

ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS
EXTERNAL QUALITY CONTROL PROGRAM

CLINICAL BIOCHEMISTRY PROGRAM-INSTRUCTIONS

CYCLE: 18

Lot: B2023, Exp: 2024-01

REF: KBUBIOC Program Code: B

Store at +2–8⁰C

Accredited to TS EN ISO/IEC 17043:2013

(TÜRKAK: AB-0010-YT)

Purpose of use

The KBUDEK Clinical Biochemistry 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

Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bicarbonate, Bilirubin (Total), Bilirubin (Direct), Calcium, Chloride, Cholesterol, Creatinine, CK, Copper, Gamma-Glutamyl Transferase, Glucose, HDL-Cholesterol, Iron, Iron Binding Capacity, Inorganic Phosphate, Lactate, Lactate Dehydrogenase, LDL-Cholesterol, Lipase, Lithium, Magnesium, Potassium, Sodium, Total Protein, Triglycerides, Urea, Uric Acid, Zinc

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. 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

Clinical Biochemistry control samples are lyophilized.

The bottle specified for each month on the label must be dissolved with 5 ml of distilled water at +15°C to +25 °C. Wait for at least 30 minutes (1 hour for ALP test) with lid closed and mix slowly until all is dissolved. Do not create foam. Do not shake. Do not use a syringe to dilute! We recommend that you dissolve using an automatic pipette of the same volume.

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.

NOTE: It is recommended to run the External Quality Control Samples (as repetition) once.

Storage Conditions

Unopened sample: Store at +2–8⁰C. Stable to expiration date printed on individual vials.

Opened sample: After reconstitution, it is stable for 8 hours at +15°C to +25 °C, for 7 days at +2°C to +8°C, for 30 days at -20°C (frozen once) (See restrictions). Only volume needed to measure should be removed and analyzed. The remaining sample after use should not be discharged back to original vial.

Limitations

- 1- Alkaline phosphatase levels in the reconstituted sample will increase during stability period. It is recommended to keep the reconstituted sample for 1 hour at +15°C to +25 °C before measurement.
- 2- Bilirubin in the sample is light sensitive and it is recommended to store it in the dark. It can be stored for 4 days at +2 °C to +8 °C in the dark. Do not store at +15°C to +25 °C. Do not freeze.

Working times of samples

The box contains 12 (twelve) labeled samples, one for each month, to be worked in a year, respectively. 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 last day of the related month by using the lab code, user code and password at www.kbudek.com. Before entering your results, be sure to make test identifications and to choose the correct test units to report the result.

If the measured value is below the device reading range, the result must be entered with < sign. If it is above the reading range, the result should be entered with > sign (please do not dilute!)

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

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

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:

Clinical Biochemistry Control samples-12 vials – lyophilised - 5 ml

Materials required but not provided:

Automatic pipette
Distilled water

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Schedule

Month	Sample Number	Recommended working date	Last date to enter results
January	1	24.01.2023	31.01.2023
February	2	21.02.2023	28.02.2023
March	3	21.03.2023	31.03.2023
April	4	25.04.2023	30.04.2023
May	5	23.05.2023	31.05.2023
June	6	20.06.2023	30.06.2023
July	7	25.07.2023	31.07.2023
August	8	22.08.2023	31.08.2023
September	9	26.09.2023	30.09.2023
October	10	24.10.2023	31.10.2023
November	11	21.11.2023	30.11.2023
December	12	26.12.2023	31.12.2023

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Tests and Methods in the program

TEST	Methods
Alanine Aminotransferase	Other methods UV (with P5P) UV (w/oP5P) Enzymatic Colorimetric
Albumin	Other methods Immuno Nefelometric Bromcresol Green (BCG) Bromcresol Purple (BCP) Immuno Turbidimetric
Alkaline Phosphatase	Other methods Aminomethylpropanol Buffer, AMP Diethanolamine Buffer, DEA
Amylase	Other methods Maltotetraose Substrate Blocked Maltoheptaoside (G7 PNP, Blocked) p-Nitrophenyl Linked Substrates (PNP-G3,PNP-malto) Amylopectin, Colorimetric CNP Maltoheptaoside CNP Triose - CNPG3
Aspartate Aminotransferase	Other methods UV (with P5P) UV (w/oP5P) Enzymatic Colorimetric
Bicarbonate	Other methods Enzymatic Colorimetric
Calcium	Other methods Ion Selective Elektrod Arsenazo Cresolphthalein Complexone Methylthymol Blue NM-BAPTA
Chloride	Other methods Direct ISE Indirect ISE Mercuric Thiocyanate / Ferric Ion
Creatine Kinase	Other methods CK-NAC Substrate
Creatinine	Other methods Enzymatic Alkaline Picrate Kinetic Alkaline Picrate Kinetic IFCC-IDMS Standard Enzymatic IFCC-IDMS standard; Colorimetric (spotchem)
*Copper	Other methods End point Enzymatic

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Direct Bilirubin	Other methods Vanadate Oxidation Dual Wavelength Reflectance Spectrophotometric Diazotization
Gamma-Glutamyl Transferase	Other methods Gamma-Glutamyl-4-nitroanilide Substrate Gamma-Glutamyl-3-carboxy-4nitroanilide Substrat
Glucose	Other methods Glucose Oxidase Hexokinase Glucose Dehydrogenase
HDL Cholesterol	Other methods Phosphotungstate/Magnesium Immune Inhibition (direct) Polymer Polyanion (direct) PEG (direct) Dextran Sulphate
Inorganic Phosphate	Other methods Phosphomolybdate Formation / UV
Iron	Other methods Colorimetric
Lactate	Other methods Elektrode Enzymatic / Pyruvate -> Lactate
Lactate Dehydrogenase	Other methods Pyruvate -> Lactate (DGKC) Lactate -> Pyruvate (IFCC)
LDL Cholesterol	Other methods Calculated Non-Immunological (Enz. /Color./Acce. Sel. Deter.) Selective Deterg.
Lipase	Other methods Enzymatic Colorimetric
*Lithium	Other methods Atomic Absorption Flame emission ISE Colorimetric
Magnesium	Other methods Enzymatic Arsenazo Methylthymol Blue Calmagite Xylidyl Blue Chlorophosphanazo III Formazan dye
Potassium	Other methods Direct ISE Indirect ISE
Sodium	Other methods Direct ISE Indirect ISE

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Total Bilirubin	Other methods Dual Wavelength Reflectance Spectrophotometric Sulfanilik acid (spotchem) Sulfonilik acid (Caffe.-Benzoate,Jendrassik Grof) Sulfonilik acid (Dimethyl Sulphoxide/Other Acc) Sulfonilik acid (Surfactant Acce.,Evelyn Malloy) Dichloroaniline (DCA) Diazonium Ion (2-5 Diclorophenyl=DPD/NBD etc) Vanadate Oxidation
Total Iron Binding Capacity	Other methods TIBC
Total Cholesterol	Other methods Cholesterol Oxidase
Total Protein	Other methods End Point (Biuret reaction) Kinetic (Biuret reaction)
Triglycerides	Other methods Enzymatic Enzymatik Colorimetric Enzymatik Colorimetric (Glycerol correction)
Urea	Other methods Urease, Colorimetric Urease, UV Colorimetric (spotchem)
Uric Acid	Other methods Uricase Colorimetric Uricase UV Phenantroline method
Zinc	Other methods End point Enzymatic

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“*” marked test is not in accreditation scope