COAGULATION PROGRAM-INSTRUCTIONS

CYCLE: 12
Lot: K2019, SKT: 2020-10, REF: KBUDCOAG
Program Code: K
Store at +2–8^{0}C

Accredited to TS EN ISO/IEC 17043:2013
(TÜRKAK: AB-0010-YT)

Purpose of use

The KBUDEK COAGULATION 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 Program:
PT/INR, aPTT, Fibrinogen, D-Dimer.

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 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. Stored specimens should be mixed before reuse.

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.

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.
When reports are published participants are informed with text messages.

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 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	22.02.2019	28.02.2019
May	2A - 2B	24.05.2019	31.05.2019
August	3A - 3B	23.08.2019	31.08.2019
November	4A - 4B	22.11.2019	30.11.2019

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Tests and Methods in the program

TESTS	METHODS	
aPTT	Actin (Siemens / Dade Behring) Alexin (Trinity Biotech) APTT (Pacific Hemostasis) APTT (RAYTO) APTT EA (MTI) APTT EA (RAYTO) APTT EA (Trinity Biotech) APTT EA Liqid (LONG ISLAND) APTT Ellagic APTT Ellagic (MTI) APTT Ellagic Acid (Biobak) APTT Ellagic Acid (Coulter) APTT Ellagic Acid (Steellex) APTT Ellagic Acid (Vacuplus) APTT H (MTI) APTT S (MTI) APTT Synthasil APTT-SP APTT-XL	BIO-CK BIO-SIL Cephalin Silica Cephascreen (STAGO) CK Prest - 2 (STAGO) CK Prest - 5 (STAGO) DG-APTT Dia APTT Liquid Diğer Yöntem / Kit Erba ECL 412 Hypen Cephen5 Liquicelin-E ***Mindray Coag*** MDA Platelin LS (Trinity Biotech) Pathromtin (Siemens / Dade Behring) QuikCoag APTT Siron LS Triniclot APTT HS Triniclot APTT
D-Dimer	Abbott Architect Quantia D-Dimer Alere Biosite Triage D-Dimer Beckman AU D-Dimer Biobak Immunoturbidimetrik D-Dimer Bio-Ksel D-Dimer Biomerieux Vidas Exclusion II Boditech i-CHROMA D-Dimer Diagnostic Grifols Latex D-Dimer Diagon D-Dimer DiaSys D-Dimer FS Diğer Yöntem / Kit Dimer (LONG ISLAND) *ERBA ECL 412* Finecare FIA *Fluorescense Immunoassay* Helena Auto-Blue D-Dimer HemosIL D-Dimer HemosIL D-Dimer 500 HemosIL D-Dimer AcuStar HemosIL D-Dimer HS HemosIL D-Dimer HS 500 MediRox D-Dimer *Mindray Coag* Mitsubishi Pathfast D-Dimer Nordic Red Nycocard D-Dimer	Radiometer AQT90 Flex D-Dimer Roche Cardiac Reader D-Dimer Roche Cobas D-DI Roche Cobas D-DI 2 Roche Cobas h232 D-Dimer Roche Hitachi/Modular Roche Integra D-DI Roche Integra D-DI 2 Scalvo Auto D-Dimer Sekisui Nanopia D-Dimer Siemens D-Dimer Plus Siemens Immulite 1000 Turbo D-Dimer Siemens Immulite 2000 D-Dimer Siemens Innovance D-Dimer Siemens/Dade Stratus CS Stago Sta Liatest D-DI Tcoag TriniLIA D-Dimer Thermo Scientific D-Dimer Tokra Medikal D-Dimer

Fibrinogen	Amax Fibrinogen (Trinity Biotech) BIO-FIBRI BIO-PT Bovine Thrombin-Clauss D-DIM (MTI) DG-FIB L Human Diagon Fibrinogen Diğer Yöntem / Kit Fibri Prest 2 (STAGO) Fibrino (MTI) Fibrinogen - Clauss *Fibrinogen – Clauss (Biobak)* Fibrinogen (M.T.I.) Fibrinogen (QFA) Fibrinogen (RAYTO) Fibrinogen liquid (LONG ISLAND) Fibroquant (Tulip)	MDA Fibrinogen Assay (Trinity Biotech) MDA Fibriquik *Mindray Coag* Multifibrin-u (Siemens / Dade Behring) STA Fibrinogen Liquid Thromborel S (Siemens / Dade Behring) Triniclot Fibrinogen (Trinity Biotech) Trombin (Siemens / Dade Behring)
INR	Alexin HS (Trinity Biotech) BIO-PT BIO-TP LI DG-PT Dia PT Liquid Dia PT R Dia PTR Liq Diğer Yöntem / Kit Erba ECL 412 Hypen Thrombophen *Mindray Coag* MTI PT with Calcium (Tokra Medikal) NEOPTİMAL (Stago) PT *PT INR (Biobak)* PT INR (LONG İSLAND) PT INR (RAYTO) PT INR (Steellex) PT ThromboPlast (MTI) PT ThromboPlast HR (MTI) PT -Fib HS (Coluter) PT R INR liquid (LONG ISLAND)	QuikCoag PT Recombiplastin Simplastin (Triniclot PT) Excel (Trinity Biotech) Simplastin (Triniclot PT) Excel-S (Trinity Biotech Simplastin (Triniclot PT) HTF (Trinity Biotech) Stago Neoplastin R Technoplastin HİS Thrombomax with Calcium Thromboplastin - DS Thromboplastin with Calcium Thromborel S (Siemens / Dade Behring) Uniplastin

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