ASSOCIATION of CLINICAL BIOCHEMISTRY SPECIALISTS
EXTERNAL QUALITY CONTROL PROGRAM

COAGULATION SPECIFIC TESTS PROGRAM-INSTRUCTIONS

CYCLE: 1
Lot: K2018, SKT: 2019-11, REF: KBUDÖCOAG,
Program Code: ÖK
Store at +2–8^{0}C

Purpose of use
The KBUDEK Coagulation Specific Tests 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
Coagulation Specific Tests Program (Free to Coagulation Program participants):
Antithrombin III, Factor II, Factor V, Factor VII, Factor VIII, Factor IX, Factor X, Factor XI, Factor XII, Plasminogen, Protein C, Protein S, vWF Ag, vWF activity (Ristocetin cofactor), Thrombin time (TT), Activated Protein C resistance

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
Coagulation Specific Test control samples are lyophilized.
The bottle specified for each month on the label must be dissolved with 1 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°C. Stable to expiration date printed on individual vials.
Opened sample: It is stable for 24 hours at +2°C to +8°C Only volume needed to measure should be removed and analyzed. The remaining sample after use should not be discharged back to original vial.

Working times of samples
The box contains 8 samples labeled for two levels of study per quarter, 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.

Analyzer or method changes
Any changes related with participant's analyzer, 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:
Coagulation Coagulation Specific Tests Control samples-8 vials – lyophilised - 1 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
February	1A - 1B	23.02.2018	28.02.2018
May	2A - 2B	25.05.2018	31.05.2018
August	3A - 3B	17.08.2018	31.08.2018
November	4A - 4B	23.11.2018	30.11.2018

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Tests and Methods in the program

TESTS	METHODS	
Antithrombin III	Stago STArchrom Siemens Innovance Siemens Berichrom	Other Chromogenic HemosIIL Other method/kit
Factor II, Factor V, Factor VII, Factor VIII, Factor X, Factor XI, Factor XII	Stago Neoplastin R Stago Neoplastine CI Plus Dade Innovin	Siemens/Dade Thromborel S HemosIL PT-Fibrinogen HS Plus HemosIL PT-Fibrinogen Recombipl.2G Other method/kit
Activated Protein C Resistance	APC Normalized Ratio APC Ratio Siemens Siemens/Dade Berichrom Protein C HemosIL Protein C	Hyphen Biophen Protein C Chromogenix Coatest APC STAChrom Protein C Other method/kit
Plasminogen	Stago Siemens Hemosil	Roche Coadata Other method/kit
Protein C	Stago Siemens Hemosil	Roche Coadata Other method/kit
Protein S	Stago Siemens Hemosil	Roche Coadata Other method/kit
vWF Ag	Stago Siemens Hemosil	Roche Coadata Other method/kit
vWF activity (Ristocetin cofactor)	Stago Siemens Hemosil	Roche Coadata Other method/kit
Thrombin time (TT)	Stago Siemens Hemosil	Roche Coadata Other method/kit