

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

CAT. NO. CG5023

LOT NO. 358CG

SIZE: 12 x 1 ml

EXPIRY: 2023-03-28

GTIN: 05055273207644

INTENDED USE

This product is intended for *in vitro* diagnostic use, and in the quality control of coagulation systems. The Coagulation Controls are for the control of accuracy and precision.

DEVICE DESCRIPTION

The Coagulation Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values section.

SAFETY PRECAUTIONS AND WARNINGS

The controls are intended for *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents and controls.

Human source material, which has been added, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and was found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). APTT, TT, PT, Fibrinogen and Antithrombin III in reconstituted control are stable for 24 hours at +2°C to +8°C, if kept capped in original container and free from contamination. Protein C, Protein S, Plasminogen, and Factors II, V, VII, VIII, IX, X, XI, XII are stable for 8 hours at +2°C to +8°C. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

LIMITATION

The Randox Level 3 Coagulation Control may not be suitable for the control of aPTT on some analysers due to a slow clotting time.

PREPARATION FOR USE

The Coagulation Controls are supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised control with exactly 1 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid the formation of foam. Do not shake the vial.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix the contents of the vial thoroughly.

MATERIALS PROVIDED

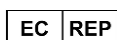
Coagulation Control - Level 3 12 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Each batch of Coagulation Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory, until it has established its own mean and SD for its test methods.



Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 23 Sep '21 me

0%

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 358CG Size 12 x 1ml Expiry 2023-03-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	76.6	61.3	91.9	Tcoag TriniCLOT aPTT S
	seconds	66.5	53.2	79.8	Tcoag TriniCLOT aPTT HS
	seconds	56.5	45.2	67.8	Siemens/Dade Actin
	seconds	56.3	45.0	67.6	Siemens/Dade Actin FS
	seconds	52.4	41.9	62.9	Siemens/Dade Actin FSL
	seconds	105	84.0	126	Siemens/Dade Pathromtin SL
	seconds	53.9	43.1	64.7	HemosIL APTT-SP Liquid
	seconds	73.5	58.8	88.2	HemosIL Synthasil
	seconds	68.8	55.0	82.6	Pacific Hemostasis APTT-XL
	seconds	62.8	50.2	75.4	Stago aPTT
	seconds	56.0	44.8	67.2	Stago Cephascreen
	seconds	68.8	55.0	82.6	Stago CK-Prest
	seconds	65.4	52.3	78.5	Stago PTT Automate
	seconds	65.4	52.3	78.5	Teco TEClot APTT
	seconds	57.9	46.3	69.5	Human Hemostat APTT
	seconds	61.5	49.2	73.8	Bio-Ksel System APTTs
	seconds	75.7	60.6	90.8	Diagon Dia-PTT
	seconds	56.6	45.3	67.9	Weiner Lab APTT
	seconds	65.8	52.6	79.0	Biolabo Bio-CK APTT
	seconds	67.6	54.1	81.1	Spinreact APTT
	seconds	55.9	44.7	67.1	Media IVD aPTT
	seconds	53.5	42.8	64.2	Biomedica QuikCoag aPTT
	seconds	58.3	46.6	70.0	Siemens/Dade Actin Cephaloplastin
	seconds	53.6	42.9	64.3	Labitec aPTT
	seconds	61.1	48.9	73.3	Dutch Diagnostics aPTT
	seconds	78.6	62.9	94.3	Sclavo APTT-S
	seconds	76.9	61.5	92.3	HemoDiagnostics aPTT
	seconds	57.5	46.0	69.0	Fortress Diagnostics aPTT
	seconds	76.8	61.4	92.2	Tokra Medikal APTT
	seconds	102	81.6	122	Cobas aPTT MedS
	seconds	57.0	45.6	68.4	Biolabo Bio-Sil (APTT)
	seconds	55.3	44.2	66.4	Diagon Dia-PTT Liquid
	seconds	63.0	50.4	75.6	Erba Actime APTT
	seconds	61.6	49.3	73.9	MTI Diagnostics APTT
	seconds	106	84.8	127	Roche Cobas APTT Screen
	seconds	94.7	75.8	114	Roche Cobas APTT
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.33	1.86	2.80	Tcoag TriniCLOT aPTT S
	ratio	1.98	1.58	2.38	Siemens/Dade Actin FSL
	ratio	1.91	1.53	2.29	Stago Cephascreen
	ratio	1.96	1.57	2.35	Stago PTT Automate
	ratio	2.02	1.62	2.42	Stago aPTT
	ratio	3.30	2.64	3.96	Siemens/Dade Pathromtin SL

0%

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 358CG

Size 12 x 1ml Expiry 2023-03-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.84	1.47	2.21	HemosIL APTT-SP Liquid
	ratio	2.48	1.98	2.98	HemosIL Synthasil
	ratio	2.28	1.82	2.74	Stago CK-Prest
	ratio	2.04	1.63	2.45	Teco TEClot APTT
	ratio	2.06	1.65	2.47	Human Hemostat APTT
	ratio	1.81	1.45	2.17	Bio-Ksel System APTTs
	ratio	2.23	1.78	2.68	Siemens/Dade Actin FS
	ratio	2.35	1.88	2.82	Diagon Dia-PTT
	ratio	2.06	1.65	2.47	Biolabo Bio-CK APTT
	ratio	1.77	1.42	2.12	Labitec aPTT
	ratio	2.79	2.23	3.35	Sclavo APTT-S
	ratio	1.49	1.19	1.79	Coagpia APTT-N
	ratio	2.06	1.65	2.47	Diagon Dia-PTT Liquid
	ratio	2.06	1.65	2.47	Erba Actime APTT
	ratio	2.10	1.68	2.52	MTI Diagnostics APTT
Antithrombin III activity	%	53.0	42.4	63.6	Siemens/Dade Berichrom ATIII
	%	48.8	39.0	58.6	Helena Chrom-Z
	%	50.6	40.5	60.7	HemosIL Liquid Antithrombin
	%	51.5	41.2	61.8	Roche Chronogenic Thrombin
	%	55.2	44.2	66.2	Hemosil Lyophilised Antithrombin III
	%	52.5	42.0	63.0	Chromogenix Substrate
	%	56.4	45.1	67.7	STACHrom ATIII
	%	50.1	40.1	60.1	Siemens/Dade Antithrombin III
	%	50.9	40.7	61.1	Siemens Innovance Antithrombin III
	%	52.4	41.9	62.9	Sclavo ATIII
	%	54.3	43.4	65.2	Roche Antithrombin
Factor II activity	%	60.9	48.7	73.1	Siemens/Dade-Behring Innovin
	%	68.8	55.0	82.6	Siemens/Dade-Behring Thromborel S
	%	55.4	44.3	66.5	HemosIL PT-Fibrinogen HS Plus
	%	65.1	52.1	78.1	HemosIL RecombiPlasTin 2G
	%	68.7	55.0	82.4	HemosIL Factor II deficient plasma
	%	59.5	47.6	71.4	Stago STA-NeoPTimal
Factor IX activity	%	52.6	42.1	63.1	Siemens/Dade Actin FS
	%	55.4	44.3	66.5	Siemens/Dade Pathromtin SL
	%	51.0	40.8	61.2	HemosIL Synthasil
	%	50.2	40.2	60.2	Siemens/Dade Actin FSL
	%	55.6	44.5	66.7	Stago Deficient / ImmunoDef IX
	%	49.9	39.9	59.9	HemosIL Factor IX deficient plasma
Factor V activity	%	47.3	37.8	56.8	Siemens/Dade-Behring Thromborel S
	%	37.8	30.2	45.4	Siemens/Dade-Behring Innovin
	%	40.3	32.2	48.4	HemosIL PT-Fibrinogen HS Plus
	%	39.5	31.6	47.4	HemosIL RecombiPlasTin 2G
	%	38.7	31.0	46.4	HemosIL Factor V deficient plasma
	%	32.2	25.8	38.6	Stago STA-NeoPTimal
Factor VII activity	%	121	96.8	145	Siemens/Dade-Behring Thromborel S
	%	158	126	190	Siemens/Dade-Behring Innovin

%

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

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Size 12 x 1ml Expiry 2023-03-28

Range					
Analyte	unit	Target	low	high	methods
Factor VII activity	%	187	150	224	HemosIL PT-Fibrinogen HS Plus
	%	182	146	218	HemosIL RecombiPlasTin 2G
	%	174	139	209	HemosIL Factor VII deficient plasma
	%	137	110	164	Stago STA-NeoPTimal
Factor VIII activity	%	22.8	18.2	27.4	Stago PTT Automate
	%	27.7	22.2	33.2	Siemens/Dade Actin FS
	%	26.9	21.5	32.3	Siemens/Dade Pathromtin SL
	%	26.5	21.2	31.8	Siemens/Dade Actin FSL
	%	27.9	22.3	33.5	HemosIL Synthasil
	%	25.9	20.7	31.1	HemosIL APTT-SP Liquid
	%	28.3	22.6	34.0	Stago STA Factor VIII
	%	27.2	21.8	32.6	Stago Deficient / ImmunoDef VIII
	%	28.6	22.9	34.3	HemosIL Factor VIII deficient plasma
Factor X activity	%	80.9	64.7	97.1	Siemens/Dade-Behring Thromborel S
	%	80.5	64.4	96.6	Siemens/Dade-Behring Innovin
	%	71.3	57.0	85.6	HemosIL PT-Fibrinogen HS Plus
	%	70.7	56.6	84.8	HemosIL RecombiPlasTin 2G
	%	69.3	55.4	83.2	HemosIL Factor X deficient plasma
	%	64.7	51.8	77.6	Stago STA-NeoPTimal
Factor XI activity	%	27.7	22.2	33.2	Siemens/Dade Actin FS
	%	35.4	28.3	42.5	HemosIL Synthasil
	%	32.8	26.2	39.4	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	58.1	46.5	69.7	Siemens/Dade Actin FS
	%	54.9	43.9	65.9	Siemens/Dade Pathromtin SL
	%	56.7	45.4	68.0	HemosIL Synthasil
	%	50.9	40.7	61.1	Siemens/Dade Actin FSL
	%	53.5	42.8	64.2	HemosIL APTT-SP Liquid
	%	51.0	40.8	61.2	HemosIL Factor XII deficient plasma
Fibrinogen	g/L	1.59	1.27	1.91	HemosIL PT-Fibrinogen HS Plus
	mg/dL	159	127	191	
	g/L	1.49	1.19	1.79	Stago Fibrinogen / Liquid-Fib
	mg/dL	149	119	179	
	g/L	1.09	0.872	1.31	Siemens/Dade Multifibren U
	mg/dL	109	87.2	131	
	g/L	1.42	1.14	1.70	HemosIL Fibrinogen C
	mg/dL	142	114	170	
	g/L	1.27	1.02	1.52	Dade Thrombin
	mg/dL	127	102	152	
	g/L	1.42	1.14	1.70	Tcoag TriniCLOT Fibrinogen
	mg/dL	142	114	170	
	g/L	1.58	1.26	1.90	Biolabo Bio-Fibri
	mg/dL	158	126	190	
	g/L	1.30	1.04	1.56	Teco Teclot Fibrinogen
	mg/dL	130	104	156	
	g/L	1.38	1.10	1.66	HemosIL QFA (bovine thrombin)
	mg/dL	138	110	166	

%

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Range					
Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	1.64	1.31	1.97	Human Fibrinogen
	mg/dL	164	131	197	
	g/L	1.53	1.22	1.84	Stago STA Fibri-Prest Automate
	mg/dL	153	122	184	
	g/L	0.906	0.725	1.09	Bio-Ksel System PT
	mg/dL	90.6	72.5	109	
	g/L	1.52	1.22	1.82	Bio-Ksel Fibrinogen
	mg/dL	152	122	182	
	g/L	1.24	0.992	1.49	Diagon Dia-F
	mg/dL	124	99.2	149	
	g/L	1.02	0.816	1.22	Dade Innovin Derived Fibrinogen
	mg/dL	102	81.6	122	
	g/L	1.29	1.03	1.55	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	129	103	155	
	g/L	1.37	1.10	1.64	Wiener Lab Fibrinogen
	mg/dL	137	110	164	
	g/L	1.36	1.09	1.63	Sclavo Fibrinogen
	mg/dL	136	109	163	
	g/L	1.38	1.10	1.66	Labitec Fibrinogen
	mg/dL	138	110	166	
	g/L	1.40	1.12	1.68	HemoDiagnostics Fibrinogen
	mg/dL	140	112	168	
	g/L	1.58	1.26	1.90	Helena Clauss Fibrinogen 100
	mg/dL	158	126	190	
	g/L	1.33	1.06	1.60	Tokra Medikal Fibrinogen
	mg/dL	133	106	160	
	g/L	1.21	0.968	1.45	Coagpia Fibrinogen
	mg/dL	121	96.8	145	
	g/L	1.42	1.14	1.70	Cobas Fibrinogen
	mg/dL	142	114	170	
	g/L	1.18	0.944	1.42	PRECIL
	mg/dL	118	94.4	142	
	g/L	1.14	0.912	1.37	Erba Thrombin Reagent
	mg/dL	114	91.2	137	
	g/L	1.14	0.912	1.37	Yumizen G Fibrinogen
	mg/dL	114	91.2	137	
	g/L	1.30	1.04	1.56	Roche Cobas t511/t711 Fibrinogen
	mg/dL	130	104	156	
	g/L	1.39	1.11	1.67	Roche Cobas t411 Fibrinogen
	mg/dL	139	111	167	
Plasminogen activity	%	52.7	42.2	63.2	HemosIL Plasminogen
	%	63.4	50.7	76.1	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	56.8	45.4	68.2	Siemens/Dade Berichrom Protein C
	%	57.8	46.2	69.4	Stago StaClot
	%	53.3	42.6	64.0	Biomerieux VIDAS Protein C
	%	54.3	43.4	65.2	IL HemosIL Protein C

0%

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Cat. No. CG5023 Lot. No. 358CG Size 12 x 1ml Expiry 2023-03-28

Range					
Analyte	unit	Target	low	high	methods
Protein C activity	%	62.0	49.6	74.4	Siemens
	%	60.7	48.6	72.8	STACHrom Protein C
Protein S activity	%	54.1	37.9	70.3	STA Liatest
	%	56.2	39.3	73.1	Stago StaClot
	%	53.3	37.3	69.3	IL HemosIL ProS
	%	53.6	37.5	69.7	IL HemosIL Free Protein S
	%	43.4	30.4	56.4	Dade Protein S Ac
	%	49.4	34.6	64.2	Siemens Innovance Free PS Ag
	%	21.7	15.2	28.2	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	26.1	20.9	31.3	Siemens/Dade-Behring Innovin
	Seconds	18.3	14.6	22.0	Siemens/Dade Thromborel IS
	Seconds	17.7	14.2	21.2	Siemens/Dade-Behring Thromborel S
	Seconds	25.6	20.5	30.7	HemosIL PT-Fibrinogen HS Plus
	Seconds	31.4	25.1	37.7	Pacific Thromboplastin DS
	Seconds	23.3	18.6	28.0	Stago Neoplastine CI Plus
	Seconds	23.6	18.9	28.3	Teco TEClot PT-S
	Seconds	17.0	13.6	20.4	Stago Neoplastin R
	Seconds	14.7	11.8	17.6	Bio-Ksel System PT
	Seconds	22.1	17.7	26.5	Human Thromboplastin
	Seconds	21.2	17.0	25.4	Diagon PT
	Seconds	22.9	18.3	27.5	Spinreact PT
	Seconds	42.0	33.6	50.4	TCoag TriniCLOT PT Excel S
	Seconds	22.4	17.9	26.9	Media IVD PT
	Seconds	22.7	18.2	27.2	Biomedica QuikCoag PT-HS
	Seconds	14.4	11.5	17.3	HemosIL RecombiPlasTin 2G
	Seconds	27.0	21.6	32.4	Helena Thromboplastin
	Seconds	22.8	18.2	27.4	Sclavo PT
	Seconds	22.7	18.2	27.2	Tokra Medikal PT
	Seconds	25.8	20.6	31.0	Coagpia PT-N
	Seconds	14.3	11.4	17.2	Bio-Ksel PT Plus
	Seconds	24.1	19.3	28.9	Beijing Succeder PT
	Seconds	18.8	15.0	22.6	Diagon PT R
	Seconds	18.7	15.0	22.4	Cobas PT Screen
	Seconds	23.9	19.1	28.7	PRECIL
	Seconds	30.0	24.0	36.0	Stago STA-NeoPTimal
	Seconds	23.4	18.7	28.1	Erba Protime PT
	Seconds	21.6	17.3	25.9	Rayto Prothrombin Time Reagent
	Seconds	15.3	12.2	18.4	HemosIL ReadPlasTin
	Seconds	36.2	29.0	43.4	Roche Cobas PT Rec
Prothrombin Time (PT) activity	%	21.9	17.5	26.3	Siemens/Dade-Behring Innovin
	%	50.0	40.0	60.0	Siemens/Dade-Behring Thromborel S
	%	43.2	34.6	51.8	Stago Neoplastine CI Plus
	%	39.9	31.9	47.9	HemosIL PT-Fibrinogen HS Plus
	%	39.4	31.5	47.3	Teco TEClot PT-S
	%	68.5	54.8	82.2	Stago Neoplastin R
	%	75.0	60.0	90.0	Bio-Ksel System PT

%

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Cat. No. CG5023 Lot. No. 358CG Size 12 x 1ml Expiry 2023-03-28

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	37.6	30.1	45.1	Human Thromboplastin
	%	40.9	32.7	49.1	Diagon PT
	%	18.6	14.9	22.3	TCoag TriniCLOT PT Excel S
	%	43.1	34.5	51.7	Media IVD PT
	%	68.5	54.8	82.2	HemosIL RecombiPlasTin 2G
	%	45.9	36.7	55.1	Labitec PT
	%	44.1	35.3	52.9	Sclavo PT
	%	45.5	36.4	54.6	Tokra Medikal PT
	%	80.9	64.7	97.1	Bio-Ksel PT Plus
	%	46.6	37.3	55.9	Cobas PT Screen
	%	32.8	26.2	39.4	Stago STA-NeoPTimal
	%	66.9	53.5	80.3	HemosIL ReadiPlasTin
	%	15.7	12.6	18.8	Roche Cobas PT Rec
Prothrombin Time (PT) INR	INR	2.67	2.14	3.20	Siemens/Dade-Behring Innovin
	INR	1.56	1.25	1.87	Siemens/Dade-Behring Thromborel S
	INR	1.90	1.52	2.28	HemosIL PT-Fibrinogen HS Plus
	INR	2.64	2.11	3.17	Pacific Thromboplastin DS
	INR	1.90	1.52	2.28	Stago Neoplastine CI Plus
	INR	1.83	1.46	2.20	Human Thromboplastin
	INR	1.92	1.54	2.30	Teco TEClot PT-S
	INR	1.05	0.840	1.26	Stago SPA
	INR	1.26	1.01	1.51	Stago Neoplastin R
	INR	1.33	1.06	1.60	Bio-Ksel System PT
	INR	1.85	1.48	2.22	Diagon PT
	INR	4.00	3.20	4.80	TCoag TriniCLOT PT Excel S
	INR	1.67	1.34	2.00	Media IVD PT
	INR	1.78	1.42	2.14	Biomedica QuikCoag PT-HS
	INR	1.28	1.02	1.54	HemosIL RecombiPlasTin 2G
	INR	1.66	1.33	1.99	Labitec PT
	INR	1.89	1.51	2.27	Sclavo PT
	INR	2.07	1.66	2.48	Haemo Diagnostics Thromboplastin
	INR	1.55	1.24	1.86	Fortress Diagnostics PT with Calcium
	INR	1.93	1.54	2.32	Technoclon Technoclot PT Plus
	INR	1.71	1.37	2.05	Tokra Medikal PT
	INR	1.30	1.04	1.56	Bio-Ksel PT Plus
	INR	1.89	1.51	2.27	Beijing Succeeder PT
	INR	1.85	1.48	2.22	Diagon PT R
	INR	1.80	1.44	2.16	Cobas PT Screen
	INR	2.36	1.89	2.83	Stago STA-NeoPTimal
	INR	1.91	1.53	2.29	Erba Prottime PT
	INR	1.32	1.06	1.58	HemosIL ReadiPlasTin
	INR	3.76	3.01	4.51	Roche Cobas PT Rec
Prothrombin Time (PT) ratio	ratio	2.69	2.15	3.23	Siemens/Dade-Behring Innovin
	ratio	1.55	1.24	1.86	Siemens/Dade-Behring Thromborel S
	ratio	1.80	1.44	2.16	Stago Neoplastine CI Plus
	ratio	1.72	1.38	2.06	HemosIL PT-Fibrinogen HS Plus

0/0

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 358CG Size 12 x 1ml Expiry 2023-03-28

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) ratio	ratio	1.28	1.02	1.54	HemosIL RecombiPlasTin 2G
	ratio	1.76	1.41	2.11	Sclavo PT
	ratio	2.25	1.80	2.70	Stago STA-NeoPTimal
Thrombin Time (TT)	Seconds	33.9	27.1	40.7	Dade Thrombin
	Seconds	29.9	23.9	35.9	Siemens/Dade Thromboclotin
	Seconds	37.1	29.7	44.5	Stago Thrombin
	Seconds	32.0	25.6	38.4	Sysmex Thrombin Time
	Seconds	33.8	27.0	40.6	Helena Thrombin Clotting Time rgt
	Seconds	27.7	22.2	33.2	HemosIL Thrombin Time 5ml
	Seconds	32.5	26.0	39.0	HemosIL Thrombin Time 8ml
	Seconds	37.3	29.8	44.8	Siemens BC Thrombin
	Seconds	27.7	22.2	33.2	PRECIL