

凝血质控品

(COAG CONTROL 2)

货号: CG5022

批号: 275CG

包装: 12 x 1 ml

效期: 2020-10-28

GTIN: 05055273207637

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。

健康和安数据表备索。

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。

1. 小心打开瓶盖，往瓶中准确加入 1 ml 蒸馏水，在15~25℃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。

凝血质控品 - LEVEL 2 (COAG CONTROL 2)

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范围					
分析物	单位	靶值	低值	高值	方法学
Activated Partial Thromboplastin Time (APTT)	seconds	57.7	46.2	69.2	Tcoag TriniCLOT aPTT S
	seconds	49.9	39.9	59.9	Tcoag TriniCLOT aPTT HS
	seconds	53.0	42.4	63.6	Siemens/Dade Actin
	seconds	46.7	37.4	56.0	Siemens/Dade Actin FS
	seconds	43.4	34.7	52.1	Siemens/Dade Actin FSL
	seconds	85.7	68.6	103	Siemens/Dade Actin SL
	seconds	81.5	65.2	97.8	Siemens/Dade Pathromtin SL
	seconds	56.5	45.2	67.8	Helena aPTT
	seconds	44.1	35.3	52.9	HemosIL APTT-SP Liquid
	seconds	59.1	47.3	70.9	HemosIL Synthasil
	seconds	59.1	47.3	70.9	Pacific Hemostasis APTT-XL
	seconds	54.3	43.4	65.2	Stago aPTT
	seconds	49.9	39.9	59.9	Stago Cephascreen
	seconds	58.0	46.4	69.6	Stago CK-Prest
	seconds	58.1	46.5	69.7	Stago PTT Automate
	seconds	54.2	43.4	65.0	Teco TEClot APTT
	seconds	51.3	41.0	61.6	Human Hemostat APTT
	seconds	48.3	38.6	58.0	Bio-Ksel System APTTs
	seconds	59.7	47.8	71.6	Diagon Dia-PTT
	seconds	51.3	41.0	61.6	Weiner Lab APTT
	seconds	54.0	43.2	64.8	Biolabo Bio-CK APTT
	seconds	55.4	44.3	66.5	Spinreact APTT
	seconds	54.0	43.2	64.8	Tcoag TriniCLOT Automated aPTT
	seconds	42.0	33.6	50.4	Biodevice aPTT
	seconds	48.1	38.5	57.7	Biomedica QuikCoag aPTT
	seconds	57.9	46.3	69.5	Siemens Dade Actin Cephaloplastin
	seconds	47.6	38.1	57.1	Labitec aPTT
	seconds	51.5	41.2	61.8	Sclavo APTT-S
	seconds	54.4	43.5	65.3	HemoDiagnostica aPTT
	seconds	53.5	42.8	64.2	Cypress Diagnostics aPTT
	seconds	57.3	45.8	68.8	Tokra Medikal APTT
	seconds	44.4	35.5	53.3	Coagpia APTT-N
	seconds	79.3	63.4	95.2	Cobas aPTT MedS
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.64	1.31	1.97	Siemens/Dade Actin FSL
	ratio	2.61	2.09	3.13	Siemens/Dade Actin SL
	ratio	1.66	1.33	1.99	Stago Cephascreen
	ratio	1.75	1.40	2.10	Stago PTT Automate
	ratio	1.73	1.38	2.08	Stago aPTT
	ratio	2.54	2.03	3.05	Siemens/Dade Pathromtin SL
	ratio	1.42	1.14	1.70	HemosIL APTT-SP Liquid
	ratio	2.03	1.62	2.44	HemosIL Synthasil
	ratio	1.75	1.40	2.10	Pacific Hemostasis APTT-XL

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Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.56	1.25	1.87	Helena aPTT
	ratio	1.88	1.50	2.26	Stago CK-Prest
	ratio	1.98	1.58	2.38	Human Hemostat APTT
	ratio	1.42	1.14	1.70	Bio-Ksel System APTTs
	ratio	1.79	1.43	2.15	Siemens/Dade Actin FS
	ratio	1.83	1.46	2.20	Diagon Dia-PTT
	ratio	1.69	1.35	2.03	Biolabo Bio-CK APTT
	ratio	1.65	1.32	1.98	Biodevice aPTT
	ratio	1.51	1.21	1.81	Labitec aPTT
	ratio	1.71	1.37	2.05	Sclavo APTT-S
	ratio	1.41	1.13	1.69	Coagpia APTT-N
Antithrombin III activity	%	70.5	56.4	84.6	Siemens/Dade Berichrom ATIII
	%	67.3	53.8	80.8	HemosIL Liquid Antithrombin
	%	71.0	56.8	85.2	Roche Chronogenic Thrombin
	%	66.3	53.0	79.6	Hemosil Lyophilised Antithrombin III
	%	72.2	57.8	86.6	STACHrom ATIII
	%	75.2	60.2	90.2	Siemens/Dade Antithrombin III
	%	71.1	56.9	85.3	Diagon ATIII
	%	72.6	58.1	87.1	Siemens Innovance Antithrombin III
	%	66.6	53.3	79.9	Sclavo ATIII
Factor II activity	%	71.2	57.0	85.4	Dade Innovin
	%	73.9	59.1	88.7	Siemens/Dade Thromborel S
	%	72.7	58.2	87.2	Stago Neoplastine CI Plus
	%	69.2	55.4	83.0	HemosIL PT-Fibrinogen HS Plus
	%	65.2	52.2	78.2	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	67.2	53.8	80.6	Siemens/Dade Actin FS
	%	64.1	51.3	76.9	Siemens/Dade Pathromtin SL
	%	58.8	47.0	70.6	HemosIL Synthasil
	%	68.0	54.4	81.6	Stago CK-Prest
	%	62.6	50.1	75.1	Siemens/Dade Actin FSL
	%	59.7	47.8	71.6	HemosIL APTT-SP Liquid
	%	72.5	58.0	87.0	Stago Deficient / ImmunoDef IX
	%	57.5	46.0	69.0	HemosIL Factor IX deficient plasma
Factor V activity	%	54.3	43.4	65.2	Stago Neoplastine CI Plus
	%	57.0	45.6	68.4	Siemens/Dade Thromborel S
	%	42.7	34.2	51.2	Dade Innovin
	%	50.3	40.2	60.4	HemosIL PT-Fibrinogen HS Plus
	%	52.5	42.0	63.0	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	53.0	42.4	63.6	HemosIL Factor V deficient plasma
Factor VII activity	%	87.5	70.0	105	Stago Neoplastine CI Plus
	%	87.0	69.6	104	Siemens/Dade Thromborel S
	%	89.4	71.5	107	Dade Innovin
	%	89.7	71.8	108	HemosIL PT-Fibrinogen HS Plus
	%	96.3	77.0	116	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	98.3	78.6	118	HemosIL Factor VII deficient plasma
Factor VIII activity	%	41.9	33.5	50.3	Siemens/Dade Actin FS

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Factor VIII activity	%	39.5	31.6	47.4	Siemens/Dade Pathromtin SL
	%	36.6	29.3	43.9	Siemens/Dade Actin FSL
	%	36.5	29.2	43.8	HemosIL Synthasil
	%	37.6	30.1	45.1	HemosIL APTT-SP Liquid
	%	40.3	32.2	48.4	Stago STA Factor VIII
	%	40.3	32.2	48.4	Stago Deficient / ImmunoDef VIII
	%	33.9	27.1	40.7	HemosIL Factor VIII deficient plasma
Factor X activity	%	75.4	60.3	90.5	Siemens/Dade Thromborel S
	%	72.8	58.2	87.4	Dade Innovin
	%	74.1	59.3	88.9	HemosIL PT-Fibrinogen HS Plus
	%	70.0	56.0	84.0	Stago Neoplastine CI Plus
	%	66.8	53.4	80.2	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	39.2	31.4	47.0	Siemens/Dade Actin FS
	%	41.2	33.0	49.4	Siemens/Dade Pathromtin SL
	%	34.0	27.2	40.8	HemosIL Synthasil
	%	22.4	17.9	26.9	Siemens/Dade Actin FSL
	%	35.4	28.3	42.5	HemosIL APTT-SP Liquid
	%	37.8	30.2	45.4	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	70.9	56.7	85.1	Siemens/Dade Actin FS
	%	64.6	51.7	77.5	Siemens/Dade Pathromtin SL
	%	60.8	48.6	73.0	HemosIL Synthasil
	%	57.2	45.8	68.6	Siemens/Dade Actin FSL
Fibrinogen	g/L	1.85	1.48	2.22	HemosIL PT-Fibrinogen HS Plus
	mg/dL	185	148	222	
	g/L	2.01	1.61	2.41	Helena Fibrinogen
	mg/dL	201	161	241	
	g/L	2.03	1.62	2.44	Stago Fibrinogen / Liquid-Fib
	mg/dL	203	162	244	
	g/L	1.77	1.42	2.12	Siemens/Dade Multifibren U
	mg/dL	177	142	212	
	g/L	1.95	1.56	2.34	HemosIL Fibrinogen C
	mg/dL	195	156	234	
	g/L	1.70	1.36	2.04	Dade Thrombin
	mg/dL	170	136	204	
	g/L	2.37	1.90	2.84	Technoclone Fibrinogen
	mg/dL	237	190	284	
	g/L	1.94	1.55	2.33	Tcoag TriniCLOT Fibrinogen
	mg/dL	194	155	233	
	g/L	1.93	1.54	2.32	Biolabo Bio-Fibri
	mg/dL	193	154	232	
	g/L	1.84	1.47	2.21	HemosIL QFA (bovine thrombin)
	mg/dL	184	147	221	
	g/L	2.01	1.61	2.41	Stago STA Fibri-Prest Automate
	mg/dL	201	161	241	
	g/L	1.80	1.44	2.16	Bio-Ksel Fibrinogen
	mg/dL	180	144	216	

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Fibrinogen	g/L	1.89	1.51	2.27	Diagon Dia-F
	mg/dL	189	151	227	
	g/L	1.50	1.20	1.80	Dade Innovin Derived Fibrinogen
	mg/dL	150	120	180	
	g/L	1.38	1.10	1.66	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	138	110	166	
	g/L	1.83	1.46	2.20	Sclavo Fibrinogen
	mg/dL	183	146	220	
	g/L	1.77	1.42	2.12	Labitec Fibrinogen
	mg/dL	177	142	212	
	g/L	1.92	1.54	2.30	HemoDiagnostica Fibrinogen
	mg/dL	192	154	230	
	g/L	2.03	1.62	2.44	Helena Clauss Fibrinogen 100
	mg/dL	203	162	244	
	g/L	1.68	1.34	2.02	Coagpia Fibrinogen
	mg/dL	168	134	202	
Plasminogen activity	g/L	1.97	1.58	2.36	Diagon PT
	mg/dL	197	158	236	
Plasminogen activity	g/L	2.02	1.62	2.42	Cobas Fibrinogen
	mg/dL	202	162	242	
Plasminogen activity	%	70.0	56.0	84.0	Stago Stachrom Plasminogen
	%	78.4	62.7	94.1	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	67.6	54.1	81.1	Siemens/Dade Berichrom Protein C
	%	61.5	49.2	73.8	IL HemosIL Protein C
	%	73.4	58.7	88.1	Siemens
	%	71.8	57.4	86.2	STACHrom Protein C
Protein S activity	%	64.9	45.4	84.4	STA Liatest
	%	65.8	46.1	85.5	Stago StaClot
	%	68.6	48.0	89.2	IL HemosIL Free Protein S
	%	50.0	35.0	65.0	Dade Protein S Ac
	%	67.6	47.3	87.9	Siemens Innovance Free PS Ag
	%	59.3	41.5	77.1	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	16.0	12.8	19.2	Tcoag TriniCLOT PT Excel
	Seconds	17.5	14.0	21.0	Dade Innovin
	Seconds	15.7	12.6	18.8	Siemens/Dade Thromborel IS
	Seconds	15.6	12.5	18.7	Siemens/Dade Thromborel S
	Seconds	20.4	16.3	24.5	HemosIL PT-Fibrinogen HS Plus
	Seconds	24.3	19.4	29.2	Pacific Thromboplastin DS
	Seconds	16.7	13.4	20.0	Stago Neoplastine CI
	Seconds	18.8	15.0	22.6	Stago Neoplastine CI Plus
	Seconds	22.2	17.8	26.6	R2 Phosphoplastin RL
	Seconds	18.9	15.1	22.7	Teco TEClot PT-S
	Seconds	19.9	15.9	23.9	Biolabo Bio-TP
	Seconds	16.9	13.5	20.3	Stago Neoplastin R
	Seconds	12.9	10.3	15.5	Bio-Ksel System PT
	Seconds	18.1	14.5	21.7	Human Thromboplastin

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Prothrombin Time (PT)	Seconds	18.9	15.1	22.7	Diagon PT
	Seconds	21.0	16.8	25.2	Spinreact PT
	Seconds	25.2	20.2	30.2	TCoag TriniCLOT PT Excel S
	Seconds	18.2	14.6	21.8	Media IVD PT
	Seconds	15.9	12.7	19.1	Biodevice PT
	Seconds	21.3	17.0	25.6	Biomedica QuikCoag PT-HS
	Seconds	13.8	11.0	16.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	19.7	15.8	23.6	Helena Thromboplastin
	Seconds	17.7	14.2	21.2	Labitec PT
	Seconds	19.4	15.5	23.3	Cypress Diagnostics PT
	Seconds	18.9	15.1	22.7	Tokra Medikal PT
	Seconds	20.9	16.7	25.1	Coagpia PT-N
	Seconds	12.4	9.92	14.9	Bio-Ksel PT Plus
	Seconds	14.3	11.4	17.2	Diagon PT R
	Seconds	16.0	12.8	19.2	Cobas PT Screen
Prothrombin Time (PT) activity	%	39.6	31.7	47.5	Tcoag TriniCLOT PT Excel
	%	39.4	31.5	47.3	Dade Innovin
	%	58.7	47.0	70.4	Siemens/Dade Thromborel S
	%	53.7	43.0	64.4	Stago Neoplastine CI
	%	54.4	43.5	65.3	Stago Neoplastine CI Plus
	%	54.5	43.6	65.4	HemosIL PT-Fibrinogen HS Plus
	%	35.2	28.2	42.2	Pacific Thromboplastin DS
	%	52.5	42.0	63.0	Teco TEClot PT-S
	%	51.3	41.0	61.6	Biolabo Bio-TP
	%	68.8	55.0	82.6	Stago Neoplastin R
	%	52.2	41.8	62.6	Human Thromboplastin
	%	55.2	44.2	66.2	Diagon PT
	%	33.2	26.6	39.8	TCoag TriniCLOT PT Excel S
	%	44.3	35.4	53.2	Media IVD PT
	%	72.5	58.0	87.0	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	51.2	41.0	61.4	Helena Thromboplastin
	%	51.0	40.8	61.2	Labitec PT
	%	36.6	29.3	43.9	Coagpia PT-N
	%	90.0	72.0	108	Bio-Ksel PT Plus
	%	57.0	45.6	68.4	Diagon PT R
	%	52.8	42.2	63.4	Cobas PT Screen
Prothrombin Time (PT) INR	INR	1.88	1.50	2.26	Tcoag TriniCLOT PT Excel
	INR	1.73	1.38	2.08	Dade Innovin
	INR	1.33	1.06	1.60	Siemens/Dade Thromborel IS
	INR	1.34	1.07	1.61	Siemens/Dade Thromborel S
	INR	1.52	1.22	1.82	HemosIL PT-Fibrinogen HS Plus
	INR	1.79	1.43	2.15	Pacific Thromboplastin DS
	INR	1.60	1.28	1.92	Stago Neoplastine CI
	INR	1.56	1.25	1.87	Stago Neoplastine CI Plus
	INR	1.51	1.21	1.81	Human Thromboplastin
	INR	1.46	1.17	1.75	Teco TEClot PT-S

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Prothrombin Time (PT) INR	INR	1.66	1.33	1.99	Biolabo Bio-TP
	INR	1.22	0.976	1.46	Stago Neoplastin R
	INR	1.17	0.936	1.40	Bio-Ksel System PT
	INR	1.48	1.18	1.78	Diagon PT
	INR	1.82	1.46	2.18	Weiner Lab Soluplastin
	INR	1.73	1.38	2.08	Spinreact PT
	INR	2.25	1.80	2.70	TCoag TriniCLOT PT Excel S
	INR	1.45	1.16	1.74	Media IVD PT
	INR	1.30	1.04	1.56	Biodevice PT
	INR	1.60	1.28	1.92	Biomedica QuikCoag PT-HS
	INR	1.21	0.968	1.45	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.34	1.07	1.61	Technoclone Technoplastin HIS
	INR	1.57	1.26	1.88	Helena Thromboplastin
	INR	1.54	1.23	1.85	Labitec PT
	INR	1.54	1.23	1.85	Cypress Diagnostics PT
	INR	1.47	1.18	1.76	Tokra Medikal PT
	INR	1.73	1.38	2.08	Coagpia PT-N
	INR	1.14	0.912	1.37	Bio-Ksel PT Plus
	INR	1.35	1.08	1.62	Diagon PT R
	INR	1.51	1.21	1.81	Cobas PT Screen
Prothrombin Time (PT) ratio	ratio	1.80	1.44	2.16	Dade Innovin
	ratio	1.35	1.08	1.62	Siemens/Dade Thromborel S
	ratio	1.53	1.22	1.84	Stago Neoplastine CI Plus
	ratio	1.20	0.960	1.44	Stago Neoplastin R
	ratio	1.54	1.23	1.85	Diagon PT
	ratio	1.38	1.10	1.66	HemosIL PT-Fibrinogen HS Plus
	ratio	1.22	0.976	1.46	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	29.9	23.9	35.9	Dade Thrombin
	Seconds	21.1	16.9	25.3	Siemens/Dade Thromboclotin
	Seconds	27.6	22.1	33.1	Stago Thrombin
	Seconds	29.6	23.7	35.5	Sysmex Thrombin Time
	Seconds	27.3	21.8	32.8	Diagon, Dia-TT
	Seconds	23.5	18.8	28.2	HemosIL Thrombin Time 5ml
	Seconds	33.6	26.9	40.3	HemosIL Thrombin Time 8ml