.997%);

6) Genetic variations of the HIV virus: The performance of the cobas® MPX test to detect subtypes of HIV-1 Group M (A-H, J, K, BF, BG) and circulating recombinant forms (CRF01_AE and CRF02_AG), HIV-1 Group O, HIV-1 Group N, and the subtypes of HIV-2 (A and B);
7) Genetic variations of the HCV virus: genotypes of HCV (1 - 6);
8) Genetic variations of the HBV virus: genotypes of HBV (A-H and precore mutant);
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). Dedicated pipette tips for each sample transfer and for transfer of extracted nucleic acid;
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.

We remain at your disposal for any further clarifications

Kindest regards

Renata Popielecka

19-Jul-2024 | 14:56 CEST

Emilian Dziemianczuk

19-Jul-2024 | 14:06 CEST