COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

CAT. NO. CG5022 **LOT NO.** 266CG
SIZE: 12 x 1 ml **EXPIRY:** 2020-04-28

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 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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Cat. No. CG5022 Lot No. 266CG Size: 12 x 1 ml Expiry: 2020-04-28

		Range			
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT)	seconds	56.5	45.2	67.8	Tcoag TriniCLOT aPTT S
	seconds	51.2	41.0	61.4	Tcoag TriniCLOT aPTT HS
	seconds	52.3	41.8	62.8	Siemens/Dade Actin
	seconds	44.8	35.8	53.8	Siemens/Dade Actin FS
	seconds	44.6	35.7	53.5	Siemens/Dade Actin FSL
	seconds	65.2	52.2	78.2	Siemens/Dade Actin SL
	seconds	64.3	51.4	77.2	Siemens/Dade Pathromtin SL
	seconds	46.2	37.0	55.4	Helena aPTT
	seconds	45.3	36.2	54.4	HemosIL APTT-SP Liquid
	seconds	50.8	40.6	61.0	HemosIL Synthasil
	seconds	44.2	35.4	53.0	HemosIL Synthafax
	seconds	57.4	45.9	68.9	Pacific Hemostasis APTT-XL
	seconds	53.6	42.9	64.3	Stago aPTT
	seconds	49.9	39.9	59.9	Stago Cephascreen
	seconds	54.4	43.5	65.3	Stago CK-Prest
	seconds	57.3	45.8	68.8	Stago PTT Automate
	seconds	51.5	41.2	61.8	Teco TEClot APTT
	seconds	50.9	40.7	61.1	Human Hemostat APTT
	seconds	52.8	42.2	63.4	Bio-Ksel System APTTs
	seconds	62.2	49.8	74.6	Diagon Dia-PTT
	seconds	53.8	43.0	64.6	Weiner Lab APTT
	seconds	53.9	43.1	64.7	Biolabo Bio-CK APTT
	seconds	57.5	46.0	69.0	Spinreact APTT
	seconds	39.8	31.8	47.8	Technology-Standard aPTT
	seconds	55.5	44.4	66.6	Tcoag TriniCLOT Automated aPTT
	seconds	52.7	42.2	63.2	Media IVD aPTT
	seconds	37.2	29.8	44.6	Biodevice aPTT
	seconds	52.0	41.6	62.4	Biomedica QuikCoag aPTT
	seconds	44.2	35.4	53.0	Hemosil aPTT Lyophilised Silica
	seconds	55.1	44.1	66.1	Siemens Dade Actin Cephaloplastin
	seconds	44.1	35.3	52.9	Renam APTT
	seconds	48.3	38.6	58.0	Labitec aPTT
	seconds	51.7	41.4	62.0	Sclavo APTT-S
	seconds	51.9	41.5	62.3	HemoDiagnostica aPTT
	seconds	58.5	46.8	70.2	Cypress Diagnostics aPTT
	seconds	52.7	42.2	63.2	Tokra Medikal APTT
	seconds	46.8	37.4	56.2	Coagpia APTT-N
	seconds	60.4	48.3	72.5	Cobas aPTT MedS
	seconds	51.8	41.4	62.2	Biolabo Bio-Sil (APTT)
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.68	1.34	2.02	Siemens/Dade Actin FSL
	ratio	2.17	1.74	2.60	Siemens/Dade Actin SL
	ratio	1.68	1.34	2.02	Stago Cephascreen

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.69	1.35	2.03	Stago PTT Automate
	ratio	1.78	1.42	2.14	Stago aPTT
	ratio	2.04	1.63	2.45	Siemens/Dade Pathromtin SL
	ratio	1.49	1.19	1.79	HemosIL APTT-SP Liquid
	ratio	1.70	1.36	2.04	HemosIL Synthasil
	ratio	1.74	1.39	2.09	Pacific Hemostasis APTT-XL
	ratio	1.74	1.39	2.09	Stago CK-Prest
	ratio	2.01	1.61	2.41	Human Hemostat APTT
	ratio	1.57	1.26	1.88	Bio-Ksel System APTTs
	ratio	1.72	1.38	2.06	Siemens/Dade Actin FS
	ratio	1.86	1.49	2.23	Diagon Dia-PTT
	ratio	1.68	1.34	2.02	Media IVD aPTT
	ratio	1.54	1.23	1.85	Biodevice aPTT
	ratio	1.72	1.38	2.06	Labitec aPTT
	ratio	1.79	1.43	2.15	Sclavo APTT-S
	ratio	1.50	1.20	1.80	Coagpia APTT-N
Antithrombin III activity	%	69.6	55.7	83.5	Siemens/Dade Berichrom ATIII
	%	63.9	51.1	76.7	HemosIL Liquid Antithrombin
	%	65.5	52.4	78.6	Roche Chronogenic Thrombin
	%	65.0	52.0	78.0	Hemosil Lyophilised Antithrombin III
	%	70.0	56.0	84.0	STAChrom ATIII
	%	77.9	62.3	93.5	Siemens/Dade Antithrombin III
	%	61.9	49.5	74.3	Diagon ATIII
	%	70.5	56.4	84.6	Siemens Innovance Antithrombin III
	%	66.5	53.2	79.8	Sclavo ATIII
	%	71.8	57.4	86.2	HemoDiagnostica Antithrombin III (Fxa)
Factor II activity	%	67.0	53.6	80.4	Dade Innovin
	%	73.2	58.6	87.8	Siemens/Dade Thromborel S
	%	70.3	56.2	84.4	Stago Neoplastine CI Plus
	%	65.5	52.4	78.6	HemosIL PT-Fibrinogen HS Plus
	%	67.9	54.3	81.5	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	77.0	61.6	92.4	Stago PTT Automate
	%	67.8	54.2	81.4	Siemens/Dade Actin FS
	%	68.0	54.4	81.6	Siemens/Dade Pathromtin SL
	%	60.8	48.6	73.0	HemosIL Synthasil
	%	76.8	61.4	92.2	Stago CK-Prest
	%	61.9	49.5	74.3	Siemens/Dade Actin FSL
	%	67.2	53.8	80.6	HemosIL APTT-SP Liquid
	%	65.8	52.6	79.0	Stago Deficient / ImmunoDef IX
	%	61.4	49.1	73.7	HemosIL Factor IX deficient plasma
Factor V activity	%	53.3	42.6	64.0	Stago Neoplastine CI Plus
	%	57.3	45.8	68.8	Siemens/Dade Thromborel S
	%	48.9	39.1	58.7	Dade Innovin
	%	49.2	39.4	59.0	HemosIL PT-Fibrinogen HS Plus
	%	53.5	42.8	64.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	52.0	41.6	62.4	HemosIL Factor V deficient plasma

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Factor VII activity	%	71.0	56.8	85.2	Stago Neoplastine CI Plus
	%	79.7	63.8	95.6	Siemens/Dade Thromborel S
	%	82.1	65.7	98.5	Dade Innovin
	%	77.8	62.2	93.4	HemosIL PT-Fibrinogen HS Plus
	%	92.3	73.8	111	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	83.3	66.6	100	HemosIL Factor VII deficient plasma
Factor VIII activity	%	35.1	28.1	42.1	Stago PTT Automate
	%	38.2	30.6	45.8	Siemens/Dade Actin FS
	%	38.1	30.5	45.7	Siemens/Dade Pathromtin SL
	%	34.9	27.9	41.9	Siemens/Dade Actin FSL
	%	37.2	29.8	44.6	HemosIL Synthasil
	%	37.0	29.6	44.4	HemosIL APTT-SP Liquid
	%	35.5	28.4	42.6	Stago STA Factor VIII
	%	35.1	28.1	42.1	HemosIL Factor VIII deficient plasma
Factor X activity	%	76.1	60.9	91.3	Siemens/Dade Thromborel S
	%	68.0	54.4	81.6	Dade Innovin
	%	70.6	56.5	84.7	HemosIL PT-Fibrinogen HS Plus
	%	69.5	55.6	83.4	Stago Neoplastine CI Plus
	%	69.2	55.4	83.0	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	42.1	33.7	50.5	Siemens/Dade Actin FS
	%	46.3	37.0	55.5	Siemens/Dade Pathromtin SL
	%	42.2	33.8	50.6	HemosIL Synthasil
	%	33.6	26.9	40.3	Siemens/Dade Actin FSL
	%	42.8	34.2	51.4	HemosIL APTT-SP Liquid
	%	38.1	30.5	45.7	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	71.3	57.0	85.6	Siemens/Dade Actin FS
	%	64.7	51.8	77.6	Siemens/Dade Pathromtin SL
	%	66.6	53.3	79.9	HemosIL Synthasil
	%	58.2	46.6	69.8	Siemens/Dade Actin FSL
Fibrinogen	g/L	1.81	1.45	2.17	HemosIL PT-Fibrinogen HS Plus
	mg/dL	181	145	217	
	g/L	1.96	1.57	2.35	Helena Fibrinogen
	mg/dL	196	157	235	
	g/L	1.93	1.54	2.32	Stago Fibrinogen / Liquid-Fib
	mg/dL	193	154	232	
	g/L	1.94	1.55	2.33	Siemens/Dade Multifibren U
	mg/dL	194	155	233	
	g/L	1.85	1.48	2.22	HemosIL Fibrinogen C
	mg/dL	185	148	222	
	g/L	1.66	1.33	1.99	Dade Thrombin
	mg/dL	166	133	199	
	g/L	2.26	1.81	2.71	Technoclone Fibrinogen
	mg/dL	226	181	271	
	g/L	1.86	1.49	2.23	Tcoag TriniCLOT Fibrinogen
	mg/dL	186	149	223	
	g/L	1.89	1.51	2.27	Biolabo Bio-Fibri
	mg/dL	189	151	227	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Fibrinogen	g/L	1.85	1.48	2.22	Teco Teclot Fibrinogen
	mg/dL	185	148	222	
	g/L	1.77	1.42	2.12	HemosIL QFA (bovine thrombin)
	mg/dL	177	142	212	
	g/L	2.15	1.72	2.58	Pacific Hemostasis Fibrinogen
	mg/dL	215	172	258	
	g/L	1.83	1.46	2.20	Human Fibrinogen
	mg/dL	183	146	220	
	g/L	1.96	1.57	2.35	Stago STA Fibri-Prest Automate
	mg/dL	196	157	235	
	g/L	1.49	1.19	1.79	Bio-Ksel System PT
	mg/dL	149	119	179	
	g/L	1.97	1.58	2.36	Bio-Ksel Fibrinogen
	mg/dL	197	158	236	
	g/L	1.67	1.34	2.00	Diagon Dia-F
	mg/dL	167	134	200	
	g/L	1.47	1.18	1.76	Dade Innovin Derived Fibrinogen
	mg/dL	147	118	176	
	g/L	1.59	1.27	1.91	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	159	127	191	
	g/L	1.90	1.52	2.28	Technology-Standard Fibrinogen
	mg/dL	190	152	228	
	g/L	1.63	1.30	1.96	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	163	130	196	
	g/L	1.76	1.41	2.11	Sclavo Fibrinogen
	mg/dL	176	141	211	
	g/L	1.84	1.47	2.21	Labitec Fibrinogen
	mg/dL	184	147	221	
	g/L	1.86	1.49	2.23	HemoDiagnostica Fibrinogen
	mg/dL	186	149	223	
	g/L	1.99	1.59	2.39	Beijing Steelex Fibrinogen
	mg/dL	199	159	239	
	g/L	1.91	1.53	2.29	Helena Clauss Fibrinogen 100
	mg/dL	191	153	229	
	g/L	1.79	1.43	2.15	Coagpia Fibrinogen
	mg/dL	179	143	215	
	g/L	2.10	1.68	2.52	HemosIL PT-Fibrinogen
	mg/dL	210	168	252	
	g/L	1.69	1.35	2.03	Erba Diagnostics FibriMax
	mg/dL	169	135	203	
	g/L	1.81	1.45	2.17	Cobas Fibrinogen
	mg/dL	181	145	217	
Plasminogen activity	%	68.3	54.6	82.0	Stago Stachrom Plasminogen
	%	67.6	54.1	81.1	HemosIL Plasminogen
	%	75.9	60.7	91.1	Siemens/Dade Berichrom Plasminogen

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Cat. No. CG5022 Lot No. 266CG Size: 12 x 1 ml Expiry: 2020-04-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein C activity	%	66.5	53.2	79.8	Siemens/Dade Berichrom Protein C
	%	67.1	53.7	80.5	Biomerieux VIDAS Protein C
	%	59.3	47.4	71.2	IL HemosIL Protein C
	%	70.0	56.0	84.0	Siemens
	%	68.9	55.1	82.7	STAChrom Protein C
Protein S activity	%	63.7	44.6	82.8	STA Liatest
	%	69.3	48.5	90.1	Stago StaClot
	%	73.8	51.7	95.9	IL HemosIL ProS
	%	68.8	48.2	89.4	IL HemosIL Free Protein S
	%	52.8	37.0	68.6	Dade Protein S Ac
	%	65.5	45.9	85.2	Siemens Innovance Free PS Ag
	%	55.7	39.0	72.4	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	15.6	12.5	18.7	Tcoag TriniCLOT PT Excel
	Seconds	15.7	12.6	18.8	Dade Innovin
	Seconds	14.7	11.8	17.6	Siemens/Dade Thromborel IS
	Seconds	14.7	11.8	17.6	Siemens/Dade Thromborel S
	Seconds	19.7	15.8	23.6	HemosIL PT-Fibrinogen HS Plus
	Seconds	23.2	18.6	27.8	Pacific Thromboplastin DS
	Seconds	17.3	13.8	20.8	Stago Neoplastine CI
	Seconds	17.5	14.0	21.0	Stago Neoplastine CI Plus
	Seconds	20.3	16.2	24.4	R2 Phosphoplastin RL
	Seconds	18.5	14.8	22.2	Teco TEClot PT-S
	Seconds	18.7	15.0	22.4	Biolabo Bio-TP
	Seconds	23.9	19.1	28.7	Stago SPA
	Seconds	16.9	13.5	20.3	Stago Neoplastin R
	Seconds	12.8	10.2	15.4	Bio-Ksel System PT
	Seconds	17.1	13.7	20.5	Human Thromboplastin
	Seconds	17.7	14.2	21.2	Diagon PT
	Seconds	20.8	16.6	25.0	Weiner Lab Soluplastin
	Seconds	20.2	16.2	24.2	Spinreact PT
	Seconds	24.3	19.4	29.2	TCoag TriniCLOT PT Excel S
	Seconds	15.4	12.3	18.5	Media IVD PT
	Seconds	16.7	13.4	20.0	Biodevice PT
	Seconds	20.2	16.2	24.2	Biomedica QuikCoag PT-HS
	Seconds	13.5	10.8	16.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	18.5	14.8	22.2	Helena Thromboplastin LI
	Seconds	16.6	13.3	19.9	Renam PT
	Seconds	18.3	14.6	22.0	Helena Thromboplastin
	Seconds	16.7	13.4	20.0	Labitec PT
	Seconds	16.3	13.0	19.6	Cypress Diagnostics PT
	Seconds	17.5	14.0	21.0	Tokra Medikal PT
	Seconds	20.2	16.2	24.2	Coagpia PT-N
	Seconds	12.6	10.1	15.1	Bio-Ksel PT Plus
	Seconds	18.7	15.0	22.4	Beijing Succeeder PT
	Seconds	13.6	10.9	16.3	Diagon PT R
	Seconds	14.6	11.7	17.5	Cobas PT Screen

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT) activity	%	47.2	37.8	56.6	Tcoag TriniCLOT PT Excel
	%	43.8	35.0	52.6	Dade Innovin
	%	64.6	51.7	77.5	Siemens/Dade Thromborel S
	%	58.3	46.6	70.0	Stago Neoplastine CI
	%	57.8	46.2	69.4	Stago Neoplastine CI Plus
	%	51.7	41.4	62.0	HemosIL PT-Fibrinogen
	%	55.1	44.1	66.1	HemosIL PT-Fibrinogen HS Plus
	%	38.9	31.1	46.7	Pacific Thromboplastin DS
	%	60.3	48.2	72.4	Teco TEClot PT-S
	%	78.9	63.1	94.7	Stago SPA
	%	70.8	56.6	85.0	Stago Neoplastin R
	%	87.2	69.8	105	Bio-Ksel System PT
	%	60.8	48.6	73.0	Human Thromboplastin
	%	56.2	45.0	67.4	Diagon PT
	%	36.7	29.4	44.0	TCoag TriniCLOT PT Excel S
	%	57.2	45.8	68.6	Media IVD PT
	%	60.8	48.6	73.0	Biodevice PT
	%	52.3	41.8	62.8	Biomedica QuikCoag PT-HS
	%	76.3	61.0	91.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	55.0	44.0	66.0	Helena Thromboplastin LI
	%	57.5	46.0	69.0	Helena Thromboplastin
	%	56.8	45.4	68.2	Labitec PT
	%	38.6	30.9	46.3	Coagpia PT-N
	%	88.0	70.4	106	Bio-Ksel PT Plus
	%	64.9	51.9	77.9	Diagon PT R
	%	58.1	46.5	69.7	Cobas PT Screen
Prothrombin Time (PT) INR	INR	1.59	1.27	1.91	Tcoag TriniCLOT PT Excel
	INR	1.57	1.26	1.88	Dade Innovin
	INR	1.21	0.968	1.45	Siemens/Dade Thromborel IS
	INR	1.28	1.02	1.54	Siemens/Dade Thromborel S
	INR	1.46	1.17	1.75	HemosIL PT-Fibrinogen HS Plus
	INR	1.80	1.44	2.16	Pacific Thromboplastin DS
	INR	1.49	1.19	1.79	Stago Neoplastine CI
	INR	1.46	1.17	1.75	Stago Neoplastine CI Plus
	INR	1.37	1.10	1.64	Human Thromboplastin
	INR	1.40	1.12	1.68	Teco TEClot PT-S
	INR	1.66	1.33	1.99	Biolabo Bio-TP
	INR	1.12	0.896	1.34	Stago SPA
	INR	1.21	0.968	1.45	Stago Neoplastin R
	INR	1.17	0.936	1.40	Bio-Ksel System PT
	INR	1.45	1.16	1.74	Diagon PT
	INR	1.77	1.42	2.12	Weiner Lab Soluplastin
	INR	2.12	1.70	2.54	TCoag TriniCLOT PT Excel S
	INR	1.41	1.13	1.69	Media IVD PT
	INR	1.42	1.14	1.70	Biodevice PT
	INR	1.65	1.32	1.98	Biomedica QuikCoag PT-HS

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT) INR	INR	1.19	0.952	1.43	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.48	1.18	1.78	Helena Thromboplastin LI
	INR	1.33	1.06	1.60	Technoclone Technoplastin HIS
	INR	1.44	1.15	1.73	Helena Thromboplastin
	INR	1.45	1.16	1.74	Labitec PT
	INR	1.34	1.07	1.61	Tokra Medikal PT
	INR	1.65	1.32	1.98	Coagpia PT-N
	INR	1.13	0.904	1.36	Bio-Ksel PT Plus
	INR	1.49	1.19	1.79	Beijing Succeeder PT
	INR	1.23	0.984	1.48	Diagon PT R
	INR	1.41	1.13	1.69	Cobas PT Screen
Prothrombin Time (PT) ratio	ratio	1.62	1.30	1.94	Dade Innovin
	ratio	1.27	1.02	1.52	Siemens/Dade Thromborel S
	ratio	1.32	1.06	1.58	Stago Neoplastine CI Plus
	ratio	1.21	0.968	1.45	Stago Neoplastin R
	ratio	1.40	1.12	1.68	Diagon PT
	ratio	1.40	1.12	1.68	HemosIL PT-Fibrinogen HS Plus
	ratio	1.21	0.968	1.45	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	25.9	20.7	31.1	Dade Thrombin
	Seconds	18.0	14.4	21.6	Siemens/Dade Thromboclotin
	Seconds	23.9	19.1	28.7	Stago Thrombin
	Seconds	26.6	21.3	31.9	Sysmex Thrombin Time
	Seconds	25.3	20.2	30.4	Diagon, Dia-TT
	Seconds	21.7	17.4	26.0	Human - Hemostat
	Seconds	19.8	15.8	23.8	Renam TT
	Seconds	21.5	17.2	25.8	HemosIL Thrombin Time 5ml
	Seconds	31.6	25.3	37.9	HemosIL Thrombin Time 8ml