

凝血质控品

(COAG CONTROL 3)

货号: CG5023
包装: 12 x 1 ml

批号: 276CG
效期: 2020-10-28

GTIN: 05055273207644

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 3 (COAG CONTROL 3)

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分析物	单位	范围			方法学
		靶值	低值	高值	
Activated Partial Thromboplastin Time (APTT)	seconds	73.8	59.0	88.6	Tcoag TriniCLOT aPTT S
	seconds	65.1	52.1	78.1	Tcoag TriniCLOT aPTT HS
	seconds	63.6	50.9	76.3	Siemens/Dade Actin
	seconds	56.8	45.4	68.2	Siemens/Dade Actin FS
	seconds	55.3	44.2	66.4	Siemens/Dade Actin FSL
	seconds	112	89.6	134	Siemens/Dade Pathromtin SL
	seconds	52.7	42.2	63.2	HemosIL APTT-SP Liquid
	seconds	78.3	62.6	94.0	HemosIL Synthasil
	seconds	69.3	55.4	83.2	Pacific Hemostasis APTT-XL
	seconds	66.4	53.1	79.7	Stago aPTT
	seconds	58.2	46.6	69.8	Stago Cephascreen
	seconds	70.7	56.6	84.8	Stago CK-Prest
	seconds	69.1	55.3	82.9	Stago PTT Automate
	seconds	70.7	56.6	84.8	Teco TEClot APTT
	seconds	61.2	49.0	73.4	Human Hemostat APTT
	seconds	57.3	45.8	68.8	Bio-Ksel System APTTs
	seconds	80.4	64.3	96.5	Diagon Dia-PTT
	seconds	51.5	41.2	61.8	Weiner Lab APTT
	seconds	64.2	51.4	77.0	Biolabo Bio-CK APTT
	seconds	68.2	54.6	81.8	Spinreact APTT
	seconds	68.6	54.9	82.3	Tcoag TriniCLOT Automated aPTT
	seconds	66.0	52.8	79.2	Media IVD aPTT
	seconds	58.8	47.0	70.6	Biomedica QuikCoag aPTT
	seconds	64.6	51.7	77.5	Siemens Dade Actin Cephaloplastin
seconds	57.8	46.2	69.4	Labitec aPTT	
seconds	66.4	53.1	79.7	Sclavo APTT-S	
seconds	65.8	52.6	79.0	HemoDiagnostica aPTT	
seconds	62.4	49.9	74.9	Cypress Diagnostics aPTT	
seconds	74.2	59.4	89.0	Tokra Medikal APTT	
seconds	53.2	42.6	63.8	Coagpia APTT-N	
seconds	106	84.8	127	Cobas aPTT MedS	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.12	1.70	2.54	Siemens/Dade Actin FSL
	ratio	3.34	2.67	4.01	Siemens/Dade Actin SL
	ratio	1.96	1.57	2.35	Stago Cephascreen
	ratio	2.07	1.66	2.48	Stago PTT Automate
	ratio	2.14	1.71	2.57	Stago aPTT
	ratio	3.48	2.78	4.18	Siemens/Dade Pathromtin SL
	ratio	1.73	1.38	2.08	HemosIL APTT-SP Liquid
	ratio	2.66	2.13	3.19	HemosIL Synthasil
	ratio	2.37	1.90	2.84	Stago CK-Prest
	ratio	2.38	1.90	2.86	Human Hemostat APTT
ratio	1.71	1.37	2.05	Bio-Ksel System APTTs	

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		靶值	低值	高值	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.19	1.75	2.63	Siemens/Dade Actin FS
	ratio	2.48	1.98	2.98	Diagon Dia-PTT
	ratio	2.29	1.83	2.75	Media IVD aPTT
	ratio	1.87	1.50	2.24	Biodevice aPTT
	ratio	1.95	1.56	2.34	Labitec aPTT
	ratio	2.31	1.85	2.77	Sclavo APTT-S
	ratio	1.63	1.30	1.96	Coagpia APTT-N
Antithrombin III activity	%	57.8	46.2	69.4	Siemens/Dade Berichrom ATIII
	%	54.5	43.6	65.4	HemosIL Liquid Antithrombin
	%	58.6	46.9	70.3	Roche Chronogenic Thrombin
	%	57.0	45.6	68.4	Hemosil Lyophilised Antithrombin III
	%	60.0	48.0	72.0	STACHrom ATIII
	%	61.2	49.0	73.4	Siemens/Dade Antithrombin III
	%	63.1	50.5	75.7	Diagon ATIII
	%	57.3	45.8	68.8	Siemens Innovance Antithrombin III
Factor II activity	%	56.3	45.0	67.6	Sclavo ATIII
	%	57.4	45.9	68.9	Dade Innovin
	%	62.4	49.9	74.9	Siemens/Dade Thromborel S
	%	63.6	50.9	76.3	Stago Neoplastine CI Plus
	%	57.5	46.0	69.0	HemosIL PT-Fibrinogen HS Plus
Factor IX activity	%	55.6	44.5	66.7	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	64.3	51.4	77.2	Stago PTT Automate
	%	50.7	40.6	60.8	Siemens/Dade Actin FS
	%	57.0	45.6	68.4	Siemens/Dade Pathromtin SL
	%	49.1	39.3	58.9	HemosIL Synthasil
	%	56.0	44.8	67.2	Stago CK-Prest
	%	51.3	41.0	61.6	Siemens/Dade Actin FSL
	%	48.8	39.0	58.6	HemosIL APTT-SP Liquid
	%	46.0	36.8	55.2	Siemens/Dade Actin
Factor V activity	%	63.3	50.6	76.0	Stago Deficient / ImmunoDef IX
	%	47.6	38.1	57.1	HemosIL Factor IX deficient plasma
	%	41.0	32.8	49.2	Stago Neoplastine CI Plus
	%	43.3	34.6	52.0	Siemens/Dade Thromborel S
	%	37.4	29.9	44.9	Dade Innovin
	%	35.6	28.5	42.7	HemosIL PT-Fibrinogen HS Plus
	%	41.6	33.3	49.9	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VII activity	%	36.0	28.8	43.2	Stago Neoplastin R
	%	38.0	30.4	45.6	HemosIL Factor V deficient plasma
	%	78.7	63.0	94.4	Stago Neoplastine CI Plus
	%	83.2	66.6	100	Siemens/Dade Thromborel S
	%	91.9	73.5	110	Dade Innovin
	%	83.5	66.8	100	HemosIL PT-Fibrinogen HS Plus
	%	108	86.4	130	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VIII activity	%	79.3	63.4	95.2	Stago Neoplastin R
	%	102	81.6	122	HemosIL Factor VII deficient plasma
	%	29.2	23.4	35.0	Stago CK-Prest

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Factor VIII activity	%	32.9	26.3	39.5	Siemens/Dade Actin FS
	%	29.2	23.4	35.0	Siemens/Dade Pathromtin SL
	%	28.1	22.5	33.7	Siemens/Dade Actin FSL
	%	29.5	23.6	35.4	HemosIL Synthasil
	%	28.6	22.9	34.3	HemosIL Factor VIII deficient plasma
Factor X activity	%	65.6	52.5	78.7	Siemens/Dade Thromborel S
	%	62.1	49.7	74.5	Dade Innovin
	%	60.8	48.6	73.0	HemosIL PT-Fibrinogen HS Plus
	%	59.2	47.4	71.0	Stago Neoplastine CI Plus
	%	64.7	51.8	77.6	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	27.0	21.6	32.4	Siemens/Dade Actin FS
	%	33.0	26.4	39.6	Siemens/Dade Pathromtin SL
	%	26.3	21.0	31.6	HemosIL Synthasil
	%	27.4	21.9	32.9	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	55.8	44.6	67.0	Siemens/Dade Actin FS
	%	57.1	45.7	68.5	Siemens/Dade Pathromtin SL
	%	53.1	42.5	63.7	HemosIL Synthasil
	%	48.5	38.8	58.2	Siemens/Dade Actin FSL
Fibrinogen	g/L	1.62	1.30	1.94	HemosIL PT-Fibrinogen HS Plus
	mg/dL	162	130	194	
	g/L	1.74	1.39	2.09	Helena Fibrinogen
	mg/dL	174	139	209	
	g/L	1.60	1.28	1.92	Stago Fibrinogen / Liquid-Fib
	mg/dL	160	128	192	
	g/L	1.07	0.856	1.28	Siemens/Dade Multifibren U
	mg/dL	107	85.6	128	
	g/L	1.48	1.18	1.78	HemosIL Fibrinogen C
	mg/dL	148	118	178	
	g/L	1.28	1.02	1.54	Dade Thrombin
	mg/dL	128	102	154	
	g/L	1.47	1.18	1.76	Tcoag TriniCLOT Fibrinogen
	mg/dL	147	118	176	
	g/L	1.42	1.14	1.70	Biolabo Bio-Fibri
	mg/dL	142	114	170	
	g/L	1.44	1.15	1.73	HemosIL QFA (bovine thrombin)
	mg/dL	144	115	173	
	g/L	2.01	1.61	2.41	Pacific Hemostasis Fibrinogen
	mg/dL	201	161	241	
g/L	1.50	1.20	1.80	Human Fibrinogen	
mg/dL	150	120	180		
g/L	1.58	1.26	1.90	Stago STA Fibri-Prest Automate	
mg/dL	158	126	190		
g/L	1.64	1.31	1.97	Bio-Ksel Fibrinogen	
mg/dL	164	131	197		
g/L	1.42	1.14	1.70	Diagon Dia-F	
mg/dL	142	114	170		

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		靶值	低值	高值		
Fibrinogen	g/L	1.09	0.872	1.31	Dade Innovin Derived Fibrinogen	
	mg/dL	109	87.2	131		
	g/L	1.12	0.896	1.34	Siemens/Dade Thromboplastin Derived Fibrinogen	
	mg/dL	112	89.6	134		
	g/L	1.50	1.20	1.80	Technology-Standard Fibrinogen	
	mg/dL	150	120	180		
	g/L	0.986	0.789	1.18	HemosIL PT-Fibrinogen Recombiplastin 2G	
	mg/dL	98.6	78.9	118		
	g/L	1.41	1.13	1.69	Sclavo Fibrinogen	
	mg/dL	141	113	169		
	g/L	1.52	1.22	1.82	Labitec Fibrinogen	
	mg/dL	152	122	182		
	g/L	1.64	1.31	1.97	Helena Clauss Fibrinogen 100	
	mg/dL	164	131	197		
Plasminogen activity	g/L	1.14	0.912	1.37	Coagpia Fibrinogen	
	mg/dL	114	91.2	137		
	g/L	1.47	1.18	1.76	HemosIL PT-Fibrinogen	
	mg/dL	147	118	176		
	g/L	1.45	1.16	1.74	Beijing Succeder Fibrinogen	
	mg/dL	145	116	174		
	g/L	1.44	1.15	1.73	Cobas Fibrinogen	
	mg/dL	144	115	173		
	%	58.6	46.9	70.3	Stago Stachrom Plasminogen	
	%	58.0	46.4	69.6	HemosIL Plasminogen	
	%	60.7	48.6	72.8	Siemens/Dade Berichrom Plasminogen	
	Protein C activity	%	57.9	46.3	69.5	Siemens/Dade Berichrom Protein C
		%	64.0	51.2	76.8	Stago StaClot
		%	52.0	41.6	62.4	Biomerieux VIDAS Protein C
%		54.3	43.4	65.2	IL HemosIL Protein C	
%		61.4	49.1	73.7	Siemens	
%		62.0	49.6	74.4	STACHrom Protein C	
Protein S activity	%	53.2	37.2	69.2	STA Liatest	
	%	57.4	40.2	74.6	Stago StaClot	
	%	55.5	38.9	72.2	IL HemosIL Free Protein S	
	%	37.6	26.3	48.9	Dade Protein S Ac	
	%	55.3	38.7	71.9	Siemens Innovance Free PS Ag	
	%	38.7	27.1	50.3	IL HemosIL Protein S Activity	
Prothrombin Time (PT)	Seconds	27.2	21.8	32.6	Dade Innovin	
	Seconds	18.8	15.0	22.6	Siemens/Dade Thromborel IS	
	Seconds	18.9	15.1	22.7	Siemens/Dade Thromborel S	
	Seconds	28.4	22.7	34.1	HemosIL PT-Fibrinogen HS Plus	
	Seconds	22.0	17.6	26.4	Stago Neoplastine CI	
	Seconds	24.7	19.8	29.6	Stago Neoplastine CI Plus	
	Seconds	24.9	19.9	29.9	Teco TEClot PT-S	
	Seconds	28.8	23.0	34.6	Biolabo Bio-TP	
	Seconds	19.7	15.8	23.6	Stago Neoplastin R	

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Prothrombin Time (PT)	Seconds	15.8	12.6	19.0	Bio-Ksel System PT
	Seconds	22.7	18.2	27.2	Human Thromboplastin
	Seconds	25.9	20.7	31.1	Diagon PT
	Seconds	26.7	21.4	32.0	Spinreact PT
	Seconds	46.8	37.4	56.2	TCoag TriniCLOT PT Excel S
	Seconds	19.3	15.4	23.2	Biodevice PT
	Seconds	27.8	22.2	33.4	Biomedica QuikCoag PT-HS
	Seconds	16.2	13.0	19.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	30.6	24.5	36.7	Helena Thromboplastin
	Seconds	21.0	16.8	25.2	Cypress Diagnostics PT
	Seconds	24.8	19.8	29.8	Tokra Medikal PT
	Seconds	15.6	12.5	18.7	Bio-Ksel PT Plus
	Seconds	29.3	23.4	35.2	Beijing Succeeder PT
	Seconds	19.7	15.8	23.6	Diagon PT R
	Seconds	19.0	15.2	22.8	Cobas PT Screen
Prothrombin Time (PT) activity	%	21.5	17.2	25.8	Dade Innovin
	%	44.8	35.8	53.8	Siemens/Dade Thromborel S
	%	38.6	30.9	46.3	Stago Neoplastine CI
	%	35.9	28.7	43.1	Stago Neoplastine CI Plus
	%	32.6	26.1	39.1	HemosIL PT-Fibrinogen HS Plus
	%	27.2	21.8	32.6	Biolabo Bio-TP
	%	54.7	43.8	65.6	Stago Neoplastin R
	%	36.9	29.5	44.3	Human Thromboplastin
	%	15.6	12.5	18.7	TCoag TriniCLOT PT Excel S
	%	40.2	32.2	48.2	Biodevice PT
	%	57.8	46.2	69.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	25.7	20.6	30.8	Helena Thromboplastin
	%	26.8	21.4	32.2	Tokra Medikal PT
	%	70.2	56.2	84.2	Bio-Ksel PT Plus
	%	27.5	22.0	33.0	Beijing Succeeder PT
%	33.3	26.6	40.0	Diagon PT R	
Prothrombin Time (PT) INR	INR	2.65	2.12	3.18	Dade Innovin
	INR	1.61	1.29	1.93	Siemens/Dade Thromborel IS
	INR	1.66	1.33	1.99	Siemens/Dade Thromborel S
	INR	2.24	1.79	2.69	HemosIL PT-Fibrinogen HS Plus
	INR	2.07	1.66	2.48	Stago Neoplastine CI
	INR	2.15	1.72	2.58	Stago Neoplastine CI Plus
	INR	1.96	1.57	2.35	Human Thromboplastin
	INR	1.89	1.51	2.27	Teco TEClot PT-S
	INR	1.40	1.12	1.68	Stago Neoplastin R
	INR	1.43	1.14	1.72	Bio-Ksel System PT
	INR	2.09	1.67	2.51	Diagon PT
	INR	2.29	1.83	2.75	Spinreact PT
	INR	4.74	3.79	5.69	TCoag TriniCLOT PT Excel S
	INR	1.84	1.47	2.21	Biodevice PT
	INR	2.12	1.70	2.54	Biomedica QuikCoag PT-HS

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Prothrombin Time (PT) INR	INR	1.42	1.14	1.70	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.86	1.49	2.23	Technoclone Technoplastin HIS
	INR	2.58	2.06	3.10	Helena Thromboplastin
	INR	2.43	1.94	2.92	Labitec PT
	INR	1.96	1.57	2.35	Tokra Medikal PT
	INR	1.40	1.12	1.68	Bio-Ksel PT Plus
	INR	2.28	1.82	2.74	Beijing Succeder PT
	INR	1.91	1.53	2.29	Diagon PT R
	INR	1.85	1.48	2.22	Cobas PT Screen
Prothrombin Time (PT) ratio	ratio	2.65	2.12	3.18	Dade Innovin
	ratio	1.65	1.32	1.98	Siemens/Dade Thromborel S
	ratio	1.66	1.33	1.99	Stago Neoplastine CI
	ratio	2.01	1.61	2.41	Stago Neoplastine CI Plus
	ratio	1.41	1.13	1.69	Stago Neoplastin R
	ratio	1.96	1.57	2.35	HemosIL PT-Fibrinogen HS Plus
	ratio	1.42	1.14	1.70	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	35.1	28.1	42.1	Dade Thrombin
	Seconds	30.8	24.6	37.0	Siemens/Dade Thromboclotin
	Seconds	38.4	30.7	46.1	Stago Thrombin
	Seconds	32.7	26.2	39.2	Sysmex Thrombin Time
	Seconds	30.9	24.7	37.1	HemosIL Thrombin Time 5ml
	Seconds	42.2	33.8	50.6	HemosIL Thrombin Time 8ml