

凝血质控品—水平3

(COAG CONTROL 3)

货号	CG5023	批号	367CG
包装:	12 x 1 ml	效期:	2023-11-28

产品描述

本品适用于体外诊断中凝血检测系统的质控，用于监测凝血测定分析的正确度或重复度。朗道供应 3 个浓度水平（水平 1：CG5021；水平 2：CG5022；水平 3：CG5023）。

安全预防措施和警告

本产品仅用于体外诊断。禁止用口吸。按照实验室常规预防措施对试剂进行处理。

该质控品采用人源性血浆，对所有源性材料均进行了HIV（HIV1、HIV2）抗体、肝炎B表面抗原（HbsAg）和肝炎C病毒（HCV）抗体的测试，发现均呈阴性。所采用的方法均经FDA认证。

然而，既然没有一种方法能够完全保证其没有传染物质，因此该质控品和所有的病人样品均应当按照能够传播疾病的样品小心处理。

健康和安数据表备案。

保存和稳定性

开瓶后，2~8℃保存。复溶后的血清如果保存在原始容器，并且无污染，活化部分凝血活酶时间（APTT）、凝血酶时间（TT）、凝血酶原时间（PT）、纤维蛋白原（FIB）、抗凝血酶III（ATIII）可在2~8℃保存24小时。C蛋白、S蛋白、血纤维蛋白溶酶原、因子II、因子V、因子VII、因子VIII、因子IX、因子X、因子XI、因子XII在2~8℃保存可稳定8小时。每次使用只吸取所需用量，剩余的样品不可返回原瓶。未开瓶，2~8℃可保存至效期末。

使用说明

该凝血质控品为冻干粉。

- 小心打开瓶盖，往瓶中准确加入 1 ml 蒸馏水，在 15~25 °C 的条件下复溶，盖上瓶盖，放置 30 分钟。轻轻翻转瓶子，确保内容物完全溶解，不要振荡，避免气泡的产生。
- 参照各个分析仪的质控说明。
- 冷藏未使用的材料，再次使用前，确保样品充分混合均匀。

需要自备的材料

移液管蒸馏水

赋值

每一批质控品都要送到大量的外部实验室，然后将结果与朗道实验室内部得到的结果用相同的统计分析进行赋值。在实验室建立起自己方法学的靶值和 SD 范围前，质控范围值用来协助实验室进行质量控制。

注：详细赋值信息请以原版英文说明书为准，原版说明书请在英国朗道公司官网 www.randox.com 进行下载。

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 367CG Size 12 x 1ml Expiry 2023-11-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT)	seconds	66.7	53.4	80.0	Tcoag TriniCLOT aPTT S
	seconds	63.0	50.4	75.6	Tcoag TriniCLOT aPTT HS
	seconds	58.6	46.9	70.3	Siemens/Dade Actin
	seconds	51.9	41.5	62.3	Siemens/Dade Actin FS
	seconds	47.7	38.2	57.2	Siemens/Dade Actin FSL
	seconds	88.5	70.8	106	Siemens/Dade Actin SL
	seconds	99.0	79.2	119	Siemens/Dade Pathromtin SL
	seconds	48.8	39.0	58.6	HemosIL APTT-SP Liquid
	seconds	73.5	58.8	88.2	HemosIL Synthasil
	seconds	64.3	51.4	77.2	Stago aPTT
	seconds	55.3	44.2	66.4	Stago Cephascreen
	seconds	65.4	52.3	78.5	Stago CK-Prest
	seconds	67.0	53.6	80.4	Stago PTT Automate
	seconds	67.3	53.8	80.8	Teco TEClot APTT
	seconds	59.9	47.9	71.9	Human Hemostat APTT
	seconds	54.0	43.2	64.8	Bio-Ksel System APTTs
	seconds	79.1	63.3	94.9	Diagon Dia-PTT
	seconds	53.6	42.9	64.3	Weiner Lab APTT
	seconds	62.4	49.9	74.9	Biolabo Bio-CK APTT
	seconds	63.7	51.0	76.4	Spinreact APTT
	seconds	63.1	50.5	75.7	Technology-Standard aPTT
	seconds	51.7	41.4	62.0	Media IVD aPTT
	seconds	56.8	45.4	68.2	Biomedica QuikCoag aPTT
	seconds	77.7	62.2	93.2	Hemosil aPTT Lyophilised Silica
	seconds	63.0	50.4	75.6	Siemens/Dade Actin Cephaloplastin
	seconds	59.8	47.8	71.8	Labitec aPTT
	seconds	65.9	52.7	79.1	Dutch Diagnostics aPTT
	seconds	54.9	43.9	65.9	Technoclone Siron aPTT
	seconds	70.3	56.2	84.4	Sclavo APTT-S
	seconds	61.2	49.0	73.4	HemoDiagnostics aPTT
	seconds	81.3	65.0	97.6	Tokra Medikal APTT
	seconds	51.3	41.0	61.6	Coagpia APTT-N
seconds	94.6	75.7	114	Cobas aPTT MedS	
seconds	71.5	57.2	85.8	Biolabo Bio-Sil (APTT)	
seconds	56.9	45.5	68.3	Diagon Dia-PTT Liquid	
seconds	54.6	43.7	65.5	PRECIL	
seconds	65.8	52.6	79.0	Erba Actime APTT	
seconds	56.0	44.8	67.2	MTI Diagnostics APTT	
seconds	64.6	51.7	77.5	Rayto aPTT Reagent	
seconds	92.6	74.1	111	Roche Cobas APTT Screen	
Activated Partial Thromboplastin Time	ratio	1.80	1.44	2.16	Siemens/Dade Actin FSL
	ratio	1.84	1.47	2.21	Stago Cephascreen

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 367CG

Size 12 x 1ml Expiry 2023-11-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.03	1.62	2.44	Stago PTT Automate
	ratio	2.05	1.64	2.46	Stago aPTT
	ratio	3.12	2.50	3.74	Siemens/Dade Pathromtin SL
	ratio	1.67	1.34	2.00	HemosIL APTT-SP Liquid
	ratio	2.47	1.98	2.96	HemosIL Synthasil
	ratio	2.16	1.73	2.59	Stago CK-Prest
	ratio	2.11	1.69	2.53	Teco TEClot APTT
	ratio	2.11	1.69	2.53	Human Hemostat APTT
	ratio	1.58	1.26	1.90	Bio-Ksel System APTTs
	ratio	2.03	1.62	2.44	Siemens/Dade Actin FS
	ratio	2.31	1.85	2.77	Diagon Dia-PTT
	ratio	2.14	1.71	2.57	Labitec aPTT
	ratio	2.56	2.05	3.07	Sclavo APTT-S
	ratio	1.99	1.59	2.39	Diagon Dia-PTT Liquid
ratio	1.95	1.56	2.34	MTI Diagnostics APTT	
Antithrombin III activity	%	57.0	45.6	68.4	Siemens/Dade Berichrom ATIII
	%	53.5	42.8	64.2	HemosIL Liquid Antithrombin
	%	59.4	47.5	71.3	Roche Chronogenic Thrombin
	%	50.4	40.3	60.5	Chromogenix Substrate
	%	60.5	48.4	72.6	STACHrom ATIII
	%	59.3	47.4	71.2	Siemens/Dade Antithrombin III
	%	55.0	44.0	66.0	Siemens Innovance Antithrombin III
	%	54.6	43.7	65.5	Sclavo ATIII
	%	57.6	46.1	69.1	Roche Antithrombin
	%	50.3	40.2	60.4	HemoDiagnostica Antithrombin III (Fxa)
Factor II activity	%	57.0	45.6	68.4	Siemens/Dade-Behring Innovin
	%	57.9	46.3	69.5	Siemens/Dade-Behring Thromborel S
	%	54.1	43.3	64.9	HemosIL PT-Fibrinogen HS Plus
	%	51.6	41.3	61.9	HemosIL RecombiPlasTin 2G
	%	52.0	41.6	62.4	HemosIL Factor II deficient plasma
	%	52.0	41.6	62.4	Stago STA-NeoPTimal
Factor IX activity	%	51.3	41.0	61.6	Siemens/Dade Actin FS
	%	55.2	44.2	66.2	Siemens/Dade Pathromtin SL
	%	47.8	38.2	57.4	HemosIL Synthasil
	%	58.8	47.0	70.6	Stago CK-Prest
	%	51.6	41.3	61.9	Siemens/Dade Actin FSL
	%	53.0	42.4	63.6	Stago Deficient / ImmunoDef IX
	%	48.9	39.1	58.7	HemosIL Factor IX deficient plasma
Factor V activity	%	47.0	37.6	56.4	Siemens/Dade-Behring Thromborel S
	%	36.0	28.8	43.2	Siemens/Dade-Behring Innovin
	%	45.2	36.2	54.2	HemosIL PT-Fibrinogen HS Plus
	%	42.8	34.2	51.4	HemosIL RecombiPlasTin 2G
	%	42.2	33.8	50.6	HemosIL Factor V deficient plasma
	%	39.4	31.5	47.3	Stago STA-NeoPTimal
Factor VII activity	%	67.1	53.7	80.5	Siemens/Dade-Behring Thromborel S
	%	68.1	54.5	81.7	Siemens/Dade-Behring Innovin

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Analyte	unit	Target	Range		methods
			low	high	
Factor VII activity	%	59.5	47.6	71.4	HemosIL PT-Fibrinogen HS Plus
	%	65.9	52.7	79.1	HemosIL RecombiPlasTin 2G
	%	66.7	53.4	80.0	HemosIL Factor VII deficient plasma
	%	66.8	53.4	80.2	Stago Deficient Factor VII
	%	61.3	49.0	73.6	Stago STA-NeoPTimal
Factor VIII activity	%	28.8	23.0	34.6	Siemens/Dade Actin FS
	%	31.5	25.2	37.8	Siemens/Dade Pathromtin SL
	%	30.8	24.6	37.0	Siemens/Dade Actin FSL
	%	28.8	23.0	34.6	HemosIL Synthasil
	%	29.3	23.4	35.2	HemosIL APTT-SP Liquid
	%	29.0	23.2	34.8	Stago Deficient / ImmunoDef VIII
	%	29.0	23.2	34.8	HemosIL Factor VIII deficient plasma
Factor X activity	%	66.7	53.4	80.0	Siemens/Dade-Behring Thromborel S
	%	62.6	50.1	75.1	Siemens/Dade-Behring Innovin
	%	56.4	45.1	67.7	HemosIL PT-Fibrinogen HS Plus
	%	56.5	45.2	67.8	HemosIL RecombiPlasTin 2G
	%	59.0	47.2	70.8	HemosIL Factor X deficient plasma
	%	57.5	46.0	69.0	Stago STA-NeoPTimal
Factor XI activity	%	33.6	26.9	40.3	Siemens/Dade Actin FS
	%	35.6	28.5	42.7	HemosIL Synthasil
	%	28.0	22.4	33.6	Siemens/Dade Actin FSL
	%	55.6	44.5	66.7	HemosIL APTT-SP Liquid
	%	36.2	29.0	43.4	Stago CK-Prest
	%	36.7	29.4	44.0	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	57.2	45.8	68.6	Siemens/Dade Actin FS
	%	58.3	46.6	70.0	Siemens/Dade Pathromtin SL
	%	52.4	41.9	62.9	HemosIL Synthasil
	%	54.3	43.4	65.2	Siemens/Dade Actin FSL
	%	56.5	45.2	67.8	HemosIL Factor XII deficient plasma
Fibrinogen	g/L	1.80	1.44	2.16	HemosIL PT-Fibrinogen HS Plus
	mg/dL	180	144	216	
	g/L	1.62	1.30	1.94	Stago Fibrinogen / Liquid-Fib
	mg/dL	162	130	194	
	g/L	1.15	0.920	1.38	Siemens/Dade Multifibren U
	mg/dL	115	92.0	138	
	g/L	1.53	1.22	1.84	HemosIL Fibrinogen C
	mg/dL	153	122	184	
	g/L	1.35	1.08	1.62	Dade Thrombin
	mg/dL	135	108	162	
	g/L	2.10	1.68	2.52	Technoclone Fibrinogen
	mg/dL	210	168	252	
	g/L	1.54	1.23	1.85	Tcoag TriniCLOT Fibrinogen
	mg/dL	154	123	185	
g/L	1.52	1.22	1.82	HemosIL QFA (bovine thrombin)	
mg/dL	152	122	182		
g/L	1.72	1.38	2.06	Human Fibrinogen	
mg/dL	172	138	206		

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Analyte	unit	Target	Range		methods
			low	high	
Fibrinogen	g/L	1.61	1.29	1.93	Stago STA Fibrin-Prest Automate
	mg/dL	161	129	193	
	g/L	0.887	0.710	1.06	Bio-Ksel System PT
	mg/dL	88.7	71.0	106	
	g/L	1.63	1.30	1.96	Bio-Ksel Fibrinogen
	mg/dL	163	130	196	
	g/L	1.31	1.05	1.57	Diagon Dia-F
	mg/dL	131	105	157	
	g/L	1.09	0.872	1.31	Dade Innovin Derived Fibrinogen
	mg/dL	109	87.2	131	
	g/L	1.17	0.936	1.40	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	117	93.6	140	
	g/L	1.60	1.28	1.92	Technology-Standard Fibrinogen
	mg/dL	160	128	192	
	g/L	1.05	0.840	1.26	HemosIL RecombiPlasTin 2G
	mg/dL	105	84.0	126	
	g/L	1.54	1.23	1.85	Sclavo Fibrinogen
	mg/dL	154	123	185	
	g/L	1.50	1.20	1.80	Labitec Fibrinogen
	mg/dL	150	120	180	
	g/L	1.44	1.15	1.73	HemoDiagnostica Fibrinogen
	mg/dL	144	115	173	
	g/L	1.69	1.35	2.03	Helena Clauss Fibrinogen 100
	mg/dL	169	135	203	
g/L	1.58	1.26	1.90	Coagpia Fibrinogen	
mg/dL	158	126	190		
g/L	1.61	1.29	1.93	HemosIL PT-Fibrinogen	
mg/dL	161	129	193		
g/L	1.59	1.27	1.91	Cobas Fibrinogen	
mg/dL	159	127	191		
g/L	1.49	1.19	1.79	PRECIL	
mg/dL	149	119	179		
g/L	1.18	0.944	1.42	Erba Thrombin Reagent	
mg/dL	118	94.4	142		
g/L	1.21	0.968	1.45	MTI Diagnostics Fibrinogen	
mg/dL	121	96.8	145		
g/L	1.31	1.05	1.57	Yumizen G Fibrinogen	
mg/dL	131	105	157		
g/L	1.42	1.14	1.70	Roche Cobas t511/t711 Fibrinogen	
mg/dL	142	114	170		
g/L	1.63	1.30	1.96	Roche Cobas t411 Fibrinogen	
mg/dL	163	130	196		
Plasminogen activity	%	53.5	42.8	64.2	HemosIL Plasminogen
	%	63.4	50.7	76.1	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	56.3	45.0	67.6	Siemens/Dade Berichrom Protein C

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			low	high	
Protein C activity	%	61.6	49.3	73.9	Stago StaClot
	%	52.4	41.9	62.9	Biomerieux VIDAS Protein C
	%	54.3	43.4	65.2	IL HemosIL Protein C
	%	64.1	51.3	76.9	Siemens
	%	59.5	47.6	71.4	STACHrom Protein C
Protein S activity	%	56.3	39.4	73.2	STA Liatest
	%	55.1	38.6	71.6	Stago StaClot
	%	60.4	42.3	78.5	IL HemosIL Free Protein S
	%	49.2	34.4	64.0	Dade Protein S Ac
	%	54.9	38.4	71.4	Siemens Innovance Free PS Ag
Prothrombin Time (PT)	Seconds	27.4	21.9	32.9	Siemens/Dade-Behring Innovin
	Seconds	18.5	14.8	22.2	Siemens/Dade Thromborel IS
	Seconds	18.1	14.5	21.7	Siemens/Dade-Behring Thromborel S
	Seconds	29.6	23.7	35.5	HemosIL PT-Fibrinogen HS Plus
	Seconds	31.0	24.8	37.2	Pacific Thromboplastin DS
	Seconds	26.1	20.9	31.3	Stago Neoplastine CI Plus
	Seconds	22.6	18.1	27.1	Teco TEClot PT-S
	Seconds	19.2	15.4	23.0	Stago Neoplastin R
	Seconds	17.2	13.8	20.6	Bio-Ksel System PT
	Seconds	24.7	19.8	29.6	Human Thromboplastin
	Seconds	25.1	20.1	30.1	Diagon PT
	Seconds	50.1	40.1	60.1	Weiner Lab Soluplastin
	Seconds	25.3	20.2	30.4	Spinreact PT
	Seconds	43.0	34.4	51.6	TCoag TriniCLOT PT Excel S
	Seconds	25.0	20.0	30.0	Biomedica QuikCoag PT-HS
	Seconds	17.2	13.8	20.6	HemosIL RecombiPlasTin 2G
	Seconds	26.7	21.4	32.0	Helena Thromboplastin LI
	Seconds	27.8	22.2	33.4	Technoclon Technoplastin HIS
	Seconds	26.9	21.5	32.3	Helena Thromboplastin
	Seconds	25.2	20.2	30.2	Dutch Diagnostics PT
	Seconds	24.6	19.7	29.5	Sclavo PT
	Seconds	26.7	21.4	32.0	Tokra Medikal PT
	Seconds	32.7	26.2	39.2	Coagpia PT-N
	Seconds	16.6	13.3	19.9	Bio-Ksel PT Plus
	Seconds	27.0	21.6	32.4	Beijing Succeeder PT
	Seconds	21.9	17.5	26.3	Diagon PT R
	Seconds	20.3	16.2	24.4	Cobas PT Screen
	Seconds	23.2	18.6	27.8	PRECIL
	Seconds	33.7	27.0	40.4	Stago STA-NeoPTimal
	Seconds	24.7	19.8	29.6	Yumizen G PT
	Seconds	23.5	18.8	28.2	Erba Protime PT
	Seconds	25.3	20.2	30.4	Rayto Prothrombin Time Reagent
Seconds	19.7	15.8	23.6	HemosIL ReadiPlasTin	
Seconds	39.4	31.5	47.3	Roche Cobas PT Rec	
Prothrombin Time (PT)	%	21.2	17.0	25.4	Siemens/Dade-Behring Innovin

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Analyte	unit	Target	Range		methods
			low	high	
Prothrombin Time (PT) activity	%	47.2	37.8	56.6	Siemens/Dade-Behring Thromborel S
	%	35.7	28.6	42.8	Stago Neoplastine CI
	%	36.0	28.8	43.2	Stago Neoplastine CI Plus
	%	34.5	27.6	41.4	HemosIL PT-Fibrinogen HS Plus
	%	64.0	51.2	76.8	Stago SPA
	%	52.9	42.3	63.5	Stago Neoplastin R
	%	13.9	11.1	16.7	Weiner Lab Soluplastin
	%	17.3	13.8	20.8	TCoag TriniCLOT PT Excel S
	%	39.1	31.3	46.9	Media IVD PT
	%	53.6	42.9	64.3	HemosIL RecombiPlasTin 2G
	%	32.7	26.2	39.2	Helena Thromboplastin
	%	39.8	31.8	47.8	Labitec PT
	%	37.6	30.1	45.1	Sclavo PT
	%	31.0	24.8	37.2	Tokra Medikal PT
	%	66.4	53.1	79.7	Bio-Ksel PT Plus
	%	38.5	30.8	46.2	Beijing Succeeder PT
	%	24.8	19.8	29.8	Diagon PT R
	%	42.4	33.9	50.9	Cobas PT Screen
	%	42.0	33.6	50.4	PRECIL
	%	28.2	22.6	33.8	Stago STA-NeoPTimal
%	46.9	37.5	56.3	HemosIL ReadiPlasTin	
%	12.5	10.0	15.0	Roche Cobas PT Rec	
Prothrombin Time (PT) INR	INR	2.80	2.24	3.36	Siemens/Dade-Behring Innovin
	INR	1.77	1.42	2.12	Siemens/Dade Thromborel IS
	INR	1.60	1.28	1.92	Siemens/Dade-Behring Thromborel S
	INR	2.18	1.74	2.62	HemosIL PT-Fibrinogen HS Plus
	INR	2.23	1.78	2.68	Pacific Thromboplastin DS
	INR	2.33	1.86	2.80	Stago Neoplastine CI
	INR	2.17	1.74	2.60	Stago Neoplastine CI Plus
	INR	2.06	1.65	2.47	Human Thromboplastin
	INR	1.82	1.46	2.18	Teco TEClot PT-S
	INR	2.05	1.64	2.46	Biolabo Bio-TP
	INR	1.23	0.984	1.48	Stago SPA
	INR	1.44	1.15	1.73	Stago Neoplastin R
	INR	1.55	1.24	1.86	Bio-Ksel System PT
	INR	2.26	1.81	2.71	Diagon PT
	INR	2.42	1.94	2.90	Spinreact PT
	INR	3.98	3.18	4.78	TCoag TriniCLOT PT Excel S
	INR	1.90	1.52	2.28	Media IVD PT
	INR	2.21	1.77	2.65	Biomedica QuikCoag PT-HS
	INR	1.52	1.22	1.82	HemosIL RecombiPlasTin 2G
	INR	2.43	1.94	2.92	Helena Thromboplastin LI
INR	1.80	1.44	2.16	Technoclone Technoplastin HIS	
INR	2.42	1.94	2.90	Helena Thromboplastin	
INR	2.02	1.62	2.42	Labitec PT	
INR	2.13	1.70	2.56	Sclavo PT	

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot. No. 367CG Size 12 x 1ml Expiry 2023-11-28

Analyte	unit	Target	Range		methods
			low	high	
Prothrombin Time (PT) INR	INR	2.08	1.66	2.50	Technoclone Technoclot PT Plus
	INR	2.13	1.70	2.56	Tokra Medikal PT
	INR	1.50	1.20	1.80	Bio-Ksel PT Plus
	INR	2.07	1.66	2.48	Beijing Succeeder PT
	INR	2.12	1.70	2.54	Diagon PT R
	INR	1.94	1.55	2.33	Cobas PT Screen
	INR	1.81	1.45	2.17	PRECIL
	INR	2.60	2.08	3.12	Stago STA-NeoPTimal
	INR	1.95	1.56	2.34	Erba Protime PT
	INR	2.51	2.01	3.01	Yumizen G PT Reco
	INR	2.21	1.77	2.65	Rayto Prothrombin Time Reagent
	INR	1.72	1.38	2.06	HemosIL ReadiPlasTin
	INR	4.06	3.25	4.87	Roche Cobas PT Rec
Prothrombin Time (PT) ratio	ratio	3.04	2.43	3.65	Siemens/Dade-Behring Innovin
	ratio	1.60	1.28	1.92	Siemens/Dade-Behring Thromborel S
	ratio	2.12	1.70	2.54	Stago Neoplastine CI Plus
	ratio	1.70	1.36	2.04	Human Thromboplastin
	ratio	1.92	1.54	2.30	HemosIL PT-Fibrinogen HS Plus
	ratio	1.51	1.21	1.81	HemosIL RecombiPlasTin 2G
	ratio	1.92	1.54	2.30	Sclavo PT
	ratio	2.53	2.02	3.04	Stago STA-NeoPTimal
Thrombin Time (TT)	Seconds	32.6	26.1	39.1	Dade Thrombin
	Seconds	30.6	24.5	36.7	Siemens/Dade Thromboclotin
	Seconds	38.3	30.6	46.0	Stago Thrombin
	Seconds	31.2	25.0	37.4	Sysmex Thrombin Time
	Seconds	36.8	29.4	44.2	Helena Thrombin Clotting Time rgt
	Seconds	29.9	23.9	35.9	HemosIL Thrombin Time 5ml
	Seconds	38.1	30.5	45.7	HemosIL Thrombin Time 8ml
	Seconds	36.3	29.0	43.6	Siemens BC Thrombin
	Seconds	23.7	19.0	28.4	PRECIL