

ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS EXTERNAL QUALITY CONTROL PROGRAM

HEMATOLOGY PROGRAM - INSTRUCTIONS

Cycle: 12

Store upright at +2-8°C



Accredited to TS EN ISO/IEC 17043:2013 (TÜRKAK: AB-0010-YT)

Purpose of use

The KBUDEK Hematology External Quality Control Program is designed to enable the comparison of the performance of each laboratory participating in this program with other laboratories on a test, method and device basis.

Privacy

KBUDEK gives great importance to the confidentiality of program participants. Each participant is identified only by a code known to them and KBUDEK. The laboratory code, user code and password are defined for each participant to input and review data on the internet. Users can change their passwords themselves.

Tests

WBC, RBC, Hemoglobin, Hematocrit, MCH, MCHC, MCV, RDW, Platelets, MPV

Safety Precautions and Warnings

♥WARNING: Biological source. Potentially infected material.

For external use only. Do not pipette by mouth. The procedures applied for handling laboratory reagents should also be applied for these materials. Samples were prepared by lyophilizing human serum pools. At the donor level, Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HBsAg) and Hepatitis C Virus (HCV) antibody were tested and found to be non-reactive. Each donor is also found negative by a serological test for Syphilis (RPR or STS). These tests were performed with FDA approved methods. However, since no method can guarantee the absence of infectious agents, this material should be handled and disposed of accordingly, assuming that it is capable of spreading infectious disease.

Product safety data sheets are available on request.

Sample Preparation

Ready to use.

Samples should be handled in the same way as patient samples. If possible, it should be taken into daily processes without the knowledge of laboratory staff.

- 1- Remove the sample from the refrigerator and allow it to warm at room temperature for **15 minutes**
- 2- Mix the sample horizontally between the palms of hands. Roll the tube back and forth, and gently invert the tube 10 times immediately before analyzing. Do not use mechanical mixer. Incomplete mixing of the tube may cause incorrect results.
- 3- Do not shake!
- 4- Return the sample to the refrigerator in 30 minutes

Note: It is recommended to run the External Quality Control Samples one time as patient samples.

Storage Conditions

Store samples **upright** when not in use. Do not allow samples to freeze (samples should not touch inner walls of the refrigerator!)

Unopened sample: Store upright at +2 to 8^{0} C. Stable to expiration date printed on individual vials.

Opened sample: Stable for 7 days at +2 to 8° C if they are handled as described above.

Working times of samples

This programme cycle consists of 12 vials. In one year 3 vials will be sent quarterly. Information on which month it should be worked is available on the label. Each sample should be run on the date indicated on the back page of this document.

Submission of results

The results should be entered to the system at the latest business day of the related month by using the internet code, user code and password that are reported to you via the internet at www.kbudek.com. Before entering your results, be sure to make test identifications and choose the correct test units to report the result.

Late and corrected results

Late or corrected results do not affect the mean and standard deviation values that are already calculated and published, but those values are used to calculate late results. The report will have an information that the results are late or corrected. No evaluation will be made for late results after the end of cycle for the previous year is published.

Results will be only corrected if it is non-analytical such as reconstitution errors, transcription errors, analyzing and/or submitting the results for the wrong sample.

Monitoring performance results

Evaluation results are published on the internet in the second week of the following month. Each participant will only be able to see their results by entering with his own laboratory code, user code and password.

When reports are published participants are informed with text messages.

Device or method changes

Any changes related with participant's device, test method or unit should be updated via the website.

For current tests and methods used in the program, please refer to the program instructions published at www.kbudek.com

Materials provided:

Hematology Controls -3 vials – 2 ml



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Lot: HE2023-1 (EXP: 2023-04) HE2023-2 (EXP: 2023-07) HE2023-3 (EXP: 2023-10) HE2023-4 (EXP: 2024-01)

HE2023-4 (EXP: 2024-01)
REF: KBUDHEM Program Code: HE
Store upright at +2-80C

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Working times of samples

Month	Sample Number	Recommended working date	Last date to enter results
January	1	25.01.2023	31.01.2023
February	2	22.02.2023	28.02.2023
March	3	22.03.2023	31.03.2023
April	4	26.04.2023	30.04.2023
May	5	24.05.2023	31.05.2023
June	6	21.06.2023	30.06.2023
July	7	26.07.2023	31.07.2023
August	8	23.08.2023	31.08.2023
September	9	27.09.2023	30.09.2023
October	10	25.10.2023	31.10.2023
November	11	22.11.2023	30.11.2023
December	12	27.12.2023	31.12.2023

ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS

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Tests and Methods in the program

TESTS	Methods
Hematocrit	Other methods Electrical Impedance Calculated
Hemoglobin	Other methods Photometric
Mean Corpuscular Hemoglobin	Other methods Calculated
Mean Corpuscular Hgb.Konsantrasyonu	Other methods Calculated
Mean Corpuscular Volume	Other methods Electrical Impedance Light Scattering Calculated
Mean Platelet Volume	Other methods Electrical Impedance Light Scattering Calculated
Platelets	Other methods Electrical Impedance Light Scattering
Red Blood Cells	Other methods Electrical Impedance Light Scattering
Red Blood Cell Distribution Width	Other methods Electrical Impedance Calculated
White Blood Cells	Other methods Electrical Impedance Light Scattering

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