



ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS
EXTERNAL QUALITY CONTROL PROGRAM

IMMUNOASSAY PROGRAM - INSTRUCTIONS

Cycle: 18
Lot: H2023, SKT: 2024-01
REF: KBUDHORM
Program Code: H
Store at +2–+8⁰C



Accredited to TS EN ISO/IEC 17043:2013

(TÜRKAK: AB-0010-YT)

Purpose of use

The KBUDEK IMMUNOASSAY 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

Immunoassay Program:

Anti-thyroglobulin, Anti TPO, C-Peptide, DHEA-SO₄, Estradiol, Ferritin, Folic acid, FSH, HCG, IgE, İnsulin, Cortisol, LH, PTH intact, Progesterone, Prolactin, Free T3, Free T4, Total T3, Total T4, TSH, Testosterone, Vitamin B12, 25-OH Vitamin D

Immunoassay Special Tests Program (Free to Immunoassay program users):

1,25 OH Vitamin D, Estriol, GH, SHBG, Androstenedion, Aldosteron, Free testosterone, 17-OH progesterone, Beta-2 Microglobulin, IGF-1

Therapeutic Drug Program (Free to Immunoassay program users):

Digoxin, Phenytoin, Phenobarbital, Carbamazepine, Lithium, Salicylates, Theophylline, Valproic acid, Vancomycin

Tumor Markers Program:

AFP, CEA, CA 125, CA 15-3, CA 19-9, Total PSA, Free PSA.

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

Immunoassay 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 with lid closed and mix slowly until all is dissolved. Do not create foam. Do not shake. Do not use an

injector 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.

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

Working times of samples

The box contains 12 labeled samples, one for each month, to be studied 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 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.

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.

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:

Immunoassay 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	26.01.2023	31.01.2023
February	2	23.02.2023	28.02.2023
March	3	23.03.2023	31.03.2023
April	4	25.04.2023	30.04.2023
May	5	26.05.2023	31.05.2023
June	6	22.06.2023	30.06.2023
July	7	27.07.2023	31.07.2023
August	8	24.08.2023	31.08.2023
September	9	28.09.2023	30.09.2023
October	10	26.10.2023	31.10.2023
November	11	23.11.2023	30.11.2023
December	12	28.12.2023	31.12.2023

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Tests and Methods in the program

TESTS	METHODS
25-OH Vitamin D	Radioactive methods (Immunoradiometric IRMA) Enzymatic Immunoassay (EIA) Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) ELISA RIA Other methods
Anti Thyroglobulin	Enzymatic Immunoassay (EIA) Florescence Polarization Immunoassay (FPIA) Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)RIA Turbidimetric RIA Other methods
Anti TPO	Enzymatic Immunoassay (EIA) Florescence Polarization Immunoassay (FPIA) Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)RIA Turbidimetric RIA Other methods
C-peptide	Enzymatic Immunoassay (EIA) Florescence Polarization Immunoassay (FPIA) Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) Nephelometric RIA Other methods
DHEA-SO4	Enzymatic Immunoassay (EIA) Florescence Polarization Immunoassay (FPIA) Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)RIA Turbidimetric RIA Other methods
Estradiol (E2)	Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) Other methods
Ferritin	Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) Turbidimetric Other methods
Folate	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)



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Follicle Stimulating Hormone (FSH)	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Human Chorionic Gonadotropin (hCG)	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) Time Resolved Fluorescence (TRF)
Immunoglobulin E (IgE)	Other methods Enzymatic Immunoassay (EIA) Fluorescence Polarization Immunoassay (FPIA) Fluorimetric Immunoassay (FIA) Luminescence (Chem/electrochem) Immunoassay Nephelometric, end point Nephelometric, fixed time, kinetic Nephelometric kinetic Spectrofotometric Immunoassay Turbidimetric
Insulin	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Cortisol	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Luteinizing Hormone (LH)	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Progesterone	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Prolactin	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
PTH, Intact	Other methods Enzymatic Immunoassay (EIA) Fluorescence Polarization Immunoassay (FPIA) Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) RIA Turbidimetric



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Free T3	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) Coated Tube (Radioactive)
Free T4	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA) Turbidimetric
Testosterone	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Thyroid Stimulating Hormone (TSH)	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Total T3	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Total T4	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)
Vitamin B12	Other methods Radioactive methods (Immunoradiometric IRMA) Spectrofotometric Immunoassay Luminescence (Chem/electrochem) Immunoassay Fluorimetric Immunoassay (FIA)

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