

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat No. CG5022
Size: 12 x 1 ml

Lot No. 163CG
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°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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COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 163CG Size: 12 x 1 ml Expiry: 2017-09

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	82.7	66.2	99.0	Trinity/Biomerieux Platelin LS/APTT HS
	seconds	90.1	72.1	108	Siemens/Dade Actin
	seconds	67.1	53.1	81.1	Siemens/Dade Actin FS
	seconds	57.9	45.3	70.5	Siemens/Dade Actin FSL
	seconds	114	91.2	137	Siemens/Dade Actin SL
	seconds	116	92.1	140	Siemens/Dade Pathromtin SL
	seconds	83.1	63.7	103	Helena aPTT
	seconds	83.5	66.8	100	Helena APTT ES
	seconds	66.0	52.8	79.2	HemosIL APTT-SP Liquid
	seconds	65.7	52.6	78.8	HemosIL Synthasil
	seconds	64.6	51.7	77.5	HemosIL Synthafax
	seconds	62.8	50.2	75.4	Pacific Hemostasis APTT-XL
	seconds	79.3	62.4	96.2	Stago aPTT
	seconds	71.1	56.9	85.3	Stago Cephascreen
	seconds	77.1	58.8	95.4	Stago CK-Prest
	seconds	82.7	66.2	99.0	Stago PTT Automate
	seconds	69.8	50.9	88.7	Teco TEClot APTT
	seconds	75.7	60.6	90.8	Human Hemostat APTT
	seconds	66.2	53.0	79.4	Bio-Ksel System APTTs
	seconds	91.3	73.0	110	Diagon Dia-PTT
	seconds	80.2	64.2	96.2	Biolabo Bio-CK APTT
	seconds	81.0	64.8	97.2	Spinreact APTT
	seconds	88.5	70.8	106	SGM Italia aPTT
	seconds	82.4	65.9	98.9	Trinity/Biomerieux Triniclot aPTT
	seconds	85.9	68.7	103	Biodevice aPTT
	seconds	62.4	49.9	74.9	Biomedica QuikCoag aPTT
	seconds	84.5	67.6	101	Siemens Dade Actin Cephaloplastin
	seconds	66.4	48.3	84.5	Beijing Steellex aPTT
	seconds	68.0	54.4	81.6	Technoclone Siron aPTT
	seconds	73.5	56.5	90.5	Sclavo APTT-S
	seconds	85.7	67.1	104	HemoDiagnostics aPTT
	seconds	80.5	64.4	96.6	Cypress Diagnostics aPTT
	seconds	44.6	35.7	53.5	LTA APTT Ellagic Acid
	seconds	83.9	67.1	101	Tokra Medikal APTT
	seconds	60.5	48.4	72.6	Coagpia APTT-N
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.15	1.72	2.58	Siemens/Dade Actin FSL
	ratio	3.92	3.14	4.70	Siemens/Dade Actin SL
	ratio	2.40	1.92	2.88	Stago Cephascreen
	ratio	2.32	1.86	2.78	Stago PTT Automate
	ratio	2.51	1.85	3.17	Stago aPTT
	ratio	3.47	2.78	4.16	Siemens/Dade Pathromtin SL
	ratio	2.17	1.74	2.60	HemosIL APTT-SP Liquid

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 163CG Size: 12 x 1 ml Expiry: 2017-09

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.16	1.73	2.59	HemosIL Synthasil
	ratio	1.99	1.59	2.39	Pacific Hemostasis APTT-XL
	ratio	2.29	1.66	2.92	Stago CK-Prest
	ratio	2.30	1.66	2.94	Human Hemostat APTT
	ratio	1.96	1.57	2.35	Bio-Ksel System APTTs
	ratio	2.49	1.99	2.99	Siemens/Dade Actin FS
	ratio	2.52	2.02	3.02	Diagon Dia-PTT
	ratio	2.58	2.06	3.10	Biolabo Bio-CK APTT
	ratio	2.30	1.84	2.76	Spinreact APTT
	ratio	3.18	2.43	3.93	Siemens/Dade Actin
	ratio	2.04	1.63	2.45	Hemosil aPTT Lyophilised Silica
	ratio	3.39	2.71	4.07	Biodevice aPTT
	ratio	2.60	1.95	3.25	Sclavo APTT-S
	ratio	2.97	2.12	3.82	HemoDiagnostics aPTT
Antithrombin III activity	%	56.7	45.4	68.0	Siemens/Dade Berichrom ATIII
	%	57.1	45.7	68.5	Helena Chrom-Z
	%	57.7	46.2	69.2	HemosIL Liquid Antithrombin
	%	62.0	49.6	74.4	Roche Chronogenic Thrombin
	%	55.2	41.0	69.4	Hemosil Lyophilised Antithrombin III
	%	60.7	48.6	72.8	STACHrom ATIII
	%	57.2	45.8	68.6	Siemens/Dade Antithrombin III
	%	65.0	49.1	80.9	Biodevice ATIII
	%	59.5	47.6	71.4	Siemens Innovance Antithrombin III
	%	63.9	51.1	76.7	Sclavo ATIII
Factor II activity	%	18.9	14.4	23.4	Dade Innovin
	%	21.4	16.8	26.0	Siemens/Dade Thromborel S
	%	19.2	15.4	23.0	HemosIL PT-Fibrinogen HS Plus
	%	18.4	14.7	22.1	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	18.6	14.9	22.3	Stago Neoplastin R
Factor IX activity	%	23.4	16.5	30.3	Stago PTT Automate
	%	19.1	15.3	22.9	Siemens/Dade Actin FS
	%	24.6	19.7	29.5	Siemens/Dade Pathromtin SL
	%	17.0	12.9	21.1	HemosIL Synthasil
	%	20.8	16.6	25.0	Stago CK-Prest
	%	22.5	18.0	27.0	Siemens/Dade Actin FSL
	%	21.4	17.1	25.7	HemosIL APTT-SP Liquid
	%	22.0	15.6	28.4	Stago aPTT
	%	29.4	23.5	35.3	Siemens Dade Actin Cephaloplastin
Factor V activity	%	38.0	30.4	45.6	Stago Neoplastine CI Plus
	%	39.8	29.1	50.5	Siemens/Dade Thromborel S
	%	36.9	29.5	44.3	Dade Innovin
	%	35.5	28.4	42.6	Stago Neoplastine CI
	%	35.7	28.6	42.8	HemosIL PT-Fibrinogen HS Plus
	%	36.2	29.0	43.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	34.3	27.0	41.6	Stago Neoplastin R
Factor VII activity	%	21.7	16.9	26.5	Stago Neoplastine CI Plus

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

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Range					
Analyte	unit	Target	low	high	methods
Factor VII activity	%	23.7	19.0	28.4	Siemens/Dade Thromborel S
	%	25.1	18.9	31.3	Dade Innovin
	%	21.0	15.3	26.7	Stago Neoplastine CI
	%	22.6	18.1	27.1	HemosIL PT-Fibrinogen HS Plus
	%	24.1	17.7	30.5	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	25.8	20.6	31.0	Stago Neoplastin R
Factor VIII activity	%	29.6	23.0	36.2	Stago CK-Prest
	%	29.7	23.8	35.6	Stago PTT Automate
	%	30.3	22.8	37.8	Siemens/Dade Actin FS
	%	33.4	25.8	41.0	Siemens/Dade Pathromtin SL
	%	30.3	24.2	36.4	Siemens/Dade Actin FSL
	%	24.6	19.7	29.5	HemosIL Synthasil
	%	34.2	27.4	41.0	HemosIL APTT-SP Liquid
	%	35.8	28.6	43.0	Stago aPTT
Factor X activity	%	21.4	16.2	26.6	Siemens/Dade Thromborel S
	%	21.6	17.3	25.9	Dade Innovin
	%	18.0	14.3	21.7	HemosIL PT-Fibrinogen HS Plus
	%	19.3	15.4	23.2	Stago Neoplastine CI Plus
	%	19.0	14.3	23.7	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	19.0	15.2	22.8	Stago Neoplastin R
Factor XI activity	%	15.3	12.2	18.4	Siemens/Dade Actin FS
	%	22.9	18.3	27.5	Siemens/Dade Pathromtin SL
	%	16.5	12.0	21.0	HemosIL Synthasil
	%	19.5	15.6	23.4	Siemens/Dade Actin FSL
	%	14.7	11.6	17.8	Stago CK-Prest
	%	17.3	13.8	20.8	Stago aPTT
Factor XII activity	%	40.1	32.1	48.1	Siemens/Dade Actin FS
	%	44.0	35.2	52.8	Siemens/Dade Pathromtin SL
	%	50.8	40.6	61.0	Siemens/Dade Actin FSL
	%	50.6	40.5	60.7	HemosIL APTT-SP Liquid
Fibrinogen	g/L	2.01	1.61	2.41	HemosIL PT-Fibrinogen HS Plus
	mg/dL	201	161	241	
	g/L	1.78	1.42	2.14	Stago Fibrinogen
	mg/dL	178	142	214	
	g/L	1.71	1.37	2.05	Trinity/AMAX Thrombin
	mg/dL	171	137	205	
	g/L	2.01	1.59	2.43	Dade Multifibrin
	mg/dL	201	159	243	
	g/L	1.78	1.42	2.14	HemosIL Fibrinogen C
	mg/dL	178	142	214	
	g/L	1.64	1.31	1.97	Dade Thrombin
	mg/dL	164	131	197	
	g/L	1.64	1.31	1.97	Technoclone Fibrinogen
	mg/dL	164	131	197	
	g/L	1.72	1.28	2.16	Trinity/Biopool Fibrinogen
	mg/dL	172	128	216	

%

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Range					
Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	1.69	1.35	2.03	Biolabo Bio-Fibri
	mg/dL	169	135	203	
	g/L	1.63	1.15	2.11	Teco Teclot Fibrinogen
	mg/dL	163	115	211	
	g/L	1.68	1.34	2.02	HemosIL QFA (bovine thrombin)
	mg/dL	168	134	202	
	g/L	1.52	1.21	1.83	Pacific Hemostasis Fibrinogen
	mg/dL	152	121	183	
	g/L	1.77	1.42	2.12	Human Fibrinogen
	mg/dL	177	142	212	
	g/L	1.82	1.45	2.19	Stago STA Fibri-Prest Automate
	mg/dL	182	145	219	
	g/L	2.14	1.71	2.57	Bio-Ksel System PT
	mg/dL	214	171	257	
	g/L	1.60	1.28	1.92	Bio-Ksel Fibrinogen
	mg/dL	160	128	192	
	g/L	1.71	1.37	2.05	Diagon Dia-FIB
	mg/dL	171	137	205	
	g/L	1.67	1.34	2.00	Dade Innovin Derived Fibrinogen
	mg/dL	167	134	200	
	g/L	1.70	1.24	2.16	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	170	124	216	
	g/L	1.60	1.28	1.92	Liofilchem Fibrinogen
	mg/dL	160	128	192	
	g/L	2.03	1.62	2.44	Biodevice PT
	mg/dL	203	162	244	
	g/L	1.82	1.46	2.18	Spinreact Fibrinogen
	mg/dL	182	146	218	
	g/L	1.96	1.57	2.35	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	196	157	235	
	g/L	1.79	1.43	2.15	Sclavo Fibrinogen
	mg/dL	179	143	215	
	g/L	2.12	1.70	2.54	Labitec Fibrinogen
	mg/dL	212	170	254	
	g/L	1.97	1.58	2.36	HemoDiagnostica Fibrinogen
	mg/dL	197	158	236	
	g/L	1.89	1.49	2.29	Beijing Steelex Fibrinogen
	mg/dL	189	149	229	
	g/L	1.40	1.12	1.68	Helena Clauss Fibrinogen 100
	mg/dL	140	112	168	
	g/L	1.59	1.27	1.91	Tokra Medikal Fibrinogen
	mg/dL	159	127	191	
	g/L	2.16	1.73	2.59	R2 Phosphoplastin RL
	mg/dL	216	173	259	
	g/L	1.93	1.54	2.32	Coagpia Fibrinogen
	mg/dL	193	154	232	

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 163CG Size: 12 x 1 ml Expiry: 2017-09

Range					
Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	2.57	2.06	3.08	HemosIL PT-Fibrinogen
	mg/dL	257	206	308	
Plasminogen activity	%	71.0	56.8	85.2	Stago Stachrom Plasminogen
	%	56.0	44.8	67.2	HemosIL Plasminogen
	%	61.7	49.4	74.0	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	21.6	17.3	25.9	Helena Elisa
	%	23.3	18.6	28.0	Siemens/Dade Berichrom Protein C
	%	21.3	17.0	25.6	Biomerieux VIDAS Protein C
	%	19.6	15.7	23.5	IL HemosIL Protein C
	%	24.4	19.5	29.3	STACHrom Protein C
	%	25.1	20.1	30.1	Chromogenix Coatest APC
	%	27.4	21.9	32.9	Siemens/Dade Protein C Clotting
Protein S activity	%	19.7	13.8	25.6	STA Liatest
	%	15.6	10.9	20.3	Stago StaClot
	%	33.5	23.5	43.6	Siemens/Dade Protein S
	%	20.3	14.2	26.4	IL HemosIL Free Protein S
	%	19.3	13.5	25.1	Siemens Innovance Free PS Ag
Prothrombin Time (PT)	Seconds	25.9	20.7	31.1	Trinity/Biomerieux Simplastin/PT HTF
	Seconds	21.5	17.2	25.8	Dade Innovin
	Seconds	27.0	21.6	32.4	Siemens/Dade Thromborel S
	Seconds	23.1	18.5	27.7	HemosIL PT-Fibrinogen
	Seconds	31.9	25.5	38.3	HemosIL PT-Fibrinogen HS Plus
	Seconds	39.3	29.4	49.2	Pacific Thromboplastin DS
	Seconds	30.8	24.6	37.0	STA Hepato Quick
	Seconds	27.4	21.9	32.9	Stago Neoplastine CI
	Seconds	29.9	23.9	35.9	Stago Neoplastine CI Plus
	Seconds	27.5	22.0	33.0	Teco TEClot PT-S
	Seconds	31.3	25.0	37.6	Biolabo Bio-TP
	Seconds	35.3	28.2	42.4	Stago Neoplastin R
	Seconds	26.1	18.9	33.3	Bio-Ksel System PT
	Seconds	28.3	22.6	34.0	Human Thromboplastin
	Seconds	29.1	23.3	34.9	Diagon, Dia-PT
	Seconds	32.0	25.6	38.4	Weiner Lab Soluplastin
	Seconds	28.6	22.9	34.3	Spinreact PT
	Seconds	30.7	24.6	36.8	Trinity/Biomerieux Simplastin/PT Excel S
	Seconds	25.0	20.0	30.0	Biodevice PT
	Seconds	25.2	20.2	30.2	Biomedica QuikCoag PT-HS
	Seconds	26.3	21.0	31.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	31.8	25.4	38.2	Helena Thromboplastin LI
	Seconds	31.0	24.8	37.2	Renam PT
	Seconds	26.5	21.2	31.8	Beijing Steellex PT
	Seconds	30.9	24.3	37.5	Labitec PT
	Seconds	29.9	23.9	35.9	SGM Italia Thromboplastin
	Seconds	27.3	21.8	32.8	Technoclone Technoclot PT Plus
	Seconds	28.7	21.5	35.9	Tokra Medikal PT
	Seconds	28.3	22.6	34.0	Coagpia PT-N

%

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	24.7	19.8	29.6	Trinity/Biomerieux Simplastin/PT HTF
	%	31.6	25.3	37.9	Dade Innovin
	%	29.3	23.4	35.2	Siemens/Dade Thromborel S
	%	29.5	23.6	35.4	Stago Neoplastine CI
	%	27.5	22.0	33.0	Stago Neoplastine CI Plus
	%	28.0	22.4	33.6	HemosIL PT-Fibrinogen
	%	27.1	21.4	32.8	HemosIL PT-Fibrinogen HS Plus
	%	19.3	15.4	23.2	Stago SPA
	%	28.1	22.5	33.7	Stago Neoplastin R
	%	43.3	34.6	52.0	Bio-Ksel System PT
	%	28.1	20.0	36.2	Human Thromboplastin
	%	32.1	25.5	38.7	Diagon, Dia-PT
	%	29.4	23.5	35.3	SGM Italia Thromboplastin
	%	27.2	19.6	34.8	Trinity/Biomerieux Simplastin/PT Excel S
	%	32.0	25.6	38.4	Biodevice PT
	%	29.5	22.4	36.6	Biomedica QuikCoag PT-HS
	%	30.0	24.0	36.0	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	25.8	20.6	31.0	Labitec PT
	%	25.6	20.5	30.7	Technoclon Technoclot PT Plus
	%	23.8	19.0	28.6	Coagpia PT-N
Prothrombin Time (PT) INR	INR	2.34	1.87	2.81	Trinity/Biomerieux Simplastin/PT HTF
	INR	2.00	1.60	2.40	Dade Innovin
	INR	2.31	1.85	2.77	Siemens/Dade Thromborel IS
	INR	2.33	1.86	2.80	Siemens/Dade Thromborel S
	INR	2.63	2.01	3.25	HemosIL PT-Fibrinogen
	INR	2.62	2.10	3.14	HemosIL PT-Fibrinogen HS Plus
	INR	3.25	2.53	3.97	Pacific Thromboplastin DS
	INR	2.99	2.39	3.59	STA Hepato Quick
	INR	3.07	2.46	3.68	Stago Neoplastine CI
	INR	2.90	2.32	3.48	Stago Neoplastine CI Plus
	INR	2.39	1.91	2.87	Human Thromboplastin
	INR	2.18	1.70	2.66	Teco TEClot PT-S
	INR	2.96	2.37	3.55	Biolabo Bio-TP
	INR	2.64	2.11	3.17	Stago SPA
	INR	2.49	1.99	2.99	Stago Neoplastin R
	INR	2.25	1.80	2.70	Bio-Ksel System PT
	INR	2.37	1.90	2.84	Grifols DG-PT
	INR	2.49	1.97	3.01	Diagon, Dia-PT
	INR	2.67	1.97	3.37	Weiner Lab Soluplastin
	INR	2.19	1.75	2.63	Spinreact PT
	INR	2.56	2.05	3.07	Technology-Standard PT
	INR	2.41	1.93	2.89	SGM Italia Thromboplastin
	INR	2.28	1.82	2.74	Biodevice PT
	INR	2.22	1.78	2.66	Biomedica QuikCoag PT-HS
	INR	2.33	1.86	2.80	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	2.20	1.76	2.64	Teco Teclot PT

%

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) INR	INR	2.46	1.97	2.95	Beijing Steellex PT
	INR	2.31	1.85	2.77	Labitec PT
	INR	2.17	1.74	2.60	LTA PT Calcium Thromboplastin
	INR	2.11	1.69	2.53	Technoclone Technoclot PT Plus
	INR	2.37	1.90	2.84	Tokra Medikal PT
	INR	2.47	1.98	2.96	Coagpia PT-N
Prothrombin Time (PT) ratio	ratio	2.01	1.61	2.41	Dade Innovin
	ratio	2.32	1.86	2.78	Siemens/Dade Thromborel S
	ratio	2.28	1.82	2.74	Stago Neoplastine CI Plus
	ratio	2.56	2.05	3.07	Stago Neoplastin R
	ratio	2.43	1.94	2.92	Diagon, Dia-PT
	ratio	2.34	1.87	2.81	HemosIL PT-Fibrinogen HS Plus
	ratio	2.31	1.85	2.77	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	2.38	1.90	2.86	Technoclone Technoplastin HIS
	ratio	2.20	1.76	2.64	Biodevice PT
Thrombin Time (TT)	Seconds	27.4	21.9	32.9	Dade Thrombin
	Seconds	18.4	14.7	22.1	Siemens/Dade Thromboclotin
	Seconds	21.6	17.3	25.9	Stago Thrombin
	Seconds	26.4	20.1	32.7	Sysmex Thrombin Time
	Seconds	24.7	19.8	29.6	Technology-Standard Thrombin
	Seconds	23.5	18.8	28.2	Human - Hemostat
	Seconds	20.7	16.6	24.8	Teco TEClot APTT