

凝血质控品

货号：CG5021

包装：12 x 1 ml

批号：252CG

效期：2019-11

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，对所有人源性材料均进行了 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。

健康和安全数据表备案。

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 °C 可保存至效期末。

使用说明

该凝血质控品为冻干粉。

1. 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。
2. 参照各个分析仪的质控说明。
3. 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。

凝血质控品-水平 1

货号: CG5021		批号: 252CG			效期: 2019-11
规格: 12 x 1 ml		范围			低值=靶值-2SD 高值=靶值+2SD
分析物	单位	靶值	低值	高值	
活化部分凝血活酶时间 (APTT)	seconds	40.5	32.4	48.6	Tcoag TriniCLOT aPTT S
	seconds	38.6	30.9	46.3	Tcoag TriniCLOT aPTT HS
	seconds	41.8	33.4	50.2	Siemens/Dade Actin
	seconds	36.0	28.8	43.2	Siemens/Dade Actin FS
	seconds	32.3	25.8	38.8	Siemens/Dade Actin FSL
	seconds	46.3	37.0	55.6	Siemens/Dade Actin SL
	seconds	45.7	36.6	54.8	Siemens/Dade Pathromtin SL
	seconds	38.9	31.1	46.7	Helena aPTT
	seconds	34.5	27.6	41.4	HemosIL APTT-SP Liquid
	seconds	37.8	30.2	45.4	HemosIL Synthasil
	seconds	33.9	27.1	40.7	HemosIL Synthafax
	seconds	40.0	32.0	48.0	Pacific Hemostasis APTT-XL
	seconds	42.8	34.2	51.4	Stago aPTT
	seconds	41.2	33.0	49.4	Stago Cephascreen
	seconds	42.1	33.7	50.5	Stago CK-Prest
	seconds	43.4	34.7	52.1	Stago PTT Automate
	seconds	40.8	32.6	49.0	Teco TEClot APTT
	seconds	37.1	29.7	44.5	Human Hemostat APTT
	seconds	38.6	30.9	46.3	Bio-Ksel System APTTs
	seconds	46.2	37.0	55.4	Grifols DG-APTT
	seconds	44.1	35.3	52.9	Diagon Dia-PTT
	seconds	38.8	31.0	46.6	Weiner Lab APTT
	seconds	42.5	34.0	51.0	Biolabo Bio-CK APTT
	seconds	44.8	35.8	53.8	Spinreact APTT
	seconds	34.9	27.9	41.9	Technology-Standard aPTT
	seconds	38.0	30.4	45.6	SGM Italia aPTT
	seconds	41.9	33.5	50.3	Tcoag TriniCLOT Automated aPTT
	seconds	36.8	29.4	44.2	Media IVD aPTT
	seconds	33.7	27.0	40.4	Biodevice aPTT
	seconds	36.5	29.2	43.8	Biomedica QuikCoag aPTT
	seconds	44.3	35.4	53.2	Siemens Dade Actin Cephaloplastin
	seconds	35.9	28.7	43.1	Labitec aPTT
	seconds	40.1	32.1	48.1	Sclavo APTT-S
	seconds	40.5	32.4	48.6	HemoDiagnostics aPTT
	seconds	43.0	34.4	51.6	Cypress Diagnostics aPTT
	seconds	39.8	31.8	47.8	Tokra Medikal APTT
	seconds	35.3	28.2	42.4	Coagpia APTT-N
	seconds	43.6	34.9	52.3	Cobas aPTT MedS
	seconds	42.7	34.2	51.2	Biolabo Bio-Sil (APTT)
活化部分凝血活酶时间 (APTT) 比	ratio	1.30	1.04	1.56	Tcoag TriniCLOT aPTT S
	ratio	1.21	0.968	1.45	Siemens/Dade Actin FSL
	ratio	1.42	1.14	1.70	Siemens/Dade Actin SL

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分析物	单位	靶值	低值	高值	
活化部分凝血活酶时间 (APTT) 比	ratio	1.37	1.10	1.64	Stago Cephascreen
	ratio	1.31	1.05	1.57	Stago PTT Automate
	ratio	1.41	1.13	1.69	Stago aPTT
	ratio	1.41	1.13	1.69	Siemens/Dade Pathromtin SL
	ratio	1.15	0.920	1.38	HemosIL APTT-SP Liquid
	ratio	1.26	1.01	1.51	HemosIL Synthasil
	ratio	1.26	1.01	1.51	Pacific Hemostasis APTT-XL
	ratio	1.38	1.10	1.66	Stago CK-Prest
	ratio	1.13	0.904	1.36	Teco TEClot APTT
	ratio	1.27	1.02	1.52	Human Hemostat APTT
	ratio	1.20	0.960	1.44	Bio-Ksel System APTTs
	ratio	1.36	1.09	1.63	Siemens/Dade Actin FS
	ratio	1.41	1.13	1.69	Diagon Dia-PTT
	ratio	1.31	1.05	1.57	Technology-Standard aPTT
	ratio	1.53	1.22	1.84	Siemens/Dade Actin
	ratio	1.31	1.05	1.57	Biodevice aPTT
	ratio	1.17	0.936	1.40	Labitec aPTT
	ratio	1.32	1.06	1.58	Sclavo APTT-S
	ratio	1.07	0.856	1.28	Coagpia APTT-N
抗凝血酶III (AT) 活性	%	82.5	66.0	99.0	Siemens/Dade Berichrom ATIII
	%	79.5	63.6	95.4	HemosIL Liquid Antithrombin
	%	75.3	60.2	90.4	Chromogenix Coamatic LR
	%	77.7	62.2	93.2	Roche Chronogenic Thrombin
	%	86.7	69.4	104	Hemosil Lyophilised Antithrombin III
	%	83.2	66.6	100	STACHrom ATIII
	%	81.5	65.2	97.8	Siemens/Dade Antithrombin III
	%	82.0	65.6	98.4	Diagon ATIII
	%	83.9	67.1	101	Siemens Innovance Antithrombin III
	%	76.9	61.5	92.3	Sclavo ATIII
	%	80.6	64.5	96.7	Teco TEChrom AT
	%	84.1	67.3	101	HemoDiagnostics Antithrombin III (Fxa)
II 因子活性	%	82.9	66.3	99.0	Dade Innovin
	%	94.6	75.7	114	Siemens/Dade Thromborel S
	%	81.6	65.3	97.9	Stago Neoplastine CI Plus
	%	86.0	68.8	103	HemosIL PT-Fibrinogen HS Plus
	%	82.0	65.6	98.4	HemosIL PT-Fibrinogen Recombiplastin 2G
IX 因子活性	%	82.4	65.9	98.9	Stago PTT Automate
	%	88.0	70.4	106	Siemens/Dade Actin FS
	%	89.9	71.9	108	Siemens/Dade Pathromtin SL
	%	78.3	62.6	94.0	HemosIL Synthasil
	%	93.3	74.6	112	Stago CK-Prest
	%	78.0	62.4	93.6	Siemens/Dade Actin FSL
	%	84.9	67.9	102	HemosIL APTT-SP Liquid
	%	92.3	73.8	111	Stago aPTT
V 因子活性	%	76.6	61.3	91.9	HemosIL Factor IX deficient plasma
	%	67.0	53.6	80.4	Stago Neoplastine CI Plus

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分析物	单位	靶值	低值	高值	
V 因子活性	%	76.3	61.0	91.6	Siemens/Dade Thromborel S
	%	64.1	51.3	76.9	Dade Innovin
	%	64.3	51.4	77.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	62.0	49.6	74.4	Stago Neoplastin R
	%	60.9	48.7	73.1	HemosIL Factor V deficient plasma
VII 因子活性	%	97.0	77.6	116	Stago Neoplastine CI Plus
	%	104	83.2	125	Siemens/Dade Thromborel S
	%	109	87.2	131	Dade Innovin
	%	113	90.4	136	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	108	86.4	130	HemosIL Factor VII deficient plasma
VIII 因子活性	%	51.4	41.1	61.7	Stago PTT Automate
	%	57.2	45.8	68.6	Siemens/Dade Actin FS
	%	57.0	45.6	68.4	Siemens/Dade Pathromtin SL
	%	52.7	42.2	63.2	Siemens/Dade Actin FSL
	%	53.0	42.4	63.6	HemosIL Synthasil
	%	53.4	42.7	64.1	HemosIL APTT-SP Liquid
	%	48.4	38.7	58.1	Stago Deficient / ImmunoDef VIII
	%	50.1	40.1	60.1	HemosIL Factor VIII deficient plasma
X 因子活性	%	97.8	78.2	117	Siemens/Dade Thromborel S
	%	86.1	68.9	103	Dade Innovin
	%	82.7	66.2	99.0	HemosIL PT-Fibrinogen HS Plus
	%	84.0	67.2	101	Stago Neoplastine CI Plus
	%	88.7	71.0	106	HemosIL PT-Fibrinogen Recombiplastin 2G
XI 因子活性	%	59.2	47.4	71.0	Siemens/Dade Actin FS
	%	65.3	52.2	78.4	Siemens/Dade Pathromtin SL
	%	53.5	42.8	64.2	HemosIL Synthasil
	%	48.0	38.4	57.6	Siemens/Dade Actin FSL
XII 因子活性	%	74.9	59.9	89.9	Siemens/Dade Actin FS
	%	79.2	63.4	95.0	Siemens/Dade Pathromtin SL
	%	79.5	63.6	95.4	HemosIL Synthasil
	%	74.5	59.6	89.4	Siemens/Dade Actin FSL
	%	77.7	62.2	93.2	HemosIL APTT-SP Liquid
纤维蛋白原	g/L	2.44	1.95	2.93	HemosIL PT-Fibrinogen HS Plus
	mg/dL	244	195	293	
	g/L	2.46	1.97	2.95	Stago Fibrinogen / Liquid-Fib
	mg/dL	246	197	295	
	g/L	2.14	1.71	2.57	Siemens/Dade Multifibren U
	mg/dL	214	171	257	
	g/L	2.39	1.91	2.87	HemosIL Fibrinogen C
	mg/dL	239	191	287	
	g/L	2.12	1.70	2.54	Dade Thrombin
	mg/dL	212	170	254	
	g/L	2.39	1.91	2.87	Tcoag TriniCLOT Fibrinogen
	mg/dL	239	191	287	
	g/L	2.39	1.91	2.87	Biolabo Bio-Fibri
	mg/dL	239	191	287	

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分析物	单位	靶值	低值	高值	
纤维蛋白原	g/L	2.17	1.74	2.60	Teco Teclot Fibrinogen
	mg/dL	217	174	260	
	g/L	2.23	1.78	2.68	HemosIL QFA (bovine thrombin)
	mg/dL	223	178	268	
	g/L	2.53	2.02	3.04	Pacific Hemostasis Fibrinogen
	mg/dL	253	202	304	
	g/L	2.37	1.90	2.84	Human Fibrinogen
	mg/dL	237	190	284	
	g/L	2.46	1.97	2.95	Stago STA Fibri-Prest Automate
	mg/dL	246	197	295	
	g/L	2.00	1.60	2.40	Bio-Ksel System PT
	mg/dL	200	160	240	
	g/L	2.38	1.90	2.86	Bio-Ksel Fibrinogen
	mg/dL	238	190	286	
	g/L	2.15	1.72	2.58	Diagon Dia-F
	mg/dL	215	172	258	
	g/L	1.70	1.36	2.04	Dade Innovin Derived Fibrinogen
	mg/dL	170	136	204	
	g/L	2.02	1.62	2.42	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	202	162	242	
	g/L	1.87	1.50	2.24	Futura System Fibrinogen
	mg/dL	187	150	224	
	g/L	2.23	1.78	2.68	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	223	178	268	
	g/L	2.30	1.84	2.76	Sclavo Fibrinogen
	mg/dL	230	184	276	
	g/L	2.57	2.06	3.08	Labitec Fibrinogen
	mg/dL	257	206	308	
	g/L	2.46	1.97	2.95	HemoDiagnostica Fibrinogen
	mg/dL	246	197	295	
	g/L	2.23	1.78	2.68	Helena Clauss Fibrinogen 100
	mg/dL	223	178	268	
	g/L	2.32	1.86	2.78	Tokra Medikal Fibrinogen
	mg/dL	232	186	278	
	g/L	2.28	1.82	2.74	Coagpia Fibrinogen
	mg/dL	228	182	274	
	g/L	2.33	1.86	2.80	HemosIL PT-Fibrinogen
	mg/dL	233	186	280	
	g/L	2.34	1.87	2.81	Erba Diagnostics FibriMax
	mg/dL	234	187	281	
	g/L	2.16	1.73	2.59	Cobas Fibrinogen
	mg/dL	216	173	259	
血浆酶原活性	%	86.5	69.2	104	Stago Stachrom Plasminogen
	%	89.8	71.8	108	HemosIL Plasminogen
	%	90.4	72.3	108	Siemens/Dade Berichrom Plasminogen
C 蛋白	%	83.8	67.0	101	Siemens/Dade Berichrom Protein C

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分析物	单位	靶值	低值	高值	
C 蛋白	%	80.0	64.0	96.0	Biomerieux VIDAS Protein C
	%	80.6	64.5	96.7	IL HemosIL Protein C
	%	86.3	69.0	104	Siemens
	%	86.7	69.4	104	STACHrom Protein C
S 蛋白	%	70.0	49.0	91.0	STA Liatest
	%	88.8	62.2	115	IL HemosIL ProS
	%	89.4	62.6	116	IL HemosIL Free Protein S
	%	82.5	57.8	107	Stago Asserachrom Free Protein S
	%	56.6	39.6	73.6	Dade Protein S Ac
	%	78.6	55.0	102	Siemens Innovance Free PS Ag
	%	58.6	41.0	76.2	IL HemosIL Protein S Activity
凝血酶原时间 (PT)	Seconds	12.5	10.0	15.0	Tcoag TriniCLOT PT Excel
	Seconds	14.6	11.7	17.5	Tcoag TriniCLOT PT HTF
	Seconds	12.1	9.68	14.5	Dade Innovin
	Seconds	12.5	10.0	15.0	Siemens/Dade Thromborel IS
	Seconds	12.7	10.2	15.2	Siemens/Dade Thromborel S
	Seconds	13.0	10.4	15.6	HemosIL PT-Fibrinogen
	Seconds	14.9	11.9	17.9	HemosIL PT-Fibrinogen HS Plus
	Seconds	16.8	13.4	20.2	Pacific Thromboplastin DS
	Seconds	14.4	11.5	17.3	STA Hepato Quick
	Seconds	14.2	11.4	17.0	Stago Neoplastine CI
	Seconds	14.7	11.8	17.6	Stago Neoplastine CI Plus
	Seconds	15.1	12.1	18.1	Teco TEClot PT-S
	Seconds	14.7	11.8	17.6	Biolabo Bio-TP
	Seconds	15.2	12.2	18.2	Stago Neoplastin R
	Seconds	11.7	9.36	14.0	Bio-Ksel System PT
	Seconds	14.1	11.3	16.9	Human Thromboplastin
	Seconds	14.3	11.4	17.2	Diagon PT
	Seconds	16.0	12.8	19.2	Weiner Lab Soluplastin
	Seconds	13.8	11.0	16.6	Spinreact PT
	Seconds	13.9	11.1	16.7	Technology-Standard PT
	Seconds	17.1	13.7	20.5	TCoag TriniCLOT PT Excel S
	Seconds	14.1	11.3	16.9	Media IVD PT
	Seconds	13.9	11.1	16.7	Biodevice PT
	Seconds	13.3	10.6	16.0	Biomedica QuikCoag PT-HS
	Seconds	11.9	9.52	14.3	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	14.1	11.3	16.9	Helena Thromboplastin LI
	Seconds	14.9	11.9	17.9	Helena Thromboplastin
	Seconds	13.9	11.1	16.7	Labitec PT
	Seconds	14.8	11.8	17.8	SGM Italia Thromboplastin
	Seconds	14.3	11.4	17.2	Cypress Diagnostics PT
	Seconds	13.8	11.0	16.6	Tokra Medikal PT
	Seconds	13.4	10.7	16.1	Coagpia PT-N
	Seconds	11.2	8.96	13.4	Bio-Ksel PT Plus
	Seconds	13.6	10.9	16.3	Beijing Succeeder PT
	Seconds	10.4	8.32	12.5	Diagon PT R

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凝血酶原时间 (PT)	Seconds	12.8	10.2	15.4	Cobas PT Screen
凝血酶原时间 (PT) 活性	%	77.3	61.8	92.8	Tcoag TriniCLOT PT Excel
	%	73.1	58.5	87.7	Dade Innovin
	%	84.9	67.9	102	Siemens/Dade Thromborel S
	%	76.6	61.3	91.9	Stago Neoplastine CI
	%	78.5	62.8	94.2	Stago Neoplastine CI Plus
	%	79.5	63.6	95.4	HemosIL PT-Fibrinogen
	%	86.9	69.5	104	HemosIL PT-Fibrinogen HS Plus
	%	67.3	53.8	80.8	Pacific Thromboplastin DS
	%	80.7	64.6	96.8	Teco TEClot PT-S
	%	88.8	71.0	107	Biolabo Bio-TP
	%	102	81.6	122	Stago SPA
	%	84.2	67.4	101	Stago Neoplastin R
	%	92.3	73.8	111	Bio-Ksel System PT
	%	84.3	67.4	101	Diagon PT
	%	83.6	66.9	100	SGM Italia Thromboplastin
	%	66.1	52.9	79.3	TCoag TriniCLOT PT Excel S
	%	76.9	61.5	92.3	Media IVD PT
	%	76.6	61.3	91.9	Biodevice PT
	%	91.4	73.1	110	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	91.5	73.2	110	Helena Thromboplastin LI
	%	85.7	68.6	103	Helena Thromboplastin
	%	74.2	59.4	89.0	Labitec PT
	%	92.4	73.9	111	Tokra Medikal PT
	%	79.4	63.5	95.3	Coagpia PT-N
	%	95.2	76.2	114	Bio-Ksel PT Plus
	%	124	99.0	149	Diagon PT R
	%	75.5	60.4	90.6	Cobas PT Screen
凝血酶原时间 (PT) INR	INR	1.14	0.912	1.37	Tcoag TriniCLOT PT Excel
	INR	1.17	0.936	1.40	Dade Innovin
	INR	1.06	0.848	1.27	Siemens/Dade Thromborel IS
	INR	1.10	0.880	1.32	Siemens/Dade Thromborel S
	INR	1.10	0.880	1.32	HemosIL PT-Fibrinogen HS Plus
	INR	1.25	1.00	1.50	Pacific Thromboplastin DS
	INR	1.14	0.912	1.37	STA Hepato Quick
	INR	1.17	0.936	1.40	Stago Neoplastine CI
	INR	1.17	0.936	1.40	Stago Neoplastine CI Plus
	INR	1.10	0.880	1.32	Human Thromboplastin
	INR	1.13	0.904	1.36	Teco TEClot PT-S
	INR	1.25	1.00	1.50	Biolabo Bio-TP
	INR	0.999	0.799	1.20	Stago SPA
	INR	1.10	0.880	1.32	Stago Neoplastin R
	INR	1.08	0.864	1.30	Bio-Ksel System PT
	INR	1.11	0.888	1.33	Diagon PT
	INR	1.26	1.01	1.51	Weiner Lab Soluplastin
	INR	1.13	0.904	1.36	Spinreact PT

凝血质控品-水平 1

货号: CG5021		批号: 252CG			效期: 2019-11
规格: 12 x 1 ml		范围			低值=靶值-2SD 高值=靶值+2SD
分析物	单位	靶值	低值	高值	方法学
凝血酶原时间 (PT) INR	INR	1.12	0.896	1.34	Technology-Standard PT
	INR	1.27	1.02	1.52	TCoag TriniCLOT PT Excel S
	INR	1.18	0.944	1.42	Media IVD PT
	INR	1.15	0.920	1.38	Biodevice PT
	INR	1.12	0.896	1.34	Biomedica QuikCoag PT-HS
	INR	1.05	0.840	1.26	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.08	0.864	1.30	Helena Thromboplastin LI
	INR	1.15	0.920	1.38	Helena Thromboplastin
	INR	1.16	0.928	1.39	Labitec PT
	INR	1.04	0.832	1.25	Tokra Medikal PT
	INR	1.11	0.888	1.33	Coagpia PT-N
	INR	1.04	0.832	1.25	Bio-Ksel PT Plus
	INR	1.06	0.848	1.27	Beijing Succeder PT
	INR	0.881	0.705	1.06	Diagon PT R
	INR	1.16	0.928	1.39	Cobas PT Screen
凝血酶原时间 (PT) 比率	ratio	1.17	0.936	1.40	Dade Innovin
	ratio	1.09	0.872	1.31	Siemens/Dade Thromborel S
	ratio	1.09	0.872	1.31	Stago Neoplastine CI
	ratio	1.10	0.880	1.32	Stago Neoplastine CI Plus
	ratio	1.09	0.872	1.31	Stago Neoplastin R
	ratio	1.07	0.856	1.28	Diagon PT
	ratio	1.03	0.824	1.24	HemosIL PT-Fibrinogen HS Plus
	ratio	1.06	0.848	1.27	HemosIL PT-Fibrinogen Recombiplastin 2G
凝血酶时间 (TT)	Seconds	25.2	20.2	30.2	Dade Thrombin
	Seconds	19.1	15.3	22.9	Siemens/Dade Thromboclotin
	Seconds	21.4	17.1	25.7	Stago Thrombin
	Seconds	26.0	20.8	31.2	Sysmex Thrombin Time
	Seconds	24.5	19.6	29.4	Trinity/AMAX Thrombin
	Seconds	28.7	23.0	34.4	Diagon, Dia-TT
	Seconds	19.3	15.4	23.2	Pacific Hemostasis Thrombin Time
	Seconds	22.9	18.3	27.5	HemosIL Thrombin Time 5ml
	Seconds	30.1	24.1	36.1	HemosIL Thrombin Time 8ml