

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG 5023 **Lot No.** 304CG
Size: 12 x 1 ml **Expiry:** 2021-11-28

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.

- 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.
- Refer to the Control section of the individual analyser application.
- 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

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 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 304CG Size 12 x 1 ml Expiry 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT)	seconds	56.9	45.5	68.3	Tcoag TriniCLOT aPTT S
	seconds	52.2	41.8	62.6	Tcoag TriniCLOT aPTT HS
	seconds	50.7	40.6	60.8	Siemens/Dade Actin
	seconds	46.7	37.4	56.0	Siemens/Dade Actin FS
	seconds	44.0	35.2	52.8	Siemens/Dade Actin FSL
	seconds	82.7	66.2	99.0	Siemens/Dade Actin SL
	seconds	84.6	67.7	102	Siemens/Dade Pathromtin SL
	seconds	43.5	34.8	52.2	HemosIL APTT-SP Liquid
	seconds	63.2	50.6	75.8	HemosIL Synthasil
	seconds	59.2	47.4	71.0	Pacific Hemostasis APTT-XL
	seconds	55.9	44.7	67.1	Stago aPTT
	seconds	49.4	39.5	59.3	Stago Cephascreen
	seconds	58.9	47.1	70.7	Stago CK-Prest
	seconds	59.4	47.5	71.3	Stago PTT Automate
	seconds	57.5	46.0	69.0	Teco TEClot APTT
	seconds	48.3	38.6	58.0	Human Hemostat APTT
	seconds	47.1	37.7	56.5	Bio-Ksel System APTTs
	seconds	67.6	54.1	81.1	Diagon Dia-PTT
	seconds	48.4	38.7	58.1	Weiner Lab APTT
	seconds	51.6	41.3	61.9	Biolabo Bio-CK APTT
	seconds	54.9	43.9	65.9	Spinreact APTT
	seconds	54.8	43.8	65.8	Technology-Standard aPTT
	seconds	54.2	43.4	65.0	Media IVD aPTT
	seconds	50.1	40.1	60.1	Biomedica QuikCoag aPTT
	seconds	68.5	54.8	82.2	Hemosil aPTT Lyophilised Silica
	seconds	51.8	41.4	62.2	Siemens/Dade Actin Cephaloplastin
	seconds	54.0	43.2	64.8	Labitec aPTT
	seconds	58.1	46.5	69.7	Sclavo APTT-S
	seconds	50.4	40.3	60.5	HemoDiagnostica aPTT
	seconds	59.8	47.8	71.8	Cypress Diagnostics aPTT
seconds	50.9	40.7	61.1	Fortress Diagnostics aPTT	
seconds	68.2	54.6	81.8	Tokra Medikal APTT	
seconds	43.5	34.8	52.2	Coagpia APTT-N	
seconds	84.3	67.4	101	Cobas aPTT MedS	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.80	1.44	2.16	Tcoag TriniCLOT aPTT S
	ratio	1.65	1.32	1.98	Siemens/Dade Actin FSL
	ratio	2.60	2.08	3.12	Siemens/Dade Actin SL
	ratio	1.64	1.31	1.97	Stago Cephascreen
	ratio	1.79	1.43	2.15	Stago PTT Automate
	ratio	1.76	1.41	2.11	Stago aPTT
	ratio	2.67	2.14	3.20	Siemens/Dade Pathromtin SL
	ratio	1.43	1.14	1.72	HemosIL APTT-SP Liquid

COAGULATION CONTROL LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 304CG Size 12 x 1 ml Expiry 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.09	1.67	2.51	HemosIL Synthasil
	ratio	1.93	1.54	2.32	Stago CK-Prest
	ratio	1.66	1.33	1.99	Human Hemostat APTT
	ratio	1.40	1.12	1.68	Bio-Ksel System APTTs
	ratio	1.83	1.46	2.20	Siemens/Dade Actin FS
	ratio	1.90	1.52	2.28	Diagon Dia-PTT
	ratio	1.86	1.49	2.23	Siemens/Dade Actin
	ratio	1.89	1.51	2.27	Media IVD aPTT
	ratio	1.94	1.55	2.33	Biodevice aPTT
	ratio	1.74	1.39	2.09	Labitec aPTT
	ratio	2.05	1.64	2.46	Sclavo APTT-S
ratio	1.36	1.09	1.63	Coagpia APTT-N	
Antithrombin III activity	%	64.1	51.3	76.9	Siemens/Dade Berichrom ATIII
	%	59.7	47.8	71.6	HemosIL Liquid Antithrombin
	%	62.3	49.8	74.8	Roche Chronogenic Thrombin
	%	59.6	47.7	71.5	Hemosil Lyophilised Antithrombin III
	%	64.6	51.7	77.5	STACHrom ATIII
	%	69.2	55.4	83.0	Siemens/Dade Antithrombin III
	%	60.6	48.5	72.7	Diagon ATIII
	%	61.8	49.4	74.2	Siemens Innovance Antithrombin III
	%	60.1	48.1	72.1	Sclavo ATIII
	%	62.0	49.6	74.4	Teco TEChrom AT
Factor II activity	%	65.8	52.6	79.0	Siemens/Dade-Behring Innovin
	%	68.4	54.7	82.1	Siemens/Dade-Behring Thromborel S
	%	64.5	51.6	77.4	HemosIL PT-Fibrinogen HS Plus
	%	63.5	50.8	76.2	HemosIL RecombiPlasTin 2G
	%	58.5	46.8	70.2	HemosIL Factor II deficient plasma
Factor IX activity	%	61.6	49.3	73.9	Stago PTT Automate
	%	57.2	45.8	68.6	Siemens/Dade Actin FS
	%	60.4	48.3	72.5	Siemens/Dade Pathromtin SL
	%	56.7	45.4	68.0	HemosIL Synthasil
	%	62.0	49.6	74.4	Stago CK-Prest
	%	59.1	47.3	70.9	Siemens/Dade Actin FSL
	%	68.7	55.0	82.4	Stago Deficient / ImmunoDef IX
	%	55.9	44.7	67.1	HemosIL Factor IX deficient plasma
Factor V activity	%	51.1	40.9	61.3	Siemens/Dade-Behring Thromborel S
	%	47.5	38.0	57.0	Siemens/Dade-Behring Innovin
	%	44.8	35.8	53.8	HemosIL PT-Fibrinogen HS Plus
	%	49.2	39.4	59.0	HemosIL RecombiPlasTin 2G
	%	40.3	32.2	48.4	Stago Neoplastin R
	%	48.3	38.6	58.0	HemosIL Factor V deficient plasma
Factor VII activity	%	75.0	60.0	90.0	Siemens/Dade-Behring Thromborel S
	%	85.5	68.4	103	Siemens/Dade-Behring Innovin
	%	70.4	56.3	84.5	HemosIL PT-Fibrinogen HS Plus
	%	89.6	71.7	108	HemosIL RecombiPlasTin 2G
	%	75.5	60.4	90.6	Stago Neoplastin R

COAGULATION CONTROL LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 304CG Size 12 x 1 ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Factor VII activity	%	85.3	68.2	102	HemosIL Factor VII deficient plasma
Factor VIII activity	%	40.1	32.1	48.1	Stago CK-Prest
	%	36.2	29.0	43.4	Stago PTT Automate
	%	40.7	32.6	48.8	Siemens/Dade Actin FS
	%	38.5	30.8	46.2	Siemens/Dade Pathromtin SL
	%	37.5	30.0	45.0	Siemens/Dade Actin FSL
	%	35.3	28.2	42.4	HemosIL Synthasil
	%	35.9	28.7	43.1	HemosIL APTT-SP Liquid
	%	35.5	28.4	42.6	Stago STA Factor VIII
	%	37.6	30.1	45.1	Stago Deficient / ImmunoDef VIII
Factor X activity	%	36.2	29.0	43.4	HemosIL Factor VIII deficient plasma
	%	70.7	56.6	84.8	Siemens/Dade-Behring Thromborel S
	%	70.0	56.0	84.0	Siemens/Dade-Behring Innovin
	%	66.1	52.9	79.3	HemosIL PT-Fibrinogen HS Plus
	%	72.0	57.6	86.4	Stago Neoplastine CI Plus
	%	66.2	53.0	79.4	HemosIL RecombiPlasTin 2G
Factor XI activity	%	66.4	53.1	79.7	HemosIL Factor X deficient plasma
	%	36.4	29.1	43.7	Siemens/Dade Actin FS
	%	37.2	29.8	44.6	Siemens/Dade Pathromtin SL
	%	34.7	27.8	41.6	HemosIL Synthasil
	%	29.5	23.6	35.4	Siemens/Dade Actin FSL
	%	39.1	31.3	46.9	HemosIL APTT-SP Liquid
Factor XII activity	%	32.9	26.3	39.5	HemosIL Factor XI Deficient Plasma
	%	59.8	47.8	71.8	Siemens/Dade Actin FS
	%	55.0	44.0	66.0	Siemens/Dade Pathromtin SL
	%	60.2	48.2	72.2	HemosIL Synthasil
	%	59.7	47.8	71.6	Siemens/Dade Actin FSL
Fibrinogen	%	66.4	53.1	79.7	HemosIL Factor XII deficient plasma
	g/L	1.89	1.51	2.27	HemosIL PT-Fibrinogen HS Plus
	mg/dL	189	151	227	
	g/L	1.91	1.53	2.29	Stago Fibrinogen / Liquid-Fib
	mg/dL	191	153	229	
	g/L	1.34	1.07	1.61	Siemens/Dade Multifibren U
	mg/dL	134	107	161	
	g/L	1.87	1.50	2.24	HemosIL Fibrinogen C
	mg/dL	187	150	224	
	g/L	1.58	1.26	1.90	Dade Thrombin
	mg/dL	158	126	190	
	g/L	2.21	1.77	2.65	Technoclone Fibrinogen
	mg/dL	221	177	265	
	g/L	1.90	1.52	2.28	Tcoag TriniCLOT Fibrinogen
	mg/dL	190	152	228	
g/L	1.67	1.34	2.00	Biolabo Bio-Fibri	
mg/dL	167	134	200		
g/L	1.75	1.40	2.10	Teco Teclot Fibrinogen	
mg/dL	175	140	210		

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Cat. No. CG5023 Lot. No. 304CG Size 12 x 1 ml Expiry 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Fibrinogen	g/L	1.71	1.37	2.05	HemosIL QFA (bovine thrombin)
	mg/dL	171	137	205	
	g/L	1.81	1.45	2.17	Human Fibrinogen
	mg/dL	181	145	217	
	g/L	1.96	1.57	2.35	Stago STA Fibri-Prest Automate
	mg/dL	196	157	235	
	g/L	1.88	1.50	2.26	Bio-Ksel Fibrinogen
	mg/dL	188	150	226	
	g/L	1.63	1.30	1.96	Diagon Dia-F
	mg/dL	163	130	196	
	g/L	1.24	0.992	1.49	Dade Innovin Derived Fibrinogen
	mg/dL	124	99.2	149	
	g/L	1.44	1.15	1.73	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	144	115	173	
	g/L	2.21	1.77	2.65	Wiener Lab Fibrinogen
	mg/dL	221	177	265	
	g/L	1.28	1.02	1.54	HemosIL RecombiPlasTin 2G
	mg/dL	128	102	154	
	g/L	1.83	1.46	2.20	Sclavo Fibrinogen
	mg/dL	183	146	220	
g/L	2.08	1.66	2.50	Labitec Fibrinogen	
mg/dL	208	166	250		
g/L	1.75	1.40	2.10	HemoDiagnostica Fibrinogen	
mg/dL	175	140	210		
g/L	1.86	1.49	2.23	Cypress Diagnostics Fibrinogen	
mg/dL	186	149	223		
g/L	1.95	1.56	2.34	Helena Clauss Fibrinogen 100	
mg/dL	195	156	234		
g/L	1.55	1.24	1.86	Tokra Medikal Fibrinogen	
mg/dL	155	124	186		
g/L	1.61	1.29	1.93	Coagpia Fibrinogen	
mg/dL	161	129	193		
g/L	1.84	1.47	2.21	HemosIL PT-Fibrinogen	
mg/dL	184	147	221		
g/L	2.07	1.66	2.48	Beijing Succeeder Fibrinogen	
mg/dL	207	166	248		
g/L	1.80	1.44	2.16	Cobas Fibrinogen	
mg/dL	180	144	216		
Plasminogen activity	%	64.5	51.6	77.4	Stago Stachrom Plasminogen
	%	65.0	52.0	78.0	HemosIL Plasminogen
	%	68.2	54.6	81.8	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	66.4	53.1	79.7	Siemens/Dade Berichrom Protein C
	%	64.3	51.4	77.2	Stago StaClot
	%	58.0	46.4	69.6	Biomerieux VIDAS Protein C
	%	63.1	50.5	75.7	IL HemosIL Protein C
	%	68.3	54.6	82.0	Siemens

COAGULATION CONTROL LEVEL 3 (COAG CONTROL 3)

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Range					
Analyte	unit	Target	low	high	methods
Protein C activity	%	66.4	53.1	79.7	STACHrom Protein C
Protein S activity	%	67.2	47.0	87.4	STA Liatest
	%	64.5	45.2	83.9	Stago StaClot
	%	64.3	45.0	83.6	IL HemosIL Free Protein S
	%	46.2	32.3	60.1	Dade Protein S Ac
	%	63.7	44.6	82.8	Siemens Innovance Free PS Ag
	%	51.0	35.7	66.3	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	20.2	16.2	24.2	Siemens/Dade-Behring Innovin
	Seconds	16.5	13.2	19.8	Siemens/Dade Thromborel IS
	Seconds	16.5	13.2	19.8	Siemens/Dade-Behring Thromborel S
	Seconds	22.7	18.2	27.2	HemosIL PT-Fibrinogen HS Plus
	Seconds	30.1	24.1	36.1	Pacific Thromboplastin DS
	Seconds	21.5	17.2	25.8	Stago Neoplastine CI
	Seconds	19.9	15.9	23.9	Stago Neoplastine CI Plus
	Seconds	31.6	25.3	37.9	R2 Phosphoplastin RL
	Seconds	19.5	15.6	23.4	Teco TEClot PT-S
	Seconds	17.9	14.3	21.5	Stago Neoplastin R
	Seconds	13.8	11.0	16.6	Bio-Ksel System PT
	Seconds	18.5	14.8	22.2	Human Thromboplastin
	Seconds	20.1	16.1	24.1	Diagon PT
	Seconds	25.7	20.6	30.8	Weiner Lab Soluplastin
	Seconds	19.4	15.5	23.3	Spinreact PT
	Seconds	28.1	22.5	33.7	TCoag TriniCLOT PT Excel S
	Seconds	22.2	17.8	26.6	Media IVD PT
	Seconds	17.6	14.1	21.1	Biodevice PT
	Seconds	21.9	17.5	26.3	Biomedica QuikCoag PT-HS
	Seconds	14.5	11.6	17.4	HemosIL RecombiPlasTin 2G
	Seconds	23.5	18.8	28.2	Helena Thromboplastin
	Seconds	20.7	16.6	24.8	Labitec PT
	Seconds	18.2	14.6	21.8	Cypress Diagnostics PT
	Seconds	28.8	23.0	34.6	Fortress Diagnostics PT with Calcium
	Seconds	18.8	15.0	22.6	Tokra Medikal PT
	Seconds	26.5	21.2	31.8	Coagpia PT-N
	Seconds	13.7	11.0	16.4	Bio-Ksel PT Plus
	Seconds	21.8	17.4	26.2	Beijing Succeeder PT
	Seconds	16.3	13.0	19.6	Diagon PT R
	Seconds	17.4	13.9	20.9	Cobas PT Screen
Seconds	27.1	21.7	32.5	Stago STA-NeoPTimal	
Prothrombin Time (PT) activity	%	32.1	25.7	38.5	Siemens/Dade-Behring Innovin
	%	53.6	42.9	64.3	Siemens/Dade-Behring Thromborel S
	%	45.0	36.0	54.0	Stago Neoplastine CI
	%	45.7	36.6	54.8	Stago Neoplastine CI Plus
	%	48.8	39.0	58.6	HemosIL PT-Fibrinogen HS Plus
	%	52.3	41.8	62.8	Teco TEClot PT-S
	%	62.8	50.2	75.4	Stago Neoplastin R
	%	73.7	59.0	88.4	Bio-Ksel System PT

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Cat. No. CG5023 Lot. No. 304CG Size 12 x 1 ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	50.5	40.4	60.6	Human Thromboplastin
	%	45.4	36.3	54.5	Diagon PT
	%	32.2	25.8	38.6	Weiner Lab Soluplastin
	%	31.5	25.2	37.8	TCoag TriniCLOT PT Excel S
	%	52.3	41.8	62.8	Biodevice PT
	%	69.1	55.3	82.9	HemosIL RecombiPlasTin 2G
	%	40.3	32.2	48.4	Helena Thromboplastin
	%	46.6	37.3	55.9	Labitec PT
	%	52.6	42.1	63.1	Tokra Medikal PT
	%	26.3	21.0	31.6	Coagpia PT-N
	%	79.8	63.8	95.8	Bio-Ksel PT Plus
	%	52.2	41.8	62.6	Beijing Succeeder PT
	%	51.1	40.9	61.3	Diagon PT R
	%	50.3	40.2	60.4	Cobas PT Screen
	%	37.2	29.8	44.6	Stago STA-NeoPTimal
Prothrombin Time (PT) INR	INR	2.01	1.61	2.41	Siemens/Dade-Behring Innovin
	INR	1.39	1.11	1.67	Siemens/Dade Thromborel IS
	INR	1.45	1.16	1.74	Siemens/Dade-Behring Thromborel S
	INR	1.68	1.34	2.02	HemosIL PT-Fibrinogen HS Plus
	INR	2.09	1.67	2.51	Pacific Thromboplastin DS
	INR	1.82	1.46	2.18	Stago Neoplastine CI
	INR	1.73	1.38	2.08	Stago Neoplastine CI Plus
	INR	1.56	1.25	1.87	Human Thromboplastin
	INR	1.51	1.21	1.81	Teco TEClot PT-S
	INR	1.17	0.936	1.40	Stago SPA
	INR	1.29	1.03	1.55	Stago Neoplastin R
	INR	1.36	1.09	1.63	Bio-Ksel System PT
	INR	1.63	1.30	1.96	Diagon PT
	INR	1.74	1.39	2.09	Spinreact PT
	INR	2.09	1.67	2.51	Technology-Standard PT
	INR	2.60	2.08	3.12	TCoag TriniCLOT PT Excel S
	INR	1.63	1.30	1.96	Biodevice PT
	INR	1.74	1.39	2.09	Biomedica QuikCoag PT-HS
	INR	1.27	1.02	1.52	HemosIL RecombiPlasTin 2G
	INR	1.91	1.53	2.29	Helena Thromboplastin
	INR	1.64	1.31	1.97	Labitec PT
	INR	1.46	1.17	1.75	Tokra Medikal PT
	INR	2.27	1.82	2.72	Coagpia PT-N
	INR	1.28	1.02	1.54	Bio-Ksel PT Plus
	INR	1.73	1.38	2.08	Beijing Succeeder PT
	INR	1.53	1.22	1.84	Diagon PT R
	INR	1.70	1.36	2.04	Cobas PT Screen
INR	2.10	1.68	2.52	Stago STA-NeoPTimal	
Prothrombin Time (PT) ratio	ratio	2.05	1.64	2.46	Siemens/Dade-Behring Innovin
	ratio	1.45	1.16	1.74	Siemens/Dade-Behring Thromborel S
	ratio	1.83	1.46	2.20	Stago Neoplastine CI Plus

COAGULATION CONTROL LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 304CG Size 12 x 1 ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) ratio	ratio	1.52	1.22	1.82	Diagon PT
	ratio	1.52	1.22	1.82	HemosIL PT-Fibrinogen HS Plus
	ratio	1.27	1.02	1.52	HemosIL RecombiPlasTin 2G
	ratio	1.56	1.25	1.87	Biodevice PT
	ratio	2.07	1.66	2.48	Stago STA-NeoPTimal
Thrombin Time (TT)	Seconds	30.2	24.2	36.2	Dade Thrombin
	Seconds	27.0	21.6	32.4	Siemens/Dade Thromboclotin
	Seconds	32.2	25.8	38.6	Stago Thrombin
	Seconds	28.6	22.9	34.3	Sysmex Thrombin Time
	Seconds	34.5	27.6	41.4	Diagon, Dia-TT
	Seconds	25.8	20.6	31.0	HemosIL Thrombin Time 5ml
	Seconds	34.8	27.8	41.8	HemosIL Thrombin Time 8ml