

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

CAT. NO. CG5023 **LOT NO.** 400CG
SIZE 12 x 1 ml **EXPIRY:** 2025-04-28
GTIN: 05055273207644

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.

LIMITATION

The Randox Level 3 Coagulation Control may not be suitable for the control of aPTT on some analysers due to a slow clotting time.

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 3 12 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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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Dungloe, Donegal,
F94 TV06, Ireland

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COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 400CG Size 12 x 1 ml Expiry 2025-04-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	77.6	62.1	93.1	Tcoag TriniCLOT aPTT S
	seconds	70.9	56.7	85.1	Tcoag TriniCLOT aPTT HS
	seconds	64.7	51.8	77.6	Siemens/Dade Actin
	seconds	61.9	49.5	74.3	Siemens/Dade Actin FS
	seconds	57.8	46.2	69.4	Siemens/Dade Actin FSL
	seconds	109	87.2	131	Siemens/Dade Pathromtin SL
	seconds	53.1	42.5	63.7	HemosIL APTT-SP Liquid
	seconds	79.6	63.7	95.5	HemosIL Synthasil
	seconds	78.4	62.7	94.1	Pacific Hemostasis APTT-XL
	seconds	70.7	56.6	84.8	Stago aPTT
	seconds	71.8	57.4	86.2	Stago Cephascreen
	seconds	75.0	60.0	90.0	Stago CK-Prest
	seconds	72.1	57.7	86.5	Stago PTT Automate
	seconds	65.2	52.2	78.2	Human Hemostat APTT
	seconds	61.1	48.9	73.3	Bio-Ksel System APTTs
	seconds	82.4	65.9	98.9	Diagon Dia-PTT
	seconds	65.1	52.1	78.1	Weiner Lab APTT
	seconds	65.3	52.2	78.4	Biolabo Bio-CK APTT
	seconds	69.7	55.8	83.6	Spinreact APTT
	seconds	51.3	41.0	61.6	Technology-Standard aPTT
	seconds	62.9	50.3	75.5	Media IVD aPTT
	seconds	63.2	50.6	75.8	Biomedica QuikCoag aPTT
	seconds	84.8	67.8	102	Hemosil aPTT Lyophilised Silica
	seconds	63.3	50.6	76.0	Siemens/Dade Actin Cephaloplastin
	seconds	53.6	42.9	64.3	Renam APTT
	seconds	73.0	58.4	87.6	Labitec aPTT
	seconds	71.8	57.4	86.2	Dutch Diagnostics aPTT
	seconds	51.4	41.1	61.7	Technoclone Siron aPTT
	seconds	89.6	71.7	108	Sclavo APTT-S
	seconds	98.4	78.7	118	Cobas aPTT MedS
	seconds	67.0	53.6	80.4	Diagon Dia-PTT Liquid
	seconds	67.6	54.1	81.1	MTI Diagnostics APTT
	seconds	109	87.2	131	Roche Cobas APTT Screen
	seconds	80.1	64.1	96.1	Roche Cobas APTT
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.80	2.24	3.36	Tcoag TriniCLOT aPTT S
	ratio	2.11	1.69	2.53	Siemens/Dade Actin FSL
	ratio	2.21	1.77	2.65	Stago Cephascreen
	ratio	2.16	1.73	2.59	Stago PTT Automate
	ratio	2.23	1.78	2.68	Stago aPTT
	ratio	3.61	2.89	4.33	Siemens/Dade Pathromtin SL
	ratio	1.82	1.46	2.18	HemosIL APTT-SP Liquid
	ratio	2.63	2.10	3.16	HemosIL Synthasil

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 400CG Size 12 x 1 ml Expiry 2025-04-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.45	1.96	2.94	Stago CK-Prest
	ratio	2.78	2.22	3.34	Teco TEClot APTT
	ratio	2.02	1.62	2.42	Human Hemostat APTT
	ratio	1.81	1.45	2.17	Bio-Ksel System APTTs
	ratio	2.48	1.98	2.98	Siemens/Dade Actin FS
	ratio	2.33	1.86	2.80	Diagon Dia-PTT
	ratio	2.29	1.83	2.75	Biolabo Bio-CK APTT
	ratio	2.11	1.69	2.53	Media IVD aPTT
	ratio	3.17	2.54	3.80	Sclavo APTT-S
	ratio	2.39	1.91	2.87	MTI Diagnostics APTT
Antithrombin III activity	%	54.1	43.3	64.9	Siemens/Dade Berichrom ATIII
	%	50.0	40.0	60.0	HemosIL Liquid Antithrombin
	%	55.4	44.3	66.5	Roche Chronogenic Thrombin
	%	53.2	42.6	63.8	Hemosil Lyophilised Antithrombin III
	%	48.9	39.1	58.7	Chromogenix Substrate
	%	58.1	46.5	69.7	STACHrom ATIII
	%	56.6	45.3	67.9	Siemens/Dade Antithrombin III
	%	52.5	42.0	63.0	Siemens Innovance Antithrombin III
	%	52.1	41.7	62.5	Sclavo ATIII
	%	54.0	43.2	64.8	Roche Antithrombin
	%	52.3	41.8	62.8	Tehnologia Standart Antithrombin III
Factor II activity	%	55.1	44.1	66.1	Siemens/Dade-Behring Innovin
	%	56.9	45.5	68.3	Siemens/Dade-Behring Thromborel S
	%	48.9	39.1	58.7	HemosIL PT-Fibrinogen HS Plus
	%	53.2	42.6	63.8	HemosIL RecombiPlasTin 2G
	%	49.6	39.7	59.5	HemosIL Factor II deficient plasma
	%	51.1	40.9	61.3	Stago STA-NeoPTimal
Factor IX activity	%	47.7	38.2	57.2	Siemens/Dade Actin FS
	%	51.3	41.0	61.6	Siemens/Dade Pathromtin SL
	%	47.2	37.8	56.6	HemosIL Synthasil
	%	46.8	37.4	56.2	Stago CK-Prest
	%	46.6	37.3	55.9	Siemens/Dade Actin FSL
	%	47.6	38.1	57.1	Stago Deficient / ImmunoDef IX
	%	44.5	35.6	53.4	HemosIL Factor IX deficient plasma
Factor V activity	%	51.9	41.5	62.3	Siemens/Dade-Behring Thromborel S
	%	37.0	29.6	44.4	Siemens/Dade-Behring Innovin
	%	42.5	34.0	51.0	HemosIL PT-Fibrinogen HS Plus
	%	42.7	34.2	51.2	HemosIL RecombiPlasTin 2G
	%	40.4	32.3	48.5	HemosIL Factor V deficient plasma
	%	40.4	32.3	48.5	Stago STA-NeoPTimal
Factor VII activity	%	76.6	61.3	91.9	Siemens/Dade-Behring Thromborel S
	%	80.5	64.4	96.6	Siemens/Dade-Behring Innovin
	%	75.9	60.7	91.1	HemosIL PT-Fibrinogen HS Plus
	%	87.7	70.2	105	HemosIL RecombiPlasTin 2G
	%	83.6	66.9	100	HemosIL Factor VII deficient plasma
	%	81.1	64.9	97.3	Stago Deficient Factor VII

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Analyte	unit	Target	low	high	methods
Factor VII activity	%	71.8	57.4	86.2	Stago STA-NeoPTimal
Factor VIII activity	%	28.1	22.5	33.7	Siemens/Dade Actin FS
	%	27.6	22.1	33.1	Siemens/Dade Pathromtin SL
	%	26.5	21.2	31.8	Siemens/Dade Actin FSL
	%	28.4	22.7	34.1	HemosIL Synthasil
	%	26.8	21.4	32.2	Stago Deficient / ImmunoDef VIII
	%	26.6	21.3	31.9	HemosIL Factor VIII deficient plasma
Factor X activity	%	65.1	52.1	78.1	Siemens/Dade-Behring Thromborel S
	%	62.5	50.0	75.0	Siemens/Dade-Behring Innovin
	%	60.0	48.0	72.0	HemosIL RecombiPlasTin 2G
	%	57.1	45.7	68.5	HemosIL Factor X deficient plasma
	%	50.5	40.4	60.6	Stago STA-NeoPTimal
Factor XI activity	%	17.9	14.3	21.5	Siemens/Dade Actin FS
	%	19.9	15.9	23.9	HemosIL Synthasil
	%	15.5	12.4	18.6	Siemens/Dade Actin FSL
	%	20.5	16.4	24.6	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	46.9	37.5	56.3	Siemens/Dade Actin FS
	%	46.9	41.8	52.0	Siemens/Dade Actin FS
	%	46.4	37.1	55.7	Siemens/Dade Pathromtin SL
	%	46.4	37.1	55.7	Siemens/Dade Pathromtin SL
	%	45.4	36.3	54.5	HemosIL Synthasil
	%	45.4	36.3	54.5	HemosIL Synthasil
	%	46.0	36.8	55.2	Siemens/Dade Actin FSL
	%	46.0	39.1	52.9	Siemens/Dade Actin FSL
	%	49.8	39.8	59.8	HemosIL Factor XII deficient plasma
	%	49.8	39.8	59.8	HemosIL Factor XII deficient plasma
Fibrinogen	g/L	1.51	1.21	1.81	HemosIL PT-Fibrinogen HS Plus
	mg/dL	151	121	181	
	g/L	1.50	1.20	1.80	Stago Fibrinogen / Liquid-Fib
	mg/dL	150	120	180	
	g/L	1.12	0.896	1.34	Siemens/Dade Multifibren U
	mg/dL	112	89.6	134	
	g/L	1.43	1.14	1.72	HemosIL Fibrinogen C
	mg/dL	143	114	172	
	g/L	1.25	1.00	1.50	Dade Thrombin
	mg/dL	125	100	150	
	g/L	1.76	1.41	2.11	Technoclone Fibrinogen
	mg/dL	176	141	211	
	g/L	1.45	1.16	1.74	Tcoag TriniCLOT Fibrinogen
	mg/dL	145	116	174	
	g/L	1.55	1.24	1.86	Biolabo Bio-Fibri
	mg/dL	155	124	186	
	g/L	1.43	1.14	1.72	Teco Teclot Fibrinogen
	mg/dL	143	114	172	
	g/L	1.39	1.11	1.67	HemosIL QFA (bovine thrombin)
	mg/dL	139	111	167	

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Range					
Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	1.69	1.35	2.03	Human Fibrinogen
	mg/dL	169	135	203	
	g/L	1.47	1.18	1.76	Stago STA Fibri-Prest Automate
	mg/dL	147	118	176	
	g/L	0.960	0.768	1.15	Bio-Ksel System PT
	mg/dL	96.0	76.8	115	
	g/L	1.59	1.27	1.91	Bio-Ksel Fibrinogen
	mg/dL	159	127	191	
	g/L	1.21	0.968	1.45	Diagon Dia-F
	mg/dL	121	96.8	145	
	g/L	1.00	0.800	1.20	Dade Innovin Derived Fibrinogen
	mg/dL	100	80.0	120	
	g/L	1.20	0.960	1.44	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	120	96.0	144	
	g/L	1.28	1.02	1.54	Renam Fibrinogen
	mg/dL	128	102	154	
	g/L	1.09	0.872	1.31	HemosIL RecombiPlasTin 2G
	mg/dL	109	87.2	131	
	g/L	1.46	1.17	1.75	Sclavo Fibrinogen
	mg/dL	146	117	175	
	g/L	1.40	1.12	1.68	Labitec Fibrinogen
	mg/dL	140	112	168	
	g/L	1.47	1.18	1.76	HemoDiagnostics Fibrinogen
	mg/dL	147	118	176	
	g/L	1.54	1.23	1.85	Helena Clauss Fibrinogen 100
	mg/dL	154	123	185	
	g/L	1.40	1.12	1.68	Beijing Succeeder Fibrinogen
	mg/dL	140	112	168	
	g/L	1.48	1.18	1.78	Cobas Fibrinogen
	mg/dL	148	118	178	
	g/L	1.30	1.04	1.56	Erba Thrombin Reagent
	mg/dL	130	104	156	
	g/L	1.15	0.920	1.38	MTI Diagnostics Fibrinogen
	mg/dL	115	92.0	138	
	g/L	1.21	0.968	1.45	Yumizen G Fibrinogen
	mg/dL	121	96.8	145	
	g/L	1.34	1.07	1.61	Roche Cobas t511/t711 Fibrinogen
	mg/dL	134	107	161	
	g/L	1.49	1.19	1.79	Roche Cobas t411 Fibrinogen
	mg/dL	149	119	179	
	g/L	1.33	1.06	1.60	Mindray/LongIsland Fibrinogen
	mg/dL	133	106	160	
Plasminogen activity	%	58.8	47.0	70.6	Stago Stachrom Plasminogen
	%	53.9	43.1	64.7	HemosIL Plasminogen
	%	59.0	47.2	70.8	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	55.6	44.5	66.7	Siemens/Dade Berichrom Protein C

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Analyte	unit	Target	low	high	methods
Protein C activity	%	61.5	49.2	73.8	Stago StaClot
	%	54.2	43.4	65.0	Biomerieux VIDAS Protein C
	%	53.1	42.5	63.7	IL HemosIL Protein C
	%	61.5	49.2	73.8	Siemens
	%	58.8	47.0	70.6	STACHrom Protein C
Protein S activity	%	53.2	37.2	69.2	STA Liatest
	%	47.0	32.9	61.1	Stago StaClot
	%	54.5	38.2	70.9	IL HemosIL Free Protein S
	%	42.9	30.0	55.8	Dade Protein S Ac
	%	50.9	35.6	66.2	Siemens Innovance Free PS Ag
	%	46.2	32.3	60.1	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	25.6	20.5	30.7	Siemens/Dade-Behring Innovin
	Seconds	15.9	12.7	19.1	Siemens/Dade Thromborel IS
	Seconds	16.2	13.0	19.4	Siemens/Dade-Behring Thromborel S
	Seconds	25.8	20.6	31.0	HemosIL PT-Fibrinogen HS Plus
	Seconds	24.4	19.5	29.3	Pacific Thromboplastin DS
	Seconds	23.1	18.5	27.7	Stago Neoplastine CI Plus
	Seconds	21.5	17.2	25.8	Teco TEClot PT-S
	Seconds	18.1	14.5	21.7	Stago Neoplastin R
	Seconds	15.3	12.2	18.4	Bio-Ksel System PT
	Seconds	20.7	16.6	24.8	Diagon PT
	Seconds	33.9	27.1	40.7	Weiner Lab Soluplastin
	Seconds	41.6	33.3	49.9	TCoag TriniCLOT PT Excel S
	Seconds	27.0	21.6	32.4	Biomedica QuikCoag PT-HS
	Seconds	15.9	12.7	19.1	HemosIL RecombiPlasTin 2G
	Seconds	27.3	21.8	32.8	Technoclone Technoplastin HIS
	Seconds	26.8	21.4	32.2	Helena Thromboplastin
	Seconds	20.3	16.2	24.4	Labitec PT
	Seconds	23.7	19.0	28.4	Dutch Diagnostics PT
	Seconds	24.2	19.4	29.0	Sclavo PT
	Seconds	27.1	21.7	32.5	Biolabo Bio-TP (Low ISI)
	Seconds	15.1	12.1	18.1	Bio-Ksel PT Plus
	Seconds	18.7	15.0	22.4	Beijing Succeder PT
	Seconds	23.1	18.5	27.7	Diagon PT R
	Seconds	16.8	13.4	20.2	Cobas PT Screen
	Seconds	30.6	24.5	36.7	Stago STA-NeoPTimal
	Seconds	26.3	21.0	31.6	MTI Diagnostics Prothrombin Time
	Seconds	22.1	17.7	26.5	Erba Protime PT
	Seconds	15.8	12.6	19.0	HemosIL ReadiPlasTin
	Seconds	34.5	27.6	41.4	Roche Cobas PT Rec
Prothrombin Time (PT) activity	%	22.5	18.0	27.0	Siemens/Dade-Behring Innovin
	%	53.9	43.1	64.7	Siemens/Dade-Behring Thromborel S
	%	37.1	29.7	44.5	Stago Neoplastine CI
	%	39.6	31.7	47.5	Stago Neoplastine CI Plus
	%	39.3	31.4	47.2	HemosIL PT-Fibrinogen HS Plus
	%	68.5	54.8	82.2	Stago SPA

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	59.7	47.8	71.6	Stago Neoplastin R
	%	39.5	31.6	47.4	Diagon PT
	%	24.6	19.7	29.5	Technology-Standard PT
	%	60.9	48.7	73.1	HemosIL RecombiPlasTin 2G
	%	53.8	43.0	64.6	Technoclone Technoplastin HIS
	%	36.5	29.2	43.8	Helena Thromboplastin
	%	41.5	33.2	49.8	Sclavo PT
	%	16.7	13.4	20.0	Haemo Diagnostics Thromboplastin
	%	39.1	31.3	46.9	Biolabo Bio-TP (Low ISI)
	%	71.9	57.5	86.3	Bio-Ksel PT Plus
	%	63.4	50.7	76.1	Beijing Succeeder PT
	%	51.0	40.8	61.2	Cobas PT Screen
	%	31.2	25.0	37.4	Stago STA-NeoPTimal
	%	45.0	36.0	54.0	Erba Protime PT
	%	25.1	20.1	30.1	Yumizen G PT
	%	61.0	48.8	73.2	HemosIL ReadiPlasTin
	%	16.1	12.9	19.3	Roche Cobas PT Rec
	%	36.4	29.1	43.7	Yumizen G PT Reco
Prothrombin Time (PT) INR	INR	2.53	2.02	3.04	Siemens/Dade-Behring Innovin
	INR	1.34	1.07	1.61	Siemens/Dade Thromborel IS
	INR	1.43	1.14	1.72	Siemens/Dade-Behring Thromborel S
	INR	1.92	1.54	2.30	HemosIL PT-Fibrinogen HS Plus
	INR	1.86	1.49	2.23	Stago Neoplastine CI Plus
	INR	2.15	1.72	2.58	Biolabo Bio-TP
	INR	1.21	0.968	1.45	Stago SPA
	INR	1.31	1.05	1.57	Stago Neoplastin R
	INR	2.12	1.70	2.54	Spinreact PT
	INR	4.10	3.28	4.92	TCoag TriniCLOT PT Excel S
	INR	2.03	1.62	2.44	Biomedica QuikCoag PT-HS
	INR	1.40	1.12	1.68	HemosIL RecombiPlasTin 2G
	INR	1.78	1.42	2.14	Helena Thromboplastin LI
	INR	1.67	1.34	2.00	Technoclone Technoplastin HIS
	INR	2.48	1.98	2.98	Helena Thromboplastin
	INR	1.79	1.43	2.15	Labitec PT
	INR	2.24	1.79	2.69	Dutch Diagnostics PT
	INR	1.94	1.55	2.33	Sclavo PT
	INR	1.64	1.31	1.97	Technoclone Technoclot PT Plus
	INR	2.17	1.74	2.60	Biolabo Bio-TP (Low ISI)
	INR	1.34	1.07	1.61	Bio-Ksel PT Plus
	INR	1.47	1.18	1.76	Beijing Succeeder PT
	INR	2.09	1.67	2.51	Diagon PT R
	INR	1.67	1.34	2.00	Cobas PT Screen
	INR	2.43	1.94	2.92	Stago STA-NeoPTimal
	INR	1.97	1.58	2.36	Erba Protime PT
	INR	1.44	1.15	1.73	HemosIL ReadiPlasTin
	INR	3.61	2.89	4.33	Roche Cobas PT Rec

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) ratio	ratio	2.72	2.18	3.26	Siemens/Dade-Behring Innovin
	ratio	1.43	1.14	1.72	Siemens/Dade-Behring Thromborel S
	ratio	1.94	1.55	2.33	Stago Neoplastine CI Plus
	ratio	1.83	1.46	2.20	Diagon PT
	ratio	1.73	1.38	2.08	HemosIL PT-Fibrinogen HS Plus
	ratio	1.40	1.12	1.68	HemosIL RecombiPlasTin 2G
	ratio	1.91	1.53	2.29	Sclavo PT
	ratio	2.40	1.92	2.88	Stago STA-NeoPTimal
	ratio	1.37	1.10	1.64	HemosIL ReadiPlasTin
Thrombin Time (TT)	Seconds	30.3	24.2	36.4	Dade Thrombin
	Seconds	29.6	23.7	35.5	Siemens/Dade Thromboclotin
	Seconds	37.5	30.0	45.0	Stago Thrombin
	Seconds	29.1	23.3	34.9	Sysmex Thrombin Time
	Seconds	34.4	27.5	41.3	Technology-Standard Thrombin
	Seconds	32.2	25.8	38.6	Helena Thrombin Clotting Time rgt
	Seconds	28.5	22.8	34.2	HemosIL Thrombin Time 5ml
	Seconds	33.4	26.7	40.1	HemosIL Thrombin Time 8ml
	Seconds	39.6	31.7	47.5	Siemens BC Thrombin
	Seconds	21.7	17.4	26.0	MTI Diagnostics Thrombin Time