COAGULATION CONTROL LEVEL 2 (COAG CONTROL 2)

Cat No.: CG5022 **Lot No.:** 164CG
Size: 12 x 1ml **Expiry:** 2017-09

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 to +8°C). APTT, TT, PT, Fibrinogen and Antithrombin III in reconstituted serum are stable for 24 hours at +2 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 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 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 1ml 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 1ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric pipette

ASSIGNED VALUES
Each batch of Coagulation Control is submitted to a number of external laboratories and 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. 164CG Size 12 x 1 ml Expiry 2017-09

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT)	seconds	79.4	63.5	95.3	Tcoag TriniCLOT aPTT HS
	seconds	85.5	68.4	103	Siemens/Dade Actin
	seconds	68.9	55.1	82.7	Siemens/Dade Actin FS
	seconds	57.1	45.7	68.5	Siemens/Dade Actin FSL
	seconds	120	96.0	144	Siemens/Dade Actin SL
	seconds	120	96.0	144	Siemens/Dade Pathromtin SL
	seconds	84.0	67.2	101	Helena aPTT
	seconds	65.6	52.5	78.7	HemosIL APTT-SP Liquid
	seconds	67.1	53.7	80.5	HemosIL Synthasil
	seconds	62.2	49.8	74.6	HemosIL Synthafax
	seconds	63.7	51.0	76.4	Pacific Hemostasis APTT-XL
	seconds	77.2	61.8	92.6	Stago aPTT
	seconds	70.5	56.4	84.6	Stago Cephascreen
	seconds	77.4	61.9	92.9	Stago CK-Prest
	seconds	85.5	68.4	103	Stago PTT Automate
	seconds	75.8	60.6	91.0	Teco TEClot APTT
	seconds	73.6	58.9	88.3	Human Hemostat APTT
	seconds	64.5	51.6	77.4	Bio-Ksel System APTTs
	seconds	89.2	71.4	107	Diagon Dia-PTT
	seconds	65.3	52.2	78.4	Weiner Lab APTT
	seconds	75.1	60.1	90.1	Biolabo Bio-CK APTT
	seconds	81.6	65.3	97.9	Tcoag TriniCLOT Automated aPTT
	seconds	86.2	69.0	103	Biodevice aPTT
	seconds	60.0	48.0	72.0	Biomedica QuikCoag aPTT
	seconds	66.5	53.2	79.8	Hemosil aPTT Lyophilised Silica
	seconds	79.8	63.8	95.8	Siemens Dade Actin Cephaloplastin
	seconds	67.0	53.6	80.4	Beijing Steellex aPTT
	seconds	67.3	53.8	80.8	Technoclone Siron aPTT
	seconds	75.7	60.6	90.8	Sclavo APTT-S
	seconds	77.7	62.2	93.2	HemoDiagnostica aPTT
	seconds	76.1	60.9	91.3	Tokra Medikal APTT
	seconds	58.3	46.6	70.0	Coagpia APTT-N
	seconds	121	96.8	145	Erba Diagnostics ActiMax XS
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.06	1.65	2.47	Siemens/Dade Actin FSL
	ratio	4.32	3.46	5.18	Siemens/Dade Actin SL
	ratio	2.33	1.86	2.80	Stago Cephascreen
	ratio	2.39	1.91	2.87	Stago PTT Automate
	ratio	2.41	1.93	2.89	Stago aPTT
	ratio	3.64	2.91	4.37	Siemens/Dade Pathromtin SL
	ratio	2.14	1.71	2.57	HemosIL APTT-SP Liquid
	ratio	2.19	1.75	2.63	HemosIL Synthasil
	ratio	1.92	1.54	2.30	Pacific Hemostasis APTT-XL

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COAGULATION CONTROL LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot. No. 164CG Size 12 x 1 ml Expiry 2017-09

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.50	2.00	3.00	Stago CK-Prest
	ratio	2.28	1.82	2.74	Human Hemostat APTT
	ratio	2.03	1.62	2.44	Bio-Ksel System APTTs
	ratio	2.58	2.06	3.10	Siemens/Dade Actin FS
	ratio	2.66	2.13	3.19	Diagon Dia-PTT
	ratio	2.43	1.94	2.92	Biolabo Bio-CK APTT
	ratio	3.35	2.68	4.02	Siemens/Dade Actin
	ratio	2.76	2.21	3.31	Siemens Dade Actin Cephaloplastin
	ratio	2.61	2.09	3.13	Sclavo APTT-S
	ratio	2.82	2.26	3.38	HemoDiagnostica aPTT
	ratio	1.69	1.35	2.03	Coagpia APTT-N
Antithrombin III activity	%	65.7	52.6	78.8	Siemens/Dade Berichrom ATIII
	%	66.4	53.1	79.7	Helena Chrom-Z
	%	65.6	52.5	78.7	HemosIL Liquid Antithrombin
	%	68.3	54.6	82.0	Roche Chronogenic Thrombin
	%	69.2	55.4	83.0	Hemosil Lyophilised Antithrombin III
	%	67.8	54.2	81.4	STAChrom ATIII
	%	64.2	51.4	77.0	Siemens/Dade Antithrombin III
	%	71.0	56.8	85.2	Biodevice ATIII
	%	66.2	53.0	79.4	Siemens Innovance Antithrombin III
	%	67.2	53.8	80.6	Sclavo ATIII
Factor II activity	%	21.6	17.3	25.9	Dade Innovin
	%	21.5	17.2	25.8	Siemens/Dade Thromborel S
	%	21.0	16.8	25.2	Stago Neoplastine CI Plus
	%	17.7	14.2	21.2	HemosIL PT-Fibrinogen HS Plus
	%	17.7	14.2	21.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	17.8	14.2	21.4	Stago Neoplastin R
Factor IX activity	%	23.3	18.6	28.0	Stago PTT Automate
	%	19.8	15.8	23.8	Siemens/Dade Actin FS
	%	22.9	18.3	27.5	Siemens/Dade Pathromtin SL
	%	16.9	13.5	20.3	HemosIL Synthasil
	%	22.5	18.0	27.0	Stago CK-Prest
	%	20.6	16.5	24.7	Siemens/Dade Actin FSL
	%	18.5	14.8	22.2	HemosIL APTT-SP Liquid
	%	24.4	19.5	29.3	Stago aPTT
	%	25.4	20.3	30.5	Siemens Dade Actin Cephaloplastin
Factor V activity	%	44.8	35.8	53.8	Stago Neoplastine CI Plus
	%	40.6	32.5	48.7	Siemens/Dade Thromborel S
	%	38.8	31.0	46.6	Dade Innovin
	%	38.5	30.8	46.2	Stago Neoplastine CI
	%	38.7	31.0	46.4	HemosIL PT-Fibrinogen HS Plus
	%	40.0	32.0	48.0	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	39.8	31.8	47.8	Stago Neoplastin R
Factor VII activity	%	20.0	16.0	24.0	Stago Neoplastine CI Plus
	%	22.7	18.2	27.2	Siemens/Dade Thromborel S
	%	23.3	18.6	28.0	Dade Innovin

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Factor VII activity	%	24.7	19.8	29.6	Stago Neoplastine CI
	%	23.6	18.9	28.3	HemosIL PT-Fibrinogen HS Plus
	%	23.0	18.4	27.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	21.8	17.4	26.2	Stago Neoplastin R
Factor VIII activity	%	36.3	29.0	43.6	Stago CK-Prest
	%	37.6	30.1	45.1	Stago PTT Automate
	%	39.3	31.4	47.2	Siemens/Dade Actin FS
	%	39.8	31.8	47.8	Siemens/Dade Pathromtin SL
	%	38.8	31.0	46.6	Siemens/Dade Actin FSL
	%	34.5	27.6	41.4	HemosIL Synthasil
	%	35.6	28.5	42.7	HemosIL APTT-SP Liquid
	%	39.2	31.4	47.0	Stago aPTT
	%	44.2	35.4	53.0	Siemens Dade Actin Cephaloplastin
Factor X activity	%	22.9	18.3	27.5	Siemens/Dade Thromborel S
	%	21.1	16.9	25.3	Dade Innovin
	%	18.6	14.9	22.3	Stago Neoplastine CI Plus
	%	18.3	14.6	22.0	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	19.4	15.5	23.3	Stago Neoplastin R
Factor XI activity	%	18.9	15.1	22.7	Siemens/Dade Actin FSL
	%	19.3	15.4	23.2	Stago CK-Prest
	%	20.0	16.0	24.0	Stago aPTT
Factor XII activity	%	46.8	37.4	56.2	Siemens/Dade Actin FS
	%	46.3	37.0	55.6	Siemens/Dade Pathromtin SL
	%	57.0	45.6	68.4	Siemens/Dade Actin FSL
	%	56.0	44.8	67.2	HemosIL APTT-SP Liquid
Fibrinogen	g/L	2.34	1.87	2.81	HemosIL PT-Fibrinogen HS Plus
	mg/dL	234	187	281	
	g/L	2.01	1.61	2.41	Stago Fibrinogen
	mg/dL	201	161	241	
	g/L	1.94	1.55	2.33	Tcoag TriniCLOT Thrombin Time
	mg/dL	194	155	233	
	g/L	2.28	1.82	2.74	Dade Multifibrin
	mg/dL	228	182	274	
	g/L	2.02	1.62	2.42	HemosIL Fibrinogen C
	mg/dL	202	162	242	
	g/L	1.83	1.46	2.20	Dade Thrombin
	mg/dL	183	146	220	
	g/L	2.04	1.63	2.45	Technoclone Fibrinogen
	mg/dL	204	163	245	
	g/L	1.96	1.57	2.35	Tcoag TriniCLOT Fibrinogen
	mg/dL	196	157	235	
	g/L	1.95	1.56	2.34	Biolabo Bio-Fibri
	mg/dL	195	156	234	
	g/L	1.93	1.54	2.32	HemosIL QFA (bovine thrombin)
	mg/dL	193	154	232	
	g/L	1.83	1.46	2.20	Pacific Hemostasis Fibrinogen
	mg/dL	183	146	220	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Fibrinogen	g/L	1.90	1.52	2.28	Human Fibrinogen
	mg/dL	190	152	228	
	g/L	2.04	1.63	2.45	Stago STA Fibri-Prest Automate
	mg/dL	204	163	245	
	g/L	2.32	1.86	2.78	Bio-Ksel System PT
	mg/dL	232	186	278	
	g/L	1.86	1.49	2.23	Bio-Ksel Fibrinogen
	mg/dL	186	149	223	
	g/L	1.87	1.50	2.24	Diagon Dia-FIB
	mg/dL	187	150	224	
	g/L	1.84	1.47	2.21	Dade Innovin Derived Fibrinogen
	mg/dL	184	147	221	
	g/L	1.97	1.58	2.36	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	197	158	236	
	g/L	2.63	2.10	3.16	Liofilchem Fibrinogen
	mg/dL	263	210	316	
	g/L	1.68	1.34	2.02	Spinreact Fibrinogen
	mg/dL	168	134	202	
	g/L	2.20	1.76	2.64	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	220	176	264	
	g/L	1.99	1.59	2.39	Sclavo Fibrinogen
	mg/dL	199	159	239	
	g/L	2.06	1.65	2.47	Labitec Fibrinogen
	mg/dL	206	165	247	
	g/L	1.87	1.50	2.24	HemoDiagnostica Fibrinogen
	mg/dL	187	150	224	
	g/L	2.07	1.66	2.48	Beijing Steelex Fibrinogen
	mg/dL	207	166	248	
	g/L	1.91	1.53	2.29	Helena Clauss Fibrinogen 100
	mg/dL	191	153	229	
	g/L	2.26	1.81	2.71	R2 Phosphoplastin RL
	mg/dL	226	181	271	
	g/L	2.15	1.72	2.58	Coagpia Fibrinogen
	mg/dL	215	172	258	
	g/L	2.61	2.09	3.13	HemosIL PT-Fibrinogen
	mg/dL	261	209	313	
Plasminogen activity	%	61.5	49.2	73.8	HemosIL Plasminogen
	%	68.6	54.9	82.3	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	21.8	17.4	26.2	Siemens/Dade Berichrom Protein C
	%	18.5	14.8	22.2	Stago StaClot
	%	17.4	13.9	20.9	IL HemosIL Protein C
	%	23.9	19.1	28.7	Siemens
	%	22.2	17.8	26.6	STAChrom Protein C
	%	21.0	16.8	25.2	Chromogenix Coatest APC
Protein S activity	%	16.5	11.6	21.5	STA Liatest

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein S activity	%	10.5	7.35	13.7	Stago StaClot
	%	14.9	10.4	19.4	IL HemosIL Free Protein S
	%	15.3	10.7	19.9	Siemens Innovance Free PS Ag
Prothrombin Time (PT)	Seconds	20.5	16.4	24.6	Tcoag TriniCLOT PT Excel
	Seconds	26.3	21.0	31.6	Tcoag TriniCLOT PT HTF
	Seconds	21.8	17.4	26.2	Dade Innovin
	Seconds	28.3	22.6	34.0	Siemens/Dade Thromborel IS
	Seconds	28.0	22.4	33.6	Siemens/Dade Thromborel S
	Seconds	22.6	18.1	27.1	HemosIL PT-Fibrinogen
	Seconds	33.2	26.6	39.8	HemosIL PT-Fibrinogen HS Plus
	Seconds	38.6	30.9	46.3	Pacific Thromboplastin DS
	Seconds	32.3	25.8	38.8	STA Hepato Quick
	Seconds	27.7	22.2	33.2	Stago Neoplastine CI
	Seconds	31.0	24.8	37.2	Stago Neoplastine CI Plus
	Seconds	25.0	20.0	30.0	R2 Phosphoplastin RL
	Seconds	27.1	21.7	32.5	Teco TEClot PT-S
	Seconds	31.5	25.2	37.8	Biolabo Bio-TP
	Seconds	36.4	29.1	43.7	Stago Neoplastin R
	Seconds	26.5	21.2	31.8	Bio-Ksel System PT
	Seconds	30.6	24.5	36.7	Human Thromboplastin
	Seconds	29.1	23.3	34.9	Grifols DG-PT
	Seconds	30.9	24.7	37.1	Diagon, Dia-PT
	Seconds	29.3	23.4	35.2	Weiner Lab Soluplastin
	Seconds	31.8	25.4	38.2	Spinreact PT
	Seconds	32.3	25.8	38.8	TCoag TriniCLOT PT Excel S
	Seconds	27.0	21.6	32.4	Biodevice PT
	Seconds	26.9	21.5	32.3	Biomedica QuikCoag PT-HS
	Seconds	26.6	21.3	31.9	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	34.4	27.5	41.3	Helena Thromboplastin LI
	Seconds	25.0	20.0	30.0	Beijing Steellex PT
	Seconds	28.6	22.9	34.3	Labitec PT
	Seconds	29.0	23.2	34.8	SGM Italia Thromboplastin
	Seconds	28.0	22.4	33.6	Technoclone Technoclot PT Plus
	Seconds	29.3	23.4	35.2	Tokra Medikal PT
	Seconds	30.3	24.2	36.4	Coagpia PT-N
	Seconds	27.5	22.0	33.0	Erba Diagnostics ThromboMax S
	Seconds	25.2	20.2	30.2	Bio-Ksel PT Plus
Prothrombin Time (PT) activity	%	31.2	25.0	37.4	Tcoag TriniCLOT PT Excel
	%	22.6	18.1	27.1	Tcoag TriniCLOT PT HTF
	%	31.6	25.3	37.9	Dade Innovin
	%	27.9	22.3	33.5	Siemens/Dade Thromborel S
	%	28.6	22.9	34.3	Stago Neoplastine CI
	%	26.0	20.8	31.2	Stago Neoplastine CI Plus
	%	28.1	22.5	33.7	HemosIL PT-Fibrinogen
	%	25.9	20.7	31.1	HemosIL PT-Fibrinogen HS Plus
	%	23.6	18.9	28.3	Pacific Thromboplastin DS

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Cat. No. CG5022 Lot. No. 164CG Size 12 x 1 ml Expiry 2017-09

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT) activity	%	28.5	22.8	34.2	R2 Phosphoplastin RL
	%	25.0	20.0	30.0	Biolabo Bio-TP
	%	19.8	15.8	23.8	Stago SPA
	%	26.2	21.0	31.4	Stago Neoplastin R
	%	44.3	35.4	53.2	Bio-Ksel System PT
	%	31.7	25.4	38.0	Human Thromboplastin
	%	30.4	24.3	36.5	Diagon, Dia-PT
	%	26.9	21.5	32.3	TCoag TriniCLOT PT Excel S
	%	28.1	22.5	33.7	Diagen Thromboplastin S
	%	29.8	23.8	35.8	Biomedica QuikCoag PT-HS
	%	29.5	23.6	35.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	30.3	24.2	36.4	Labitec PT
	%	27.9	22.3	33.5	Technoclone Technoclot PT Plus
	%	22.9	18.3	27.5	Coagpia PT-N
	%	40.3	32.2	48.4	Bio-Ksel PT Plus
Prothrombin Time (PT) INR	INR	3.14	2.51	3.77	Tcoag TriniCLOT PT Excel
	INR	2.48	1.98	2.98	Tcoag TriniCLOT PT HTF
	INR	2.05	1.64	2.46	Dade Innovin
	INR	2.45	1.96	2.94	Siemens/Dade Thromborel IS
	INR	2.44	1.95	2.93	Siemens/Dade Thromborel S
	INR	2.49	1.99	2.99	HemosIL PT-Fibrinogen
	INR	2.74	2.19	3.29	HemosIL PT-Fibrinogen HS Plus
	INR	3.16	2.53	3.79	Pacific Thromboplastin DS
	INR	3.26	2.61	3.91	STA Hepato Quick
	INR	2.99	2.39	3.59	Stago Neoplastine CI
	INR	3.04	2.43	3.65	Stago Neoplastine CI Plus
	INR	2.23	1.78	2.68	R2 Phosphoplastin RL
	INR	2.52	2.02	3.02	Human Thromboplastin
	INR	2.13	1.70	2.56	Teco TEClot PT-S
	INR	2.98	2.38	3.58	Biolabo Bio-TP
	INR	2.79	2.23	3.35	Stago SPA
	INR	2.52	2.02	3.02	Stago Neoplastin R
	INR	2.20	1.76	2.64	Bio-Ksel System PT
	INR	2.43	1.94	2.92	Grifols DG-PT
	INR	2.71	2.17	3.25	Diagon, Dia-PT
	INR	2.57	2.06	3.08	Weiner Lab Soluplastin
	INR	2.78	2.22	3.34	Technology-Standard PT
	INR	2.90	2.32	3.48	TCoag TriniCLOT PT Excel S
	INR	2.44	1.95	2.93	Biodevice PT
	INR	2.30	1.84	2.76	Biomedica QuikCoag PT-HS
	INR	2.35	1.88	2.82	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	2.91	2.33	3.49	Helena Thromboplastin LI
	INR	2.19	1.75	2.63	Labitec PT
	INR	2.16	1.73	2.59	Technoclone Technoclot PT Plus
	INR	2.29	1.83	2.75	Tokra Medikal PT
	INR	2.53	2.02	3.04	Coagpia PT-N

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COAGULATION CONTROL LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot. No. 164CG Size 12 x 1 ml Expiry 2017-09

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT) INR	INR	1.69	1.35	2.03	Erba Diagnostics ThromboMax S
	INR	2.38	1.90	2.86	Bio-Ksel PT Plus
Prothrombin Time (PT) ratio	ratio	2.09	1.67	2.51	Dade Innovin
	ratio	2.45	1.96	2.94	Siemens/Dade Thromborel S
	ratio	2.19	1.75	2.63	Stago Neoplastine CI
	ratio	2.36	1.89	2.83	Stago Neoplastine CI Plus
	ratio	2.56	2.05	3.07	Stago Neoplastin R
	ratio	2.53	2.02	3.04	Diagon, Dia-PT
	ratio	2.39	1.91	2.87	HemosIL PT-Fibrinogen HS Plus
	ratio	2.35	1.88	2.82	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	2.54	2.03	3.05	Technoclone Technoplastin HIS
Thrombin Time (TT)	Seconds	28.0	22.4	33.6	Dade Thrombin
	Seconds	19.4	15.5	23.3	Siemens/Dade Thromboclotin
	Seconds	23.4	18.7	28.1	Stago Thrombin
	Seconds	23.9	19.1	28.7	Sysmex Thrombin Time
	Seconds	21.9	17.5	26.3	Teco TEClot APTT
	Seconds	17.7	14.2	21.2	Technoclone Thrombin Reagent
	Seconds	29.5	23.6	35.4	HemosIL Thrombin Time 5ml