24.09.2025

To: Center for Centralized Public Procurement in Health

Re: **Tender no.** ocds-b3wdp1-MD-1754900307693 **from 10.10.2025**

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 the contracted quantity of tests on **cobas pro e801 instrument;**

1.1 Requirements for Regents:

a) stability when placed in the medical device for at least 28 days up to 4 months;

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

1.2 Consumables Requirements:

a) non-reusable assay tips and cups;

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

c) delivered in a safe "ready to use" packaging, marked and labeled by the manufacturer with identification data (name, batch/serial number, validity terms, storage conditions). - The RFID readers are mounted inside the reagent loader shaft. The RFID tag contains the following information: the reagent pack name, lot number, expiry date, reagent container code…;

Immunoassay detection of hepatitis B surface antigen (HBsAg) - Elecsys HBsAg II

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 on cobas e 801

b) fully automated;

c) electrochemiluminescence immunoassay "ECLIA";

Total duration of assay: 18 minutes.

Diagnostic product:

1) test for the screening of donated blood, 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. Elecsys HBsAg II assay was specifically developed to detect a multitude of mutants;
2) test with 100% sensitivity on blood donor samples (performance panels);
3) test with specificity not less than 99.88% 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 "ready to use" packaging, marked and labeled by the manufacturer with RFID 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.

Immunoassay for detection of antibodies to hepatitis C virus – Elecsys Anti-HCV II
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) closed type technology on cobas e 801
b) fully automated;
c) electrochemiluminescence immunoassay "ECLIA";
Total duration of assay: 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 99.85% 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 "ready to use" packaging, marked and labeled by the manufacturer with RFID 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.

Immunoassay for detection of total antibodies (IgG and IgM) to Treponema pallidum – Elecsys Syphilis

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) closed type technology on cobas e 801

b) fully automated;

c) electrochemiluminescence immunoassay “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 donated blood 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.

Immunoassay for simultaneous determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 - Elecsys HIV Duo

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, including the screening of blood donations;

Application method in the test reaction:

a) closed type technology on cobas e 801

b) fully automated;

c) electrochemiluminescence immunoassay “ECLIA”;

Total duration of assay: 18 minutes.

Diagnostic product:

1) test for the screening of donated blood 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 – 99.92 % and not less than 99.87% for blood donor samples;

4) test with analytical sensitivity (detection limit) – Antigen detection (HIVAg P24/HIVDUO) ≤ 1.0 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 "ready to use" packaging, marked and labeled by the manufacturer with RFID 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.

The offered devices:

cobas pro e 801 instrument - laboratory medical device – 2 (two), 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 to:

1.HBsAg – 80 000 tests;

2. antibodies to hepatitis C virus (HCV) – 80 000 tests;

3. antibodies against Treponema Pallidum - 80 0000 tests;

4. HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 – 80 000 tests;

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

1. Medical device – 2 pieces, cobas pro e801, year of production: new instruments, not older than 2024;

2. The e 801 analytical unit is a fully automated, high throughput immunology analyzer:

a) closed technology analyzer: Reagent pack type - *cobas e pack green*;

b) fully automated technology analyzer;

c) analyzer with electrochemiluminescent technology (ECL) used by the instrument is based on the reaction of a ruthenium complex with tripropylamine (TPA). The chemiluminescent reactions that lead to the emission of light from the ruthenium complex are initiated electrically. The advantage of electrically initiating the chemiluminescent reaction is that the entire reaction can be precisely controlled.

d) analyzer with the simultaneous identification technique of HBsAg markers,
anti HCV antibodies, anti-Treponema Pallidum antibodies, HIV Ag/Ac and other markers according to the attached Parameter list.

3. Accessories/consumables/reagents/calibrators/solutions and other mandatory products required in the testing process are included;

4. Sample loading capacity for testing:

a) loading capacity: 60 racks (300 samples);

b) the possibility of continuous loading starting from 1 (one) sample;

5. Test processing speed - up to 300 tests/h per each device;

6. Requirements to the functionality of the device:

a) loads/unloads racks automatically. Automatic reagent loading during Operation and Stand By;

b) automated pipetting for reagents/calibrators/solutions and samples. Software-supported management Colors indicate the status: Empty, Sufficient, Onboard stability, shelf life.

c) automatic dilutions: 1:1.1 to 1:27 000;

d) automatic waste disposal, including software-supported management (permanent waste inventory);

e) permanent monitoring of the status of the samples in the work list;

f) quality control (QC) system ensure quality analysis of the samples, reagents/calibrators/solutions;

The system informs if any alarm is issued during operation (visually and sonically);

g) provided with the specially designed mode for emergency tests: STAT port;

h) a database manages the sample records, calibration and QC data as well as system parameters and results;

i) most of the barcode readers use LED technology with low output power. One laser barcode reader is used in the sample upply unit;

k) provided with mobile barcode laser readers;

l) cobas system software is embedded in the laboratory IT setup;

7. Software database management system and its functionality:

a) Operating system: Windows 10. Monitor: 21.5" touch-screen LCD Monitor. Cobas link automatically updates software. Cobas e-library is updated daily via an automatic download from the remote service platform.

b) receiving/monitoring/printing in electronic form or by manual input of analysis results, quality control results, notifications and device maintenance events;

c) database storage capacity: sample records (routine/STAT/QC) 12 000 samples (including rerun tests); and reaction process data 12 000 samples;

d) to access the system, each operator and administrator needs a user ID and a password.

e) cobas link provides a secure remote connection for data transfer between the cobas systems in your laboratory

and the remote service platform: statistical data from your system, to monitor performance, for QC management, and for service purposes;

f) possibility to mask reagent packs, tests, or analytical units;

g) the system allows to: generate, view or print reports, take a screenshot. During or after a run, you can view the results of selected patient samples and QC measurements.

8. Accessories related to the device but mandatory for the conditions of

its operation: the PC has a DVD-RAM drive and two USB ports accessible from the front door of the sample supply unit.

e) UPS with the capacity to ensure the electricity supply source for at least 60 minutes is offered

f) a water filtration and deionization system is offered with a tank for at least 300 samples in testing: WSU II with accessories;

9. Location and conditions needed for installment:

a) Line voltage: 200-240 V, Line frequency: 50/60Hz +/- 10%;

c) Instrument dimensions: (m) 2,82 (L) × 2,32 (W) × 1,43 (H);

We remain at your disposal for any further clarifications

Kindest regards,

Signed by:
Jacek Sopek
E89CC6BC3BB24F1...
07-Oct-2025 | 15:59 CEST

Signed by:
Renata Popielecka
E83A3DD1E56C4C3...
06-Oct-2025 | 11:20 CEST

24.09.2025

To: Center for Centralized Public Procurement in Health

Re: **Tender no.** ocds-b3wdp1-MD-1754900307693 **from 10.10.2025**

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:

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.

The offer for lot II includes:
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 – 75 000 examination, no. of controls/calibrators/solutions and other mandatory products, including 2% repeated examinations on **cobas 5800 instrument x2 units**.
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;

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;

- 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;
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);

We remain at your disposal for any further clarifications

Kindest regard,

Signed by:
Jacek Topek
E89CC6BC3BB24F1...
07-Oct-2025 | 15:59 CEST

Signed by:
Renata Popielecka
E83A3DD1E56C4C3...
06-Oct-2025 | 11:20 CEST

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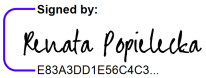
Renata Popielecka renata.popielecka@roche.com Sales Enabling Lead Warsaw Security Level: Email, Account Authentication (None)	Signed by:  E83A3DD1E56C4C3... Signature Adoption: Pre-selected Style Using IP Address: 194.120.84.9	Sent: 10/6/2025 9:43:51 AM Viewed: 10/6/2025 11:19:56 AM Signed: 10/6/2025 11:20:13 AM
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Envelope Summary Events	Status	Timestamps
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Certified Delivered	Security Checked	10/6/2025 11:19:56 AM
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How to contact us

You may contact us to let us know of your changes as to how we may contact you electronically, to request certain information from us and to withdraw your prior consent to receive notices and disclosures electronically. To do so contact the sender of the envelope.

To advise us of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to the sender of the envelope and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address. In addition, you must notify DocuSign, Inc. to arrange for your new email address to be reflected in your DocuSign account by following the process for changing email in the DocuSign system.

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