



ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS
EXTERNAL QUALITY CONTROL PROGRAM



CARDIAC PROGRAM-INSTRUCTIONS

Cycle: 6

Lot: KP2018, SKT: 2021-11, REF: KBUDCARD

Program Code: KP

Store at +2-8⁰C

Purpose of use

The KBUDEK Cardiac 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

BNP, CK, CK-MB (activity), CK-MB (mass), Digoxin, Homocystein, hsCRP, Myoglobin, NT-ProBNP, Troponin I, Troponin T

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

Cardiac 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 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. Stable to expiration date printed on individual vials.

Opened sample: After reconstitution, it is stable for 5 days at +2°C to +8°C, for 30 days at -20°C (frozen once). Troponin I is stable for 2 weeks at -20 °C'de (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:

Cardiac Control samples-12 vials – lyophilised - 2 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	23.01.2018	31.01.2018
February	2	20.02.2018	28.02.2018
March	3	20.03.2018	31.03.2018
April	4	17.04.2018	30.04.2018
May	5	22.05.2018	31.05.2018
June	6	19.06.2018	30.06.2018
July	7	24.07.2018	31.07.2018
August	8	14.08.2018	31.08.2018
September	9	18.09.2018	30.09.2018
October	10	23.10.2018	31.10.2018
November	11	20.11.2018	30.11.2018
December	12	18.12.2018	31.12.2018

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Tests and Methods in the program

TEST	Methods
BNP	Other methods Abbott Architect Abbott AxSYM bioMerieux Vidas Biosystems Maplab Plus Lifesign DxPress Reader Mitsubishi Pathfast Radiometer AQT90 Flex Roche Cardiac Reader Roche h232 Roche Elecsys/E170/c6000/e411 Siemens ADVIA Centaur Siemens/Dade Stratus Siemens/DPC Immulite 2000/2500 Siemens/DPC Immulite 1000 Siemens/Dade Dimension/RxL/Max Siemens/Dade Opus Siemens/Dade Dimension Vista/ExL LOCI Vitros 3600/5600/ECi
CK-MB (Activity)	Other methods Immunologic Inhibition Immunologic Inhibition serum start Immunologic Inhibition substrate start Ortho Vitros MicroSlide Systems Vitros DT60/DT60 II/DTSC II
CK-MB (mass)	Other methods Abbott Architect Abbott AxSYM Abbott IMx Abbott i-STAT Beckman Coulter Access, DxI bioMerieux Vidas Biosite Triage Meter Plus Diasorin Liaison I-Chroma Mitsubishi Pathfast Radiometer AQT90 Flex Randox Evidence/Investigator Response Biomedical Ramp Roche Cardiac Reader Roche h232 Roche Elecsys/E170/c6000/e411 Siemens ADVIA Centaur Siemens/Bayer ACS 180 Siemens/Bayer Immuno 1 Siemens/Dade Dimension Vista/ExL LOCI Siemens/Dade Dimension/RxL/Max Siemens/Dade Opus Siemens/Dade Stratus Siemens/DPC Immulite 2000/2500 Siemens/DPC Immulite 1000 Tosoh Vitros 3600/5600/ECi



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Digoxin	Other methods Abbott Aeroset C4000/C8000/C16000 Abbott IMx Abbott AxSYM Abbott TDx/TDx FLx Beckman Coulter Access, DxI Beckman CX/LX/DX bioMerieux Vidas RIA Roche Integra Roche Elecsys/E170/c6000/e411 Siemens Advia 1200/1650/1800/2400 Siemens Advia Centaur Siemens/DPC Immulite 2000/2500 Siemens/DPC Immulite 1000 Siemens/Bayer ACS 180 Siemens/Dade Dimension/RxL/Max Vitros
Homocystein	Other methods Abbott Architect Abbott AxSYM Abbott IMx Beckman CX/LX/DX Beckman Immage Beckman AU400/600/640/2700/5400 Roche Integra Siemens Advia Centaur Siemens/Dade Nephelometre Siemens/DPC Immulite 2000/2500 Response Biomedical Ramp Roche/Hitachi Cobas c311/c501
hs CRP	Other methods Abbott Aeroset C4000/C8000/C16000 Beckman AU series Beckman ICS/Array Beckman Immage Erba XL 400/XL 600/XL 1000 series KONELAB 20İ/30İ/60İ Mindray/Mindray Perfect Plus Mitsubishi Pathfast Prestige 24i Radiometer AQT90 Flex Roche/Hitachi Cobas c311/c501 Roche Integra Roche Modular/900 series Siemens/DPC Immulite 2000/2500 Siemens/Bayer ACS 180 Siemens/Dade Dimension/RxL/Max Siemens/Dade Nephelometre Siemens Advia 1200/1650/1800/2400 Toshiba Accute Vitros Vitros (IFCC Cal.) Vitros (Non IFCC Cal.)
Creatine Kinase	Other methods CK-NAC Substrate



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Myoglobin	Other methods Abbott Architect Abbott AxSYM Beckman Coulter Access, DxI Biosite Triage Meter Plus bioMerieux Vidas Diasorin Liaison Radiometer AQT90 Flex Randox Daytona / Imola Randox Evidence/Investigator Roche Cardiac Reader Roche h232 Roche/Hitachi Cobas c311/c501 Roche Integra Roche Elecsys/E170/c6000/e411 Siemens ADVIA Centaur Siemens/Dade Dimension Vista/ExL LOCI Siemens/Dade Opus Siemens/Dade Nephelometer Siemens/Dade Stratus Siemens/DPC Immulite 2000/2500 Siemens/DPC Immulite 1000 Tosoh
NT-Pro-BNP	Other methods Abbott AxSYM bioMerieux Vidas Biosystems Maplab Plus Lifesign DxPress Reader Mitsubishi Pathfast Radiometer AQT90 Flex Roche Cardiac Reader Roche h232 Roche Elecsys/E170/c6000/e411 Siemens ADVIA Centaur Siemens/Dade Stratus Siemens/DPC Immulite 2000/2500 Siemens/DPC Immulite 1000 Siemens/Dade Dimension/RxL/Max Siemens/Dade Opus Siemens/Dade Dimension Vista/ExL LOCI Vitros 3600/5600/ECi



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Troponin I	Other methods Abbott Architect Abbott AxSYM Abbott i-STAT Biosite Triage Meter Plus bioMerieux Vidas Beckman Coulter Access, DxI Diasorin Liaison I-Chroma Innotrac Aio Mitsubishi Pathfast Nanosphere VeriSens hs-cTnI Radiometer AQT90 Flex Randox Evidence/Investigator Response Biomedical Ramp Roche Elecsys/E170/c6000/e411 Siemens Advia Centaur Siemens/Bayer ACS 180 Siemens/Bayer Immuno 1 Siemens/Dade Stratus Siemens/Dade Dimension/RxL/Max Siemens/Dade Dimension Vista/ExL LOCI Siemens/Dade Opus Siemens/DPC Immulite 2000/2500 Siemens/DPC Immulite 1000 Singulex hs-cTnI Tosoh Vitros 3600/5600/ECi
Troponin T	Other methods Radiometer AQT90 Flex Roche Cardiac Reader Roche cobas Troponin T kit Roche cobas Troponin T hs kit Roche h232 Roche Elecsys/E170/c6000/e411 Siemens/Bayer ACS 180