

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

CAT. NO. CG5022

LOT NO. 349CG

SIZE: 12 x 1 ml

EXPIRY: 2022-09-28

GTIN: 05055273207637

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.

PREPARATION FOR USE

The Coagulation Controls are supplied lyophilised.

- 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.
- Refer to the Control section of the individual analyser application.
- 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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Cat. No. CG5022 Lot No. 349CG

Size: 12 x 1 ml Expiry: 2022-09-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT)	seconds	54.6	43.7	65.5	Tcoag TriniCLOT aPTT S
	seconds	51.5	41.2	61.8	Tcoag TriniCLOT aPTT HS
	seconds	50.7	40.6	60.8	Siemens/Dade Actin
	seconds	44.1	35.3	52.9	Siemens/Dade Actin FS
	seconds	40.6	32.5	48.7	Siemens/Dade Actin FSL
	seconds	70.8	56.6	85.0	Siemens/Dade Actin SL
	seconds	73.7	59.0	88.4	Siemens/Dade Pathromtin SL
	seconds	42.6	34.1	51.1	HemosIL APTT-SP Liquid
	seconds	56.9	45.5	68.3	HemosIL Synthasil
	seconds	68.7	55.0	82.4	Pacific Hemostasis APTT-XL
	seconds	54.6	43.7	65.5	Stago aPTT
	seconds	46.8	37.4	56.2	Stago Cephascreen
	seconds	56.6	45.3	67.9	Stago CK-Prest
	seconds	55.8	44.6	67.0	Stago PTT Automate
	seconds	53.1	42.5	63.7	Teco TEClot APTT
	seconds	48.6	38.9	58.3	Human Hemostat APTT
	seconds	46.6	37.3	55.9	Bio-Ksel System APTTs
	seconds	61.3	49.0	73.6	Diagon Dia-PTT
	seconds	44.6	35.7	53.5	Weiner Lab APTT
	seconds	56.4	45.1	67.7	Biolabo Bio-CK APTT
	seconds	51.8	41.4	62.2	Spinreact APTT
	seconds	41.5	33.2	49.8	Technology-Standard aPTT
	seconds	47.8	38.2	57.4	Tcoag TriniCLOT Automated aPTT
	seconds	48.4	38.7	58.1	Biomedica QuikCoag aPTT
	seconds	56.1	44.9	67.3	Hemosil aPTT Lyophilised Silica
	seconds	48.6	38.9	58.3	Siemens/Dade Actin Cephaloplastin
	seconds	48.4	38.7	58.1	Labitec aPTT
	seconds	54.6	43.7	65.5	Dutch Diagnostics aPTT
	seconds	50.4	40.3	60.5	Technoclone Siron aPTT
	seconds	52.3	41.8	62.8	Sclavo APTT-S
seconds	58.2	46.6	69.8	HemoDiagnostics aPTT	
seconds	56.1	44.9	67.3	Fortress Diagnostics aPTT	
seconds	58.9	47.1	70.7	Tokra Medikal APTT	
seconds	40.8	32.6	49.0	Coagpia APTT-N	
seconds	72.6	58.1	87.1	Cobas aPTT MedS	
seconds	54.1	43.3	64.9	Biolabo Bio-Sil (APTT)	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.75	1.40	2.10	Tcoag TriniCLOT aPTT S
	ratio	1.53	1.22	1.84	Siemens/Dade Actin FSL
	ratio	2.35	1.88	2.82	Siemens/Dade Actin SL
	ratio	1.56	1.25	1.87	Stago Cephascreen
	ratio	1.74	1.39	2.09	Stago PTT Automate
	ratio	1.83	1.46	2.20	Stago aPTT

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 349CG Size: 12 x 1 ml Expiry: 2022-09-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.31	1.85	2.77	Siemens/Dade Pathromtin SL
	ratio	1.43	1.14	1.72	HemosIL APTT-SP Liquid
	ratio	1.71	1.37	2.05	HemosIL Synthafax
	ratio	1.87	1.50	2.24	HemosIL Synthasil
	ratio	1.81	1.45	2.17	Stago CK-Prest
	ratio	1.81	1.45	2.17	Human Hemostat APTT
	ratio	1.33	1.06	1.60	Bio-Ksel System APTTs
	ratio	1.72	1.38	2.06	Siemens/Dade Actin FS
	ratio	1.77	1.42	2.12	Diagon Dia-PTT
	ratio	1.70	1.36	2.04	Biolabo Bio-CK APTT
	ratio	1.50	1.20	1.80	Biodevice aPTT
	ratio	1.61	1.29	1.93	Labitec aPTT
	ratio	1.88	1.50	2.26	Sclavo APTT-S
	ratio	1.23	0.984	1.48	Coagpia APTT-N
Antithrombin III activity	%	67.1	53.7	80.5	Siemens/Dade Berichrom ATIII
	%	64.8	51.8	77.8	Helena Chrom-Z
	%	64.4	51.5	77.3	HemosIL Liquid Antithrombin
	%	66.6	53.3	79.9	Roche Chronogenic Thrombin
	%	64.6	51.7	77.5	Hemosil Lyophilised Antithrombin III
	%	69.2	55.4	83.0	STACHrom ATIII
	%	62.1	49.7	74.5	Siemens/Dade Antithrombin III
	%	68.4	54.7	82.1	Biodevice ATIII
	%	66.5	53.2	79.8	Siemens Innovance Antithrombin III
	%	63.5	50.8	76.2	Sclavo ATIII
	%	60.7	48.6	72.8	HemoDiagnostica Antithrombin III (Fxa)
Factor II activity	%	68.8	55.0	82.6	Siemens/Dade-Behring Innovin
	%	73.3	58.6	88.0	Siemens/Dade-Behring Thromborel S
	%	64.1	51.3	76.9	HemosIL PT-Fibrinogen HS Plus
	%	67.0	53.6	80.4	HemosIL RecombiPlasTin 2G
	%	68.4	54.7	82.1	HemosIL Factor II deficient plasma
	%	65.0	52.0	78.0	Stago STA-NeoPTimal
Factor IX activity	%	61.9	49.5	74.3	Siemens/Dade Actin FS
	%	67.4	53.9	80.9	Siemens/Dade Pathromtin SL
	%	64.1	51.3	76.9	HemosIL Synthasil
	%	62.7	50.2	75.2	Siemens/Dade Actin FSL
	%	66.7	53.4	80.0	Stago Deficient / ImmunoDef IX
	%	62.0	49.6	74.4	HemosIL Factor IX deficient plasma
Factor V activity	%	57.0	45.6	68.4	Stago Neoplastine CI Plus
	%	61.7	49.4	74.0	Siemens/Dade-Behring Thromborel S
	%	51.9	41.5	62.3	Siemens/Dade-Behring Innovin
	%	54.6	43.7	65.5	HemosIL PT-Fibrinogen HS Plus
	%	55.5	44.4	66.6	HemosIL RecombiPlasTin 2G
	%	56.5	45.2	67.8	HemosIL Factor V deficient plasma
	%	56.0	44.8	67.2	Stago STA-NeoPTimal
Factor VII activity	%	84.6	67.7	102	Siemens/Dade-Behring Thromborel S
	%	85.9	68.7	103	Siemens/Dade-Behring Innovin

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

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Range					
Analyte	unit	Target	low	high	methods
Factor VII activity	%	77.5	62.0	93.0	HemosIL PT-Fibrinogen HS Plus
	%	87.9	70.3	105	HemosIL RecombiPlasTin 2G
	%	88.9	71.1	107	HemosIL Factor VII deficient plasma
	%	86.3	69.0	104	Stago STA-NeoPTimal
Factor VIII activity	%	45.5	36.4	54.6	Siemens/Dade Actin FS
	%	42.8	34.2	51.4	Siemens/Dade Pathromtin SL
	%	45.0	36.0	54.0	Siemens/Dade Actin FSL
	%	41.0	32.8	49.2	HemosIL Synthasil
	%	45.5	36.4	54.6	HemosIL APTT-SP Liquid
	%	44.0	35.2	52.8	Stago STA Factor VIII
	%	42.1	33.7	50.5	Stago Deficient / ImmunoDef VIII
	%	39.5	31.6	47.4	HemosIL Factor VIII deficient plasma
Factor X activity	%	79.1	63.3	94.9	Siemens/Dade-Behring Thromborel S
	%	72.0	57.6	86.4	Siemens/Dade-Behring Innovin
	%	70.2	56.2	84.2	HemosIL RecombiPlasTin 2G
	%	73.5	58.8	88.2	HemosIL Factor X deficient plasma
	%	62.5	50.0	75.0	Stago STA-NeoPTimal
Factor XI activity	%	31.8	25.4	38.2	Siemens/Dade Actin FS
	%	42.8	34.2	51.4	Siemens/Dade Pathromtin SL
	%	42.2	33.8	50.6	HemosIL Synthasil
	%	30.8	24.6	37.0	Siemens/Dade Actin FSL
	%	41.6	33.3	49.9	Stago CK-Prest
	%	35.9	28.7	43.1	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	72.3	57.8	86.8	Siemens/Dade Actin FS
	%	68.0	54.4	81.6	Siemens/Dade Pathromtin SL
	%	66.0	52.8	79.2	HemosIL Synthasil
	%	62.6	50.1	75.1	Siemens/Dade Actin FSL
	%	70.8	56.6	85.0	HemosIL Factor XII deficient plasma
Fibrinogen	g/L	1.84	1.47	2.21	HemosIL PT-Fibrinogen HS Plus
	mg/dL	184	147	221	
	g/L	2.09	1.67	2.51	Helena Fibrinogen
	mg/dL	209	167	251	
	g/L	2.00	1.60	2.40	Stago Fibrinogen / Liquid-Fib
	mg/dL	200	160	240	
	g/L	1.80	1.44	2.16	Siemens/Dade Multifibren U
	mg/dL	180	144	216	
	g/L	1.87	1.50	2.24	HemosIL Fibrinogen C
	mg/dL	187	150	224	
	g/L	1.76	1.41	2.11	Dade Thrombin
	mg/dL	176	141	211	
	g/L	2.07	1.66	2.48	Technoclone Fibrinogen
	mg/dL	207	166	248	
	g/L	1.91	1.53	2.29	Tcoag TriniCLOT Fibrinogen
	mg/dL	191	153	229	
g/L	1.97	1.58	2.36	Biolabo Bio-Fibri	
mg/dL	197	158	236		

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Analyte	unit	Target	Range		methods
			low	high	
Fibrinogen	g/L	1.76	1.41	2.11	Teco Teclot Fibrinogen
	mg/dL	176	141	211	
	g/L	1.80	1.44	2.16	HemosIL QFA (bovine thrombin)
	mg/dL	180	144	216	
	g/L	1.97	1.58	2.36	Human Fibrinogen
	mg/dL	197	158	236	
	g/L	1.94	1.55	2.33	Stago STA Fibri-Prest Automate
	mg/dL	194	155	233	
	g/L	1.27	1.02	1.52	Bio-Ksel System PT
	mg/dL	127	102	152	
	g/L	2.08	1.66	2.50	Bio-Ksel Fibrinogen
	mg/dL	208	166	250	
	g/L	1.77	1.42	2.12	Diagon Dia-F
	mg/dL	177	142	212	
	g/L	1.36	1.09	1.63	Dade Innovin Derived Fibrinogen
	mg/dL	136	109	163	
	g/L	1.58	1.26	1.90	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	158	126	190	
	g/L	1.88	1.50	2.26	Technology-Standard Fibrinogen
	mg/dL	188	150	226	
g/L	1.38	1.10	1.66	HemosIL RecombiPlasTin 2G	
mg/dL	138	110	166		
g/L	1.91	1.53	2.29	Sclavo Fibrinogen	
mg/dL	191	153	229		
g/L	1.77	1.42	2.12	Labitec Fibrinogen	
mg/dL	177	142	212		
g/L	1.72	1.38	2.06	HemoDiagnostica Fibrinogen	
mg/dL	172	138	206		
g/L	2.00	1.60	2.40	Helena Clauss Fibrinogen 100	
mg/dL	200	160	240		
g/L	1.90	1.52	2.28	Tokra Medikal Fibrinogen	
mg/dL	190	152	228		
g/L	1.82	1.46	2.18	Coagpia Fibrinogen	
mg/dL	182	146	218		
g/L	2.02	1.62	2.42	HemosIL PT-Fibrinogen	
mg/dL	202	162	242		
g/L	1.72	1.38	2.06	Beijing Succeeder Fibrinogen	
mg/dL	172	138	206		
g/L	1.88	1.50	2.26	Cobas Fibrinogen	
mg/dL	188	150	226		
Plasminogen activity	%	69.3	55.4	83.2	Stago Stachrom Plasminogen
	%	68.2	54.6	81.8	HemosIL Plasminogen
	%	74.3	59.4	89.2	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	70.2	56.2	84.2	Siemens/Dade Berichrom Protein C
	%	70.9	56.7	85.1	Stago StaClot
	%	64.5	51.6	77.4	Biomerieux VIDAS Protein C

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Cat. No. CG5022 Lot No. 349CG

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Protein C activity	%	66.1	52.9	79.3	IL HemosIL Protein C
	%	64.7	51.8	77.6	Siemens
	%	71.6	57.3	85.9	STACHrom Protein C
Protein S activity	%	69.0	48.3	89.7	STA Liatest
	%	66.3	46.4	86.2	Stago StaClot
	%	67.5	47.3	87.8	IL HemosIL ProS
	%	67.5	47.3	87.8	IL HemosIL Free Protein S
	%	54.9	38.4	71.4	Dade Protein S Ac
	%	64.7	45.3	84.1	Siemens Innovance Free PS Ag
	%	57.5	40.3	74.8	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	17.8	14.2	21.4	Siemens/Dade-Behring Innovin
	Seconds	15.6	12.5	18.7	Siemens/Dade Thromborel IS
	Seconds	15.2	12.2	18.2	Siemens/Dade-Behring Thromborel S
	Seconds	20.9	16.7	25.1	HemosIL PT-Fibrinogen HS Plus
	Seconds	22.9	18.3	27.5	Pacific Thromboplastin DS
	Seconds	18.6	14.9	22.3	Stago Neoplastine CI
	Seconds	19.2	15.4	23.0	Stago Neoplastine CI Plus
	Seconds	17.8	14.2	21.4	Teco TEClot PT-S
	Seconds	19.4	15.5	23.3	Biolabo Bio-TP
	Seconds	16.3	13.0	19.6	Stago Neoplastin R
	Seconds	14.0	11.2	16.8	Bio-Ksel System PT
	Seconds	17.7	14.2	21.2	Human Thromboplastin
	Seconds	19.0	15.2	22.8	Diagon PT
	Seconds	19.7	15.8	23.6	Spinreact PT
	Seconds	15.0	12.0	18.0	Shanghai Changdao Biotech PT
	Seconds	19.0	15.2	22.8	Technology-Standard PT
	Seconds	24.0	19.2	28.8	TCoag TriniCLOT PT Excel S
	Seconds	20.7	16.6	24.8	Media IVD PT
	Seconds	15.7	12.6	18.8	Biodevice PT
	Seconds	20.5	16.4	24.6	Biomedica QuikCoag PT-HS
	Seconds	13.9	11.1	16.7	HemosIL RecombiPlasTin 2G
	Seconds	16.9	13.5	20.3	Helena Thromboplastin LI
	Seconds	19.2	15.4	23.0	Helena Thromboplastin
	Seconds	16.2	13.0	19.4	Labitec PT
	Seconds	15.4	12.3	18.5	Fortress Diagnostics PT with Calcium
	Seconds	17.3	13.8	20.8	Tokra Medikal PT
	Seconds	20.4	16.3	24.5	Coagpia PT-N
	Seconds	13.2	10.6	15.8	Bio-Ksel PT Plus
	Seconds	17.5	14.0	21.0	Beijing Succeeder PT
	Seconds	13.6	10.9	16.3	Diagon PT R
Seconds	15.9	12.7	19.1	Cobas PT Screen	
Seconds	23.1	18.5	27.7	Stago STA-NeoPTimal	
Prothrombin Time (PT) activity	%	36.9	29.5	44.3	Siemens/Dade-Behring Innovin
	%	62.5	50.0	75.0	Siemens/Dade-Behring Thromborel S
	%	54.9	43.9	65.9	Stago Neoplastine CI
	%	52.9	42.3	63.5	Stago Neoplastine CI Plus

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Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	54.7	43.8	65.6	HemosIL PT-Fibrinogen
	%	55.8	44.6	67.0	HemosIL PT-Fibrinogen HS Plus
	%	45.4	36.3	54.5	Biolabo Bio-TP
	%	70.4	56.3	84.5	Stago Neoplastin R
	%	55.8	44.6	67.0	Human Thromboplastin
	%	54.0	43.2	64.8	Diagon PT
	%	57.1	45.7	68.5	Technology-Standard PT
	%	35.8	28.6	43.0	TCoag TriniCLOT PT Excel S
	%	62.2	49.8	74.6	Biodevice PT
	%	73.1	58.5	87.7	HemosIL RecombiPlasTin 2G
	%	54.7	43.8	65.6	Helena Thromboplastin
	%	56.6	45.3	67.9	Labitec PT
	%	56.3	45.0	67.6	Tokra Medikal PT
	%	33.7	27.0	40.4	Coagpia PT-N
	%	84.6	67.7	102	Bio-Ksel PT Plus
	%	63.7	51.0	76.4	Beijing Succeeder PT
	%	54.3	43.4	65.2	Diagon PT R
	%	57.1	45.7	68.5	Cobas PT Screen
%	45.2	36.2	54.2	Stago STA-NeoPTimal	
Prothrombin Time (PT) INR	INR	1.78	1.42	2.14	Siemens/Dade-Behring Innovin
	INR	1.29	1.03	1.55	Siemens/Dade Thromborel IS
	INR	1.33	1.06	1.60	Siemens/Dade-Behring Thromborel S
	INR	1.38	1.10	1.66	HemosIL PT-Fibrinogen
	INR	1.51	1.21	1.81	HemosIL PT-Fibrinogen HS Plus
	INR	1.65	1.32	1.98	Pacific Thromboplastin DS
	INR	1.62	1.30	1.94	Stago Neoplastine CI
	INR	1.55	1.24	1.86	Stago Neoplastine CI Plus
	INR	1.44	1.15	1.73	Human Thromboplastin
	INR	1.39	1.11	1.67	Teco TEClot PT-S
	INR	1.92	1.54	2.30	Biolabo Bio-TP
	INR	1.09	0.872	1.31	Stago SPA
	INR	1.22	0.976	1.46	Stago Neoplastin R
	INR	1.28	1.02	1.54	Bio-Ksel System PT
	INR	1.50	1.20	1.80	Diagon PT
	INR	1.86	1.49	2.23	Spinreact PT
	INR	1.42	1.14	1.70	Technology-Standard PT
	INR	2.12	1.70	2.54	TCoag TriniCLOT PT Excel S
	INR	1.50	1.20	1.80	Media IVD PT
	INR	1.37	1.10	1.64	Biodevice PT
	INR	1.60	1.28	1.92	Biomedica QuikCoag PT-HS
	INR	1.22	0.976	1.46	HemosIL RecombiPlasTin 2G
	INR	1.38	1.10	1.66	Technoclon Technoplastin HIS
	INR	1.60	1.28	1.92	Helena Thromboplastin
	INR	1.38	1.10	1.66	Labitec PT
	INR	1.49	1.19	1.79	Fortress Diagnostics PT with Calcium
	INR	1.32	1.06	1.58	Tokra Medikal PT

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) INR	INR	1.80	1.44	2.16	Coagpia PT-N
	INR	1.21	0.968	1.45	Bio-Ksel PT Plus
	INR	1.37	1.10	1.64	Beijing Succeeder PT
	INR	1.30	1.04	1.56	Diagon PT R
	INR	1.51	1.21	1.81	Cobas PT Screen
	INR	1.80	1.44	2.16	Stago STA-NeoPTimal
Prothrombin Time (PT) ratio	ratio	1.69	1.35	2.03	Siemens/Dade-Behring Innovin
	ratio	1.32	1.06	1.58	Siemens/Dade-Behring Thromborel S
	ratio	1.59	1.27	1.91	Stago Neoplastine CI Plus
	ratio	1.37	1.10	1.64	Diagon PT
	ratio	1.37	1.10	1.64	HemosIL PT-Fibrinogen HS Plus
	ratio	2.00	1.60	2.40	TCoag TriniCLOT PT Excel S
	ratio	1.21	0.968	1.45	HemosIL RecombiPlasTin 2G
	ratio	1.75	1.40	2.10	Stago STA-NeoPTimal
Thrombin Time (TT)	Seconds	27.6	22.1	33.1	Dade Thrombin
	Seconds	23.1	18.5	27.7	Siemens/Dade Thromboclotin
	Seconds	27.6	22.1	33.1	Stago Thrombin
	Seconds	26.8	21.4	32.2	Sysmex Thrombin Time
	Seconds	27.5	22.0	33.0	Diagon, Dia-TT
	Seconds	22.8	18.2	27.4	HemosIL Thrombin Time 5ml
	Seconds	28.8	23.0	34.6	HemosIL Thrombin Time 8ml