ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS
EXTERNAL QUALITY CONTROL PROGRAM

THERAPEUTIC DRUG PROGRAM - INSTRUCTIONS

Cycle: 13
Lot: H2018, SKT: 2020-10,
REF: KBUDTD
Program Code: TI
Store at +2–8^{0}C

Purpose of use

The KBUDEK THERAPEUTIC DRUG 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 user codes and passwords themselves.

Tests

Therapeutic Drug Program (Free to Immunoassay program users):
Digoxin, Phenytoin, Phenobarbital, Carbamazepine, Lithium, Salicylates, Theophylline, Valproic acid, Vancomycin

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

Therapeutic Drug 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 +2–8^{0}C. Stable to expiration date printed on individual vials.
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 (twelve) 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 to report the result.

Late results

Late 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 contains information that the results are late. No evaluation shall be made for late results after the cycle is closed. Late results are not included in the End of Cycle Reports.

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:

Therapeutic Drug 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	24.01.2018	31.01.2018
February	2	21.02.2018	28.02.2018
March	3	21.03.2018	31.03.2018
April	4	18.04.2018	30.04.2018
May	5	23.05.2018	31.05.2018
June	6	20.06.2018	30.06.2018
July	7	25.07.2018	31.07.2018
August	8	15.08.2018	31.08.2018
September	9	19.09.2018	30.09.2018
October	10	24.10.2018	31.10.2018
November	11	21.11.2018	30.11.2018
December	12	19.12.2018	31.12.2018

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Tests and Methods in the program

TESTS	METHODS
Digoxin	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Radioactive methods
Phenytoin	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Radioactive methods
Phenobarbital	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Radioactive methods
Carbamazepine	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Radioactive methods
Lithium	Other methods Colorimetric Atomic absorption Flame emission Ion selective electrode
Salicylates	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Enzymatic (Non-Immunologic) Radioactive methods
Theophylline	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Enzymatic (Non-Immunologic) Radioactive methods
Valproic acid	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Radioactive methods
Vancomycin	Other methods Enzyme immunoassay (Immunologic) Non-Enzymatic immunoassay (Immunologic) Radioactive methods