

CERTIFICATE

Abnormal Multi Control

GHI167B

Lot: 19820 Expiry date: 2021 09

Analyte	Reference range for healthy ind.	Result of analysis (n=6 vials)	CV (n=6vials)
PT	INR 0.83-1.20 (> 70 %)	2.79 INR (17 %)	2 %
APTT	23-34 s	57 s	2 %
Fibrinogen	2.0-4.0 g/L	1.4 g/L	5 %
Antithrombin	0.70-1.30 IU/mL	0.38 IU/mL	3 %
D-Dimer MRX143	<0.25 mg/L	0.8 mg/L	3 %
D-Dimer IL HS	<0.25 mg/L	1.1 mg/L	3 %

Analyses were performed within one hour after reconstitution.

Based on the analytical results above and on other quality assurance procedures, this lot is released for sale.

Sofia Wennerberg Eriksson, QC, MediRox 2019-03-25

PT Owren, Prothrombin Complex Activity is determined at 37°C. One part of citrated plasma, diluted 1:7 with buffer, is mixed with two parts of PT reagent. The clotting time is recorded. The PT reagent contains bovine plasma depleted of vitamin K- dependent factors, and thromboplastin from rabbit brain.
 Calibrators: Swedish National Calibrators Normal and High (EQUALIS, Uppsala)
 Reagent: MediRox Owrens PT, prod no GHI131-10

APTT, Activated Partial Prothrombin Time, is determined at 37°C by mixing one part citrated plasma with one part APTT reagent, incubating for 5 minutes, adding one part CaCl₂ and recording the clotting time. The APTT-reagent contains phospholipids and silica. The method is not calibrated and is thus dependent on the characteristics of the reagent.
 Reagent: HemosIL APTT-SP (liquid), prod no 20006300.

Fibrinogen is determined at 37°C by mixing citrated plasma and Fibrinogen reagent and record the increase of absorbance per time unit. The Fibrinogen reagent contains Thrombin and a Heparin antagonist. The method is calibrated with human citrated plasma with a known concentration of Fibrinogen.
 Calibrator: IL Calibration Plasma, prod no 20003700
 Reagent: HemosIL QFA Thrombin, prod no 20301800

Antithrombin, is determined at 37°C by incubating citrated plasma with FXa reagent for a fixed period of time, followed by addition of the chromogenic substrate S-2772. The rate of release of the chromophore para-nitroaniline (pNA), determined at 405 nm, is inversely proportional to the AT activity.
 Calibrator: IL Calibration Plasma, prod no 20003700
 Liquid Antithrombin, prod no 20030100.

D-Dimer MRX143, Photometric measurement of the change in optical density in a sample containing the fibrin degradation product D-dimer, resulting from the reaction and agglutination of microparticle-coupled antibodies against Fibrin D-Dimer. The measurement is carried out at 671 nm.
 Calibrator: MediRox D-Dimer Calibrator, prod no MRX144
 Reagent: MediRox D-Dimer, prod no MRX143

D-Dimer HS HemosIL is determined by turbidimetry, using monoclonal antibodies against an epitope that is formed during the plasmin degradation of fibrin. The epitope is situated at the D-domain of the protein. The antibodies are coupled to latex particles. The formed immuno precipitate forms a well-defined turbidity that is proportional to the D-dimer concentration.
 The measurement is carried out at 671nm.
 Calibrator, HemosIL D-Dimer HS calibrator, prod no 20007700
 Reagent: HemosIL D-Dimer HS, prod no 20007700