COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG 5021 **Lot No.** 207CG
Size: 12 x 1 ml **Expiry:** 2018-04-28
GTIN: 05055273207620

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 1 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. CG5021 Lot No. 207CG Size: 12 x 1 ml Expiry: 2018-04-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT)	seconds	46.2	37.0	55.4	Tcoag TriniCLOT aPTT S
	seconds	55.7	44.6	66.8	Tcoag TriniCLOT aPTT HS
	seconds	50.5	40.4	60.6	Siemens/Dade Actin
	seconds	43.4	34.7	52.1	Siemens/Dade Actin FS
	seconds	41.8	33.4	50.2	Siemens/Dade Actin FSL
	seconds	61.5	49.2	73.8	Siemens/Dade Actin SL
	seconds	58.5	46.8	70.2	Siemens/Dade Pathromtin SL
	seconds	43.5	34.8	52.2	HemosIL APTT-SP Liquid
	seconds	44.5	35.6	53.4	HemosIL Synthasil
	seconds	49.8	39.8	59.8	Pacific Hemostasis APTT-XL
	seconds	51.4	41.1	61.7	Stago aPTT
	seconds	49.5	39.6	59.4	Stago Cephascreen
	seconds	51.9	41.5	62.3	Stago CK-Prest
	seconds	52.2	41.8	62.6	Stago PTT Automate
	seconds	52.0	41.6	62.4	Teco TEClot APTT
	seconds	51.3	41.0	61.6	Human Hemostat APTT
	seconds	49.0	39.2	58.8	Bio-Ksel System APTTs
	seconds	61.1	48.9	73.3	Grifols DG-APTT
	seconds	55.3	44.2	66.4	Diagon Dia-PTT
	seconds	45.8	36.6	55.0	Weiner Lab APTT
	seconds	50.8	40.6	61.0	Biolabo Bio-CK APTT
	seconds	53.4	42.7	64.1	Spinreact APTT
	seconds	39.7	31.8	47.6	Technology-Standard aPTT
	seconds	56.0	44.8	67.2	Tcoag TriniCLOT Automated aPTT
	seconds	40.8	32.6	49.0	Biodevice aPTT
	seconds	45.2	36.2	54.2	Biomedica QuikCoag aPTT
	seconds	53.0	42.4	63.6	Technoclone DaPTTin TC
	seconds	54.6	43.7	65.5	Siemens Dade Actin Cephaloplastin
	seconds	47.3	37.8	56.8	Renam APTT
	seconds	45.3	36.2	54.4	Beijing Steellex aPTT
	seconds	48.2	38.6	57.8	Technoclone Siron aPTT
	seconds	47.4	37.9	56.9	Sclavo APTT-S
	seconds	49.5	39.6	59.4	Cypress Diagnostics aPTT
	seconds	42.6	34.1	51.1	Coagpia APTT-N
	seconds	58.3	46.6	70.0	Cobas aPTT MedS
	seconds	52.4	41.9	62.9	Biolabo Bio-Sil (APTT)
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.45	1.16	1.74	Tcoag TriniCLOT aPTT S
	ratio	1.53	1.22	1.84	Siemens/Dade Actin FSL
	ratio	2.02	1.62	2.42	Siemens/Dade Actin SL
	ratio	1.64	1.31	1.97	Stago Cephascreen
	ratio	1.55	1.24	1.86	Stago PTT Automate
	ratio	1.59	1.27	1.91	Stago aPTT

%

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 207CG Size: 12 x 1 ml Expiry: 2018-04-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.79	1.43	2.15	Siemens/Dade Pathromtin SL
	ratio	1.44	1.15	1.73	HemosIL APTT-SP Liquid
	ratio	1.50	1.20	1.80	HemosIL Synthasil
	ratio	1.55	1.24	1.86	Pacific Hemostasis APTT-XL
	ratio	1.67	1.34	2.00	Stago CK-Prest
	ratio	1.42	1.14	1.70	Bio-Ksel System APTTs
	ratio	1.61	1.29	1.93	Siemens/Dade Actin FS
	ratio	1.69	1.35	2.03	Diagon Dia-PTT
	ratio	1.78	1.42	2.14	Siemens/Dade Actin
	ratio	1.68	1.34	2.02	Technoclone DaPTTin TC
	ratio	1.73	1.38	2.08	Siemens Dade Actin Cephaloplastin
	ratio	1.59	1.27	1.91	Biodevice aPTT
	ratio	1.63	1.30	1.96	Sclavo APTT-S
	ratio	1.42	1.14	1.70	Coagpia APTT-N
Antithrombin III activity	%	82.2	65.8	98.6	Siemens/Dade Berichrom ATIII
	%	75.3	60.2	90.4	Helena Chrom-Z
	%	80.9	64.7	97.1	HemosIL Liquid Antithrombin
	%	82.0	65.6	98.4	Chromogenix Coamatic LR
	%	84.6	67.7	102	Roche Chronogenic Thrombin
	%	84.2	67.4	101	Hemosil Lyophilised Antithrombin III
	%	83.5	66.8	100	STAChrom ATIII
	%	87.2	69.8	105	Siemens/Dade Antithrombin III
	%	89.3	71.4	107	Biodevice ATIII
	%	82.5	66.0	99.0	Siemens Innovance Antithrombin III
	%	78.2	62.6	93.8	Sclavo ATIII
Factor II activity	%	82.5	66.0	99.0	Siemens/Dade Thromborel S
	%	68.0	54.4	81.6	Stago Neoplastine CI Plus
	%	80.8	64.6	97.0	HemosIL PT-Fibrinogen HS Plus
	%	78.7	63.0	94.4	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	68.9	55.1	82.7	Siemens/Dade Actin FS
	%	69.5	55.6	83.4	Siemens/Dade Pathromtin SL
	%	64.4	51.5	77.3	HemosIL Synthasil
	%	65.7	52.6	78.8	Siemens/Dade Actin FSL
	%	59.6	47.7	71.5	HemosIL APTT-SP Liquid
	%	77.1	61.7	92.5	Stago aPTT
	%	72.3	57.8	86.8	Stago Deficient / ImmunoDef IX
Factor V activity	%	59.0	47.2	70.8	Stago Neoplastine CI Plus
	%	64.2	51.4	77.0	Siemens/Dade Thromborel S
	%	56.0	44.8	67.2	Dade Innovin
	%	50.3	40.2	60.4	HemosIL PT-Fibrinogen HS Plus
	%	58.6	46.9	70.3	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	53.5	42.8	64.2	Stago Neoplastin R
	%	59.3	47.4	71.2	HemosIL Factor V deficient plasma
Factor VII activity	%	104	83.2	125	Stago Neoplastine CI Plus
	%	99.0	79.2	119	Siemens/Dade Thromborel S
	%	112	89.6	134	Dade Innovin

%

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Factor VII activity	%	107	85.6	128	HemosIL PT-Fibrinogen HS Plus
	%	125	100	150	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	94.0	75.2	113	HemosIL Factor VII deficient plasma
Factor VIII activity	%	44.0	35.2	52.8	Stago CK-Prest
	%	47.1	37.7	56.5	Siemens/Dade Actin FS
	%	47.8	38.2	57.4	Siemens/Dade Pathromtin SL
	%	45.6	36.5	54.7	Siemens/Dade Actin FSL
	%	45.7	36.6	54.8	HemosIL Synthasil
	%	42.6	34.1	51.1	HemosIL APTT-SP Liquid
	%	41.5	33.2	49.8	Stago aPTT
	%	47.3	37.8	56.8	Stago STA Factor VIII
	%	42.8	34.2	51.4	Stago Deficient / ImmunoDef VIII
Factor X activity	%	79.2	63.4	95.0	Siemens/Dade Thromborel S
	%	74.6	59.7	89.5	Dade Innovin
	%	81.5	65.2	97.8	HemosIL PT-Fibrinogen HS Plus
	%	71.3	57.0	85.6	Stago Neoplastine CI Plus
	%	73.4	58.7	88.1	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	34.8	27.6	42.0	HemosIL Synthasil
	%	30.3	24.2	36.4	HemosIL APTT-SP Liquid
Factor XII activity	%	74.8	59.8	89.8	Siemens/Dade Pathromtin SL
	%	76.8	61.4	92.2	HemosIL Synthasil
	%	70.7	56.6	84.8	Siemens/Dade Actin FSL
	%	79.6	63.7	95.5	HemosIL APTT-SP Liquid
Fibrinogen	g/L	2.26	1.81	2.71	HemosIL PT-Fibrinogen HS Plus
	mg/dL	226	181	271	
	g/L	2.28	1.82	2.74	Stago Fibrinogen / Liquid-Fib
	mg/dL	228	182	274	
	g/L	2.19	1.75	2.63	Dade Multifibrin
	mg/dL	219	175	263	
	g/L	2.28	1.82	2.74	HemosIL Fibrinogen C
	mg/dL	228	182	274	
	g/L	2.01	1.61	2.41	Dade Thrombin
	mg/dL	201	161	241	
	g/L	2.38	1.90	2.86	Technoclone Fibrinogen
	mg/dL	238	190	286	
	g/L	2.09	1.67	2.51	Tcoag TriniCLOT Fibrinogen
	mg/dL	209	167	251	
	g/L	2.13	1.70	2.56	Biolabo Bio-Fibri
	mg/dL	213	170	256	
	g/L	2.18	1.74	2.62	Teco Teclot Fibrinogen
	mg/dL	218	174	262	
	g/L	2.16	1.73	2.59	HemosIL QFA (bovine thrombin)
	mg/dL	216	173	259	
	g/L	2.41	1.93	2.89	Pacific Hemostasis Fibrinogen
	mg/dL	241	193	289	
	g/L	2.22	1.78	2.66	Human Fibrinogen
	mg/dL	222	178	266	

%

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Fibrinogen	g/L	2.31	1.85	2.77	Stago STA Fibri-Prest Automate
	mg/dL	231	185	277	
	g/L	2.15	1.72	2.58	Bio-Ksel System PT
	mg/dL	215	172	258	
	g/L	1.98	1.58	2.38	Bio-Ksel Fibrinogen
	mg/dL	198	158	238	
	g/L	2.10	1.68	2.52	Diagon Dia-F
	mg/dL	210	168	252	
	g/L	1.51	1.21	1.81	Dade Innovin Derived Fibrinogen
	mg/dL	151	121	181	
	g/L	1.89	1.51	2.27	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	189	151	227	
	g/L	2.46	1.97	2.95	Technology-Standard Fibrinogen
	mg/dL	246	197	295	
	g/L	2.17	1.74	2.60	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	217	174	260	
	g/L	2.26	1.81	2.71	Sclavo Fibrinogen
	mg/dL	226	181	271	
	g/L	2.00	1.60	2.40	HemoDiagnostica Fibrinogen
	mg/dL	200	160	240	
	g/L	2.13	1.70	2.56	Beijing Steelex Fibrinogen
	mg/dL	213	170	256	
	g/L	2.13	1.70	2.56	Helena Clauss Fibrinogen 100
	mg/dL	213	170	256	
	g/L	2.10	1.68	2.52	Tokra Medikal Fibrinogen
	mg/dL	210	168	252	
	g/L	2.21	1.77	2.65	Coagpia Fibrinogen
	mg/dL	221	177	265	
	g/L	2.22	1.78	2.66	HemosIL PT-Fibrinogen
	mg/dL	222	178	266	
	g/L	2.15	1.72	2.58	Cobas Fibrinogen
	mg/dL	215	172	258	
Plasminogen activity	%	88.3	70.6	106	Stago Stachrom Plasminogen
	%	76.8	61.4	92.2	HemosIL Plasminogen
	%	88.0	70.4	106	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	85.8	68.6	103	Siemens/Dade Berichrom Protein C
	%	80.7	64.6	96.8	Stago StaClot
	%	74.9	59.9	89.9	Biomerieux VIDAS Protein C
	%	78.9	63.1	94.7	IL HemosIL Protein C
	%	83.8	67.0	101	Siemens
	%	85.1	68.1	102	STAChrom Protein C
	%	84.0	67.2	101	Chromogenix Coatest APC
Protein S activity	%	76.7	53.7	100	STA Liatest
	%	88.4	61.9	115	Helena Elisa
	%	60.3	42.2	78.4	Stago StaClot

%

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein S activity	%	84.0	58.8	109	IL HemosIL Free Protein S
	%	55.6	38.9	72.3	Dade Protein S Ac
	%	79.0	55.3	103	Siemens Innovance Free PS Ag
Prothrombin Time (PT)	Seconds	12.9	10.3	15.5	Tcoag TriniCLOT PT Excel
	Seconds	14.9	11.9	17.9	Tcoag TriniCLOT PT HTF
	Seconds	12.7	10.2	15.2	Dade Innovin
	Seconds	14.2	11.4	17.0	Siemens/Dade Thromborel S
	Seconds	14.7	11.8	17.6	HemosIL PT-Fibrinogen
	Seconds	15.7	12.6	18.8	HemosIL PT-Fibrinogen HS Plus
	Seconds	17.6	14.1	21.1	Pacific Thromboplastin DS
	Seconds	15.1	12.1	18.1	Stago Neoplastine CI
	Seconds	15.6	12.5	18.7	Stago Neoplastine CI Plus
	Seconds	17.0	13.6	20.4	R2 Phosphoplastin RL
	Seconds	15.6	12.5	18.7	Teco TEClot PT-S
	Seconds	16.0	12.8	19.2	Biolabo Bio-TP
	Seconds	15.5	12.4	18.6	Stago Neoplastin R
	Seconds	11.0	8.80	13.2	Bio-Ksel System PT
	Seconds	14.9	11.9	17.9	Human Thromboplastin
	Seconds	15.2	12.2	18.2	Grifols DG-PT
	Seconds	15.2	12.2	18.2	Diagon PT
	Seconds	16.6	13.3	19.9	Weiner Lab Soluplastin
	Seconds	15.2	12.2	18.2	Spinreact PT
	Seconds	16.5	13.2	19.8	Technology-Standard PT
	Seconds	17.5	14.0	21.0	TCoag TriniCLOT PT Excel S
	Seconds	16.2	13.0	19.4	Media IVD PT
	Seconds	15.3	12.2	18.4	Biodevice PT
	Seconds	14.7	11.8	17.6	Biomedica QuikCoag PT-HS
	Seconds	12.3	9.84	14.8	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	17.0	13.6	20.4	Helena Thromboplastin LI
	Seconds	14.4	11.5	17.3	Teco Teclot PT
	Seconds	15.8	12.6	19.0	Beijing Steellex PT
	Seconds	15.4	12.3	18.5	Technoclone Technoclot PT Plus
	Seconds	16.4	13.1	19.7	Tokra Medikal PT
	Seconds	13.9	11.1	16.7	Coagpia PT-N
	Seconds	15.1	12.1	18.1	Biodevice Goldplastin
	Seconds	11.6	9.28	13.9	Bio-Ksel PT Plus
	Seconds	16.1	12.9	19.3	Beijing Succeeder PT
	Seconds	11.6	9.28	13.9	Diagon PT R
	Seconds	13.4	10.7	16.1	Cobas PT Screen
Prothrombin Time (PT) activity	%	78.1	62.5	93.7	Tcoag TriniCLOT PT Excel
	%	73.0	58.4	87.6	Tcoag TriniCLOT PT HTF
	%	64.7	51.8	77.6	Dade Innovin
	%	70.5	56.4	84.6	Siemens/Dade Thromborel S
	%	70.0	56.0	84.0	Stago Neoplastine CI
	%	72.2	57.8	86.6	Stago Neoplastine CI Plus
	%	71.6	57.3	85.9	HemosIL PT-Fibrinogen

%

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT) activity	%	76.9	61.5	92.3	HemosIL PT-Fibrinogen HS Plus
	%	63.2	50.6	75.8	Pacific Thromboplastin DS
	%	80.7	64.6	96.8	Teco TEClot PT-S
	%	71.5	57.2	85.8	Biolabo Bio-TP
	%	79.9	63.9	95.9	Stago Neoplastin R
	%	94.2	75.4	113	Bio-Ksel System PT
	%	75.2	60.2	90.2	Diagon PT
	%	63.7	51.0	76.4	TCoag TriniCLOT PT Excel S
	%	67.1	53.7	80.5	Media IVD PT
	%	88.6	70.9	106	Biodevice PT
	%	80.2	64.2	96.2	Biomedica QuikCoag PT-HS
	%	86.8	69.4	104	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	69.3	55.4	83.2	Technoclone Technoclot PT Plus
	%	75.8	60.6	91.0	Coagpia PT-N
	%	94.0	75.2	113	Bio-Ksel PT Plus
	%	78.2	62.6	93.8	Diagon PT R
Prothrombin Time (PT) INR	INR	1.18	0.944	1.42	Tcoag TriniCLOT PT Excel
	INR	1.19	0.952	1.43	Tcoag TriniCLOT PT HTF
	INR	1.23	0.984	1.48	Dade Innovin
	INR	1.22	0.976	1.46	Siemens/Dade Thromborel S
	INR	1.21	0.968	1.45	HemosIL PT-Fibrinogen
	INR	1.18	0.944	1.42	HemosIL PT-Fibrinogen HS Plus
	INR	1.31	1.05	1.57	Pacific Thromboplastin DS
	INR	1.30	1.04	1.56	Stago Neoplastine CI
	INR	1.24	0.992	1.49	Stago Neoplastine CI Plus
	INR	1.21	0.968	1.45	Human Thromboplastin
	INR	1.18	0.944	1.42	Teco TEClot PT-S
	INR	1.36	1.09	1.63	Biolabo Bio-TP
	INR	1.02	0.816	1.22	Stago SPA
	INR	1.13	0.904	1.36	Stago Neoplastin R
	INR	1.06	0.848	1.27	Bio-Ksel System PT
	INR	1.14	0.912	1.37	Grifols DG-PT
	INR	1.21	0.968	1.45	Diagon PT
	INR	1.37	1.10	1.64	Weiner Lab Soluplastin
	INR	1.22	0.976	1.46	Technology-Standard PT
	INR	1.34	1.07	1.61	TCoag TriniCLOT PT Excel S
	INR	1.27	1.02	1.52	Media IVD PT
	INR	1.12	0.896	1.34	Biodevice PT
	INR	1.19	0.952	1.43	Biomedica QuikCoag PT-HS
	INR	1.10	0.880	1.32	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.38	1.10	1.66	Helena Thromboplastin LI
	INR	1.14	0.912	1.37	LTA PT Calcium Thromboplastin
	INR	1.20	0.960	1.44	Technoclone Technoclot PT Plus
	INR	1.15	0.920	1.38	Coagpia PT-N
	INR	1.31	1.05	1.57	Biodevice Goldplastin
	INR	1.08	0.864	1.30	Bio-Ksel PT Plus

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT) INR	INR	1.26	1.01	1.51	Beijing Succeeder PT
	INR	1.27	1.02	1.52	Diagon PT R
	INR	1.27	1.02	1.52	Cobas PT Screen
Prothrombin Time (PT) ratio	ratio	1.23	0.984	1.48	Dade Innovin
	ratio	1.21	0.968	1.45	Siemens/Dade Thromborel S
	ratio	1.18	0.944	1.42	Stago Neoplastine CI Plus
	ratio	1.13	0.904	1.36	Stago Neoplastin R
	ratio	1.19	0.952	1.43	Diagon PT
	ratio	1.15	0.920	1.38	HemosIL PT-Fibrinogen HS Plus
	ratio	1.19	0.952	1.43	Technology-Standard PT
	ratio	1.31	1.05	1.57	TCoag TriniCLOT PT Excel S
	ratio	1.09	0.872	1.31	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	1.23	0.984	1.48	Biodevice PT
Thrombin Time (TT)	Seconds	25.7	20.6	30.8	Dade Thrombin
	Seconds	20.7	16.6	24.8	Siemens/Dade Thromboclotin
	Seconds	21.0	16.8	25.2	Stago Thrombin
	Seconds	32.1	25.7	38.5	Sysmex Thrombin Time
	Seconds	20.4	16.3	24.5	Trinity/AMAX Thrombin
	Seconds	25.7	20.6	30.8	DiaMed DiaThrombin
	Seconds	23.7	19.0	28.4	Diagon, Dia-TT
	Seconds	18.7	15.0	22.4	Pacific Hemostasis Thrombin Time
	Seconds	16.6	13.3	19.9	Technoclone Thrombin Reagent
	Seconds	22.4	17.9	26.9	HemosIL Thrombin Time 5ml
	Seconds	30.9	24.7	37.1	HemosIL Thrombin Time 8ml