

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat No. CG5022 **Lot No.** 199CG
Size: 12 x 1 ml **Expiry:** 2017-11

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 serum 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.

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 2 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.

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COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 199CG Size: 12 x 1 ml Expiry: 2017-11

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	66.5	53.2	79.8	Tcoag TriniCLOT aPTT S
	seconds	63.1	50.5	75.7	Tcoag TriniCLOT aPTT HS
	seconds	62.1	49.7	74.5	Siemens/Dade Actin
	seconds	56.0	44.8	67.2	Siemens/Dade Actin FS
	seconds	53.7	43.0	64.4	Siemens/Dade Actin FSL
	seconds	77.1	61.7	92.5	Siemens/Dade Actin SL
	seconds	82.9	66.3	99.0	Siemens/Dade Pathromtin SL
	seconds	56.0	44.8	67.2	HemosIL APTT-SP Liquid
	seconds	53.1	42.5	63.7	HemosIL Synthasil
	seconds	67.7	54.2	81.2	Pacific Hemostasis APTT-XL
	seconds	63.8	51.0	76.6	Stago aPTT
	seconds	62.7	50.2	75.2	Stago Cephascreen
	seconds	66.7	53.4	80.0	Stago CK-Prest
	seconds	67.7	54.2	81.2	Stago PTT Automate
	seconds	66.2	53.0	79.4	Teco TEClot APTT
	seconds	70.4	56.3	84.5	Human Hemostat APTT
	seconds	54.4	43.5	65.3	Bio-Ksel System APTTs
	seconds	69.2	55.4	83.0	Grifols DG-APTT
	seconds	70.0	56.0	84.0	Diagon Dia-PTT
	seconds	63.0	50.4	75.6	Weiner Lab APTT
	seconds	59.4	47.5	71.3	Futura System APTT
	seconds	63.9	51.1	76.7	Biolabo Bio-CK APTT
	seconds	65.1	52.1	78.1	Spinreact APTT
	seconds	43.4	34.7	52.1	Technology-Standard aPTT
	seconds	47.1	37.7	56.5	SGM Italia aPTT
	seconds	67.2	53.8	80.6	Tcoag TriniCLOT Automated aPTT
	seconds	57.1	45.7	68.5	Biomedica QuikCoag aPTT
	seconds	49.8	39.8	59.8	Hemosil aPTT Lyophilised Silica
	seconds	62.2	49.8	74.6	Siemens Dade Actin Cephaloplastin
	seconds	60.0	48.0	72.0	Technoclone Siron aPTT
	seconds	67.0	53.6	80.4	Sclavo APTT-S
	seconds	52.2	41.8	62.6	Coagpia APTT-N
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.14	1.71	2.57	Tcoag TriniCLOT aPTT S
	ratio	2.00	1.60	2.40	Siemens/Dade Actin FSL
	ratio	2.71	2.17	3.25	Siemens/Dade Actin SL
	ratio	2.10	1.68	2.52	Stago Cephascreen
	ratio	1.98	1.58	2.38	Stago PTT Automate
	ratio	1.99	1.59	2.39	Stago aPTT
	ratio	2.52	2.02	3.02	Siemens/Dade Pathromtin SL
	ratio	1.83	1.46	2.20	HemosIL APTT-SP Liquid
	ratio	1.84	1.47	2.21	HemosIL Synthasil
	ratio	2.22	1.78	2.66	Pacific Hemostasis APTT-XL

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COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 199CG

Size: 12 x 1 ml Expiry: 2017-11

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.07	1.66	2.48	Stago CK-Prest
	ratio	2.04	1.63	2.45	Human Hemostat APTT
	ratio	1.67	1.34	2.00	Bio-Ksel System APTTs
	ratio	2.13	1.70	2.56	Siemens/Dade Actin FS
	ratio	2.06	1.65	2.47	Diagon Dia-PTT
	ratio	2.12	1.70	2.54	Futura System APTT
	ratio	2.34	1.87	2.81	Tcoag TriniCLOT Automated aPTT
	ratio	2.37	1.90	2.84	Sclavo APTT-S
	ratio	1.60	1.28	1.92	Coagpia APTT-N
Antithrombin III activity	%	66.7	53.4	80.0	Siemens/Dade Berichrom ATIII
	%	62.0	49.6	74.4	HemosIL Liquid Antithrombin
	%	68.5	54.8	82.2	Chromogenix Coamatic LR
	%	71.0	56.8	85.2	Roche Chronogenic Thrombin
	%	65.5	52.4	78.6	Bio-Ksel Antithrombin III
	%	61.1	48.9	73.3	Hemosil Lyophilised Antithrombin III
	%	66.4	53.1	79.7	STACHrom ATIII
	%	66.1	52.9	79.3	Siemens/Dade Antithrombin III
	%	66.9	53.5	80.3	Siemens Innovance Antithrombin III
Factor II activity	%	62.3	49.8	74.8	Sclavo ATIII
	%	62.6	50.1	75.1	Dade Innovin
	%	70.4	56.3	84.5	Siemens/Dade Thromborel S
	%	58.3	46.6	70.0	Stago Neoplastine CI Plus
	%	60.4	48.3	72.5	HemosIL PT-Fibrinogen HS Plus
	%	64.4	51.5	77.3	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	57.7	46.2	69.2	Stago Neoplastin R
	%	55.0	44.0	66.0	Stago PTT Automate
	%	55.8	44.6	67.0	Siemens/Dade Actin FS
	%	55.6	44.5	66.7	Siemens/Dade Pathromtin SL
	%	49.2	39.4	59.0	HemosIL Synthasil
	%	51.8	41.4	62.2	Siemens/Dade Actin FSL
	%	48.9	39.1	58.7	HemosIL APTT-SP Liquid
	%	56.5	45.2	67.8	Stago aPTT
Factor V activity	%	62.1	49.7	74.5	Siemens Dade Actin Cephaloplastin
	%	35.6	28.5	42.7	Stago Neoplastine CI Plus
	%	43.0	34.4	51.6	Siemens/Dade Thromborel S
	%	33.7	27.0	40.4	Dade Innovin
	%	46.4	37.1	55.7	HemosIL PT-Fibrinogen HS Plus
	%	42.8	34.2	51.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	36.0	28.8	43.2	Stago Neoplastin R
Factor VII activity	%	37.3	29.8	44.8	HemosIL Factor V deficient plasma
	%	94.3	75.4	113	Stago Neoplastine CI Plus
	%	100	80.0	120	Siemens/Dade Thromborel S
	%	109	87.2	131	Dade Innovin
	%	107	85.6	128	HemosIL PT-Fibrinogen HS Plus
	%	128	102	154	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	92.3	73.8	111	Stago Neoplastin R

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

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Size: 12 x 1 ml Expiry: 2017-11

Range					
Analyte	unit	Target	low	high	methods
Factor VIII activity	%	22.7	18.2	27.2	Stago CK-Prest
	%	21.6	17.3	25.9	Siemens/Dade Actin FS
	%	25.6	20.5	30.7	Siemens/Dade Pathromtin SL
	%	22.5	18.0	27.0	Siemens/Dade Actin FSL
	%	23.9	19.1	28.7	HemosIL Synthasil
	%	23.8	19.0	28.6	HemosIL APTT-SP Liquid
	%	22.4	17.9	26.9	Stago aPTT
	%	25.7	20.6	30.8	HemosIL Factor VIII deficient plasma
Factor X activity	%	73.2	58.6	87.8	Siemens/Dade Thromborel S
	%	70.1	56.1	84.1	Dade Innovin
	%	63.7	51.0	76.4	Stago Neoplastine CI Plus
	%	62.9	50.3	75.5	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	55.0	44.0	66.0	Stago Neoplastin R
Factor XI activity	%	37.3	29.8	44.8	Siemens/Dade Actin FS
	%	28.5	22.8	34.2	Siemens/Dade Pathromtin SL
	%	27.6	22.1	33.1	HemosIL APTT-SP Liquid
Factor XII activity	%	55.9	44.7	67.1	Siemens/Dade Pathromtin SL
	%	59.6	47.7	71.5	HemosIL Synthasil
	%	59.1	47.3	70.9	Siemens/Dade Actin FSL
	%	54.7	43.8	65.6	HemosIL APTT-SP Liquid
Fibrinogen	g/L	1.27	1.02	1.52	HemosIL PT-Fibrinogen HS Plus
	mg/dL	127	102	152	
	g/L	1.33	1.06	1.60	Stago Fibrinogen
	mg/dL	133	106	160	
	g/L	1.34	1.07	1.61	Tcoag TriniCLOT Thrombin Time
	mg/dL	134	107	161	
	g/L	1.27	1.02	1.52	Dade Multifibrin
	mg/dL	127	102	152	
	g/L	1.31	1.05	1.57	HemosIL Fibrinogen C
	mg/dL	131	105	157	
	g/L	1.26	1.01	1.51	Dade Thrombin
	mg/dL	126	101	151	
	g/L	1.26	1.01	1.51	Technoclone Fibrinogen
	mg/dL	126	101	151	
	g/L	1.32	1.06	1.58	Tcoag TriniCLOT Fibrinogen
	mg/dL	132	106	158	
	g/L	1.31	1.05	1.57	Biolabo Bio-Fibri
	mg/dL	131	105	157	
	g/L	1.18	0.944	1.42	Teco Teclot Fibrinogen
	mg/dL	118	94.4	142	
	g/L	1.35	1.08	1.62	HemosIL QFA (bovine thrombin)
	mg/dL	135	108	162	
	g/L	1.33	1.06	1.60	Stago STA Fibri-Prest Automate
	mg/dL	133	106	160	
	g/L	0.924	0.739	1.11	Bio-Ksel System PT
	mg/dL	92.4	73.9	111	

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

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Size: 12 x 1 ml Expiry: 2017-11

Range					
Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	1.17	0.936	1.40	Bio-Ksel Fibrinogen
	mg/dL	117	93.6	140	
	g/L	1.23	0.984	1.48	Grifols DG-FIB
	mg/dL	123	98.4	148	
	g/L	1.20	0.960	1.44	Diagon Dia-FIB
	mg/dL	120	96.0	144	
	g/L	1.02	0.816	1.22	Dade Innovin Derived Fibrinogen
	mg/dL	102	81.6	122	
	g/L	1.17	0.936	1.40	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	117	93.6	140	
	g/L	1.55	1.24	1.86	Liofilchem Fibrinogen
	mg/dL	155	124	186	
	g/L	1.64	1.31	1.97	Futura System Fibrinogen
	mg/dL	164	131	197	
	g/L	1.38	1.10	1.66	Biodevice PT
	mg/dL	138	110	166	
	g/L	1.15	0.920	1.38	Spinreact Fibrinogen
	mg/dL	115	92.0	138	
	g/L	1.06	0.848	1.27	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	106	84.8	127	
Plasminogen activity	g/L	1.41	1.13	1.69	Sclavo Fibrinogen
	mg/dL	141	113	169	
Protein C activity	g/L	1.30	1.04	1.56	Beijing Steelex Fibrinogen
	mg/dL	130	104	156	
Protein S activity	g/L	1.04	0.832	1.25	Cypress Diagnostics Fibrinogen
	mg/dL	104	83.2	125	
Prothrombin Time (PT)	g/L	1.38	1.10	1.66	Coagpia Fibrinogen
	mg/dL	138	110	166	
Protein C activity	g/L	1.42	1.14	1.70	Biodevice Fibrinogen
	mg/dL	142	114	170	
Plasminogen activity	%	73.8	59.0	88.6	HemosIL Plasminogen
	%	73.0	58.4	87.6	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	57.1	45.7	68.5	Siemens/Dade Berichrom Protein C
	%	65.9	52.7	79.1	Biomerieux VIDAS Protein C
	%	49.7	39.8	59.6	IL HemosIL Protein C
	%	53.6	42.9	64.3	Siemens
	%	59.1	47.3	70.9	STACHrom Protein C
	%	53.0	42.4	63.6	Chromogenix Coatest APC
Protein S activity	%	64.6	45.2	84.0	STA Liatest
	%	63.0	44.1	81.9	Stago StaClot
	%	49.9	34.9	64.9	IL HemosIL ProS
	%	62.9	44.0	81.8	IL HemosIL Free Protein S
	%	65.9	46.1	85.7	Siemens Innovance Free PS Ag
	%	36.7	25.7	47.7	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	16.1	12.9	19.3	Tcoag TriniCLOT PT Excel
	Seconds	20.3	16.2	24.4	Tcoag TriniCLOT PT HTF

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 199CG Size: 12 x 1 ml Expiry: 2017-11

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT)	Seconds	16.0	12.8	19.2	Dade Innovin
	Seconds	17.2	13.8	20.6	Siemens/Dade Thromborel S
	Seconds	19.5	15.6	23.4	HemosIL PT-Fibrinogen
	Seconds	19.5	15.6	23.4	HemosIL PT-Fibrinogen HS Plus
	Seconds	21.6	17.3	25.9	Pacific Thromboplastin DS
	Seconds	19.2	15.4	23.0	STA Hepato Quick
	Seconds	18.4	14.7	22.1	Stago Neoplastine CI
	Seconds	19.5	15.6	23.4	Stago Neoplastine CI Plus
	Seconds	19.5	15.6	23.4	Teco TEClot PT-S
	Seconds	19.8	15.8	23.8	Biolabo Bio-TP
	Seconds	21.2	17.0	25.4	Stago SPA
	Seconds	18.8	15.0	22.6	Stago Neoplastin R
	Seconds	13.8	11.0	16.6	Bio-Ksel System PT
	Seconds	18.4	14.7	22.1	Human Thromboplastin
	Seconds	17.3	13.8	20.8	Grifols DG-PT
	Seconds	18.5	14.8	22.2	Diagon, Dia-PT
	Seconds	19.8	15.8	23.8	Weiner Lab Soluplastin
	Seconds	24.7	19.8	29.6	TCoag TriniCLOT PT Excel S
	Seconds	20.1	16.1	24.1	Biodevice PT
	Seconds	19.1	15.3	22.9	Biomedica QuikCoag PT-HS
	Seconds	14.8	11.8	17.8	Siemens/Dade Thromboplastin C Plus
	Seconds	14.5	11.6	17.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	20.2	16.2	24.2	Helena Thromboplastin LI
	Seconds	19.5	15.6	23.4	Technoclone Technoplastin HIS
	Seconds	19.4	15.5	23.3	Teco Teclot PT
	Seconds	18.6	14.9	22.3	SGM Italia Thromboplastin
	Seconds	18.0	14.4	21.6	Technoclone Technoclot PT Plus
	Seconds	17.4	13.9	20.9	Coagpia PT-N
	Seconds	18.7	15.0	22.4	Biodevice Goldplastin
	Seconds	13.8	11.0	16.6	Bio-Ksel PT Plus
	Seconds	18.0	14.4	21.6	Beijing Succeder PT
Prothrombin Time (PT) activity	%	42.9	34.3	51.5	Tcoag TriniCLOT PT Excel
	%	44.1	35.3	52.9	Dade Innovin
	%	50.9	40.7	61.1	Siemens/Dade Thromborel S
	%	50.8	40.6	61.0	Stago Neoplastine CI
	%	50.1	40.1	60.1	Stago Neoplastine CI Plus
	%	53.3	42.6	64.0	HemosIL PT-Fibrinogen
	%	53.9	43.1	64.7	HemosIL PT-Fibrinogen HS Plus
	%	44.6	35.7	53.5	Pacific Thromboplastin DS
	%	51.2	41.0	61.4	Teco TEClot PT-S
	%	49.5	39.6	59.4	Biolabo Bio-TP
	%	88.0	70.4	106	Stago SPA
	%	61.3	49.0	73.6	Stago Neoplastin R
	%	75.5	60.4	90.6	Bio-Ksel System PT
	%	62.2	49.8	74.6	Human Thromboplastin
	%	58.8	47.0	70.6	Diagon, Dia-PT

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 199CG

Size: 12 x 1 ml Expiry: 2017-11

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	44.4	35.5	53.3	Futura System Thromboplastin S
	%	43.7	35.0	52.4	TCoag TriniCLOT PT Excel S
	%	58.8	47.0	70.6	Biodevice PT
	%	58.9	47.1	70.7	Biomedica QuikCoag PT-HS
	%	66.0	52.8	79.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	50.1	40.1	60.1	Technoclone Technoclot PT Plus
	%	52.4	41.9	62.9	Coagpia PT-N
	%	57.0	45.6	68.4	Biodevice Goldplastin
Prothrombin Time (PT) INR	INR	1.92	1.54	2.30	Tcoag TriniCLOT PT Excel
	INR	1.57	1.26	1.88	Tcoag TriniCLOT PT HTF
	INR	1.54	1.23	1.85	Dade Innovin
	INR	1.51	1.21	1.81	Siemens/Dade Thromborel IS
	INR	1.50	1.20	1.80	Siemens/Dade Thromborel S
	INR	1.48	1.18	1.78	HemosIL PT-Fibrinogen
	INR	1.50	1.20	1.80	HemosIL PT-Fibrinogen HS Plus
	INR	1.68	1.34	2.02	Pacific Thromboplastin DS
	INR	1.69	1.35	2.03	STA Hepato Quick
	INR	1.67	1.34	2.00	Stago Neoplastine CI
	INR	1.65	1.32	1.98	Stago Neoplastine CI Plus
	INR	1.48	1.18	1.78	Human Thromboplastin
	INR	1.54	1.23	1.85	Teco TEClot PT-S
	INR	1.63	1.30	1.96	Biolabo Bio-TP
	INR	1.07	0.856	1.28	Stago SPA
	INR	1.35	1.08	1.62	Stago Neoplastin R
	INR	1.34	1.07	1.61	Bio-Ksel System PT
	INR	1.32	1.06	1.58	Grifols DG-PT
	INR	1.51	1.21	1.81	Diagon, Dia-PT
	INR	1.92	1.54	2.30	Weiner Lab Soluplastin
	INR	1.68	1.34	2.02	Futura System Thromboplastin S
	INR	1.58	1.26	1.90	SGM Italia Thromboplastin
	INR	1.80	1.44	2.16	TCoag TriniCLOT PT Excel S
	INR	1.55	1.24	1.86	Biodevice PT
	INR	1.55	1.24	1.86	Biomedica QuikCoag PT-HS
	INR	1.30	1.04	1.56	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.71	1.37	2.05	Helena Thromboplastin LI
	INR	1.54	1.23	1.85	Technoclone Technoplastin HIS
	INR	1.41	1.13	1.69	Teco Teclot PT
	INR	1.38	1.10	1.66	Technoclone Technoclot PT Plus
	INR	1.42	1.14	1.70	Coagpia PT-N
	INR	1.59	1.27	1.91	Biodevice Goldplastin
	INR	1.27	1.02	1.52	Bio-Ksel PT Plus
	INR	1.43	1.14	1.72	Beijing Succeder PT
Prothrombin Time (PT) ratio	ratio	1.69	1.35	2.03	Dade Innovin
	ratio	1.46	1.17	1.75	Siemens/Dade Thromborel S
	ratio	1.46	1.17	1.75	Stago Neoplastine CI
	ratio	1.52	1.22	1.82	Stago Neoplastine CI Plus

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COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 199CG Size: 12 x 1 ml Expiry: 2017-11

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) ratio	ratio	1.39	1.11	1.67	Stago Neoplastin R
	ratio	1.47	1.18	1.76	Diagon, Dia-PT
	ratio	1.46	1.17	1.75	HemosIL PT-Fibrinogen HS Plus
	ratio	1.32	1.06	1.58	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	20.7	16.6	24.8	Siemens/Dade Thromboclotin
	Seconds	25.3	20.2	30.4	Stago Thrombin
	Seconds	36.7	29.4	44.0	Sysmex Thrombin Time
	Seconds	27.3	21.8	32.8	Diagon, Dia-TT
	Seconds	19.0	15.2	22.8	Technoclone Thrombin Reagent
	Seconds	25.2	20.2	30.2	HemosIL Thrombin Time 5ml
	Seconds	34.0	27.2	40.8	HemosIL Thrombin Time 8ml