

凝血质控品

(COAG CONTROL 1)

货号: CG 5021
包装: 12 x 1 ml

批号: 271CG
效期: 2020-10-28

GTIN: 05055273207620

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。

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分析物	单位	靶值	低值	高值	方法学
Activated Partial Thromboplastin Time (APTT)	seconds	44.2	35.4	53.0	Tcoag TriniCLOT aPTT S
	seconds	44.3	35.4	53.2	Tcoag TriniCLOT aPTT HS
	seconds	44.0	35.2	52.8	Siemens/Dade Actin
	seconds	38.4	30.7	46.1	Siemens/Dade Actin FS
	seconds	36.4	29.1	43.7	Siemens/Dade Actin FSL
	seconds	49.8	39.8	59.8	Siemens/Dade Actin SL
	seconds	50.8	40.6	61.0	Siemens/Dade Pathromtin SL
	seconds	40.4	32.3	48.5	Helena aPTT
	seconds	37.5	30.0	45.0	HemosIL APTT-SP Liquid
	seconds	42.0	33.6	50.4	HemosIL Synthasil
	seconds	42.4	33.9	50.9	Pacific Hemostasis APTT-XL
	seconds	46.6	37.3	55.9	Stago aPTT
	seconds	44.8	35.8	53.8	Stago Cephascreen
	seconds	46.3	37.0	55.6	Stago CK-Prest
	seconds	47.2	37.8	56.6	Stago PTT Automate
	seconds	43.9	35.1	52.7	Teco TEClot APTT
	seconds	42.2	33.8	50.6	Human Hemostat APTT
	seconds	43.4	34.7	52.1	Bio-Ksel System APTTs
	seconds	51.6	41.3	61.9	Diagon Dia-PTT
	seconds	44.1	35.3	52.9	Weiner Lab APTT
	seconds	44.4	35.5	53.3	Biolabo Bio-CK APTT
	seconds	46.4	37.1	55.7	Spinreact APTT
	seconds	46.2	37.0	55.4	Tcoag TriniCLOT Automated aPTT
	seconds	38.6	30.9	46.3	Media IVD aPTT
	seconds	40.6	32.5	48.7	Biomedica QuikCoag aPTT
	seconds	46.6	37.3	55.9	Hemosil aPTT Lyophilised Silica
	seconds	49.7	39.8	59.6	Siemens Dade Actin Cephaloplastin
	seconds	39.5	31.6	47.4	Labitec aPTT
	seconds	40.5	32.4	48.6	Sclavo APTT-S
	seconds	45.6	36.5	54.7	HemoDiagnostics aPTT
	seconds	42.2	33.8	50.6	Cypress Diagnostics aPTT
	seconds	46.1	36.9	55.3	Tokra Medikal APTT
	seconds	38.8	31.0	46.6	Coagpia APTT-N
	seconds	49.0	39.2	58.8	Cobas aPTT MedS
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.38	1.10	1.66	Siemens/Dade Actin FSL
	ratio	1.56	1.25	1.87	Siemens/Dade Actin SL
	ratio	1.50	1.20	1.80	Stago Cephascreen
	ratio	1.38	1.10	1.66	Stago PTT Automate
	ratio	1.57	1.26	1.88	Stago aPTT
	ratio	1.60	1.28	1.92	Siemens/Dade Pathromtin SL
	ratio	1.23	0.984	1.48	HemosIL APTT-SP Liquid
	ratio	1.39	1.11	1.67	HemosIL Synthasil

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Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.51	1.21	1.81	Stago CK-Prest
	ratio	1.56	1.25	1.87	Human Hemostat APTT
	ratio	1.26	1.01	1.51	Bio-Ksel System APTTs
	ratio	1.47	1.18	1.76	Siemens/Dade Actin FS
	ratio	1.49	1.19	1.79	Diagon Dia-PTT
	ratio	1.44	1.15	1.73	Biodevice aPTT
	ratio	1.35	1.08	1.62	Labitec aPTT
	ratio	1.40	1.12	1.68	Sclavo APTT-S
	ratio	1.20	0.960	1.44	Coagpia APTT-N
Antithrombin III activity	%	83.5	66.8	100	Siemens/Dade Berichrom ATIII
	%	80.3	64.2	96.4	HemosIL Liquid Antithrombin
	%	82.3	65.8	98.8	Roche Chronogenic Thrombin
	%	82.2	65.8	98.6	Hemosil Lyophilised Antithrombin III
	%	83.4	66.7	100	STACHrom ATIII
	%	85.4	68.3	102	Siemens/Dade Antithrombin III
	%	91.3	73.0	110	Diagon ATIII
	%	86.1	68.9	103	Biodevice ATIII
	%	82.7	66.2	99.0	Siemens Innovance Antithrombin III
	%	78.6	62.9	94.3	Sclavo ATIII
	%	80.9	64.7	97.1	Teco TECHrom AT
	%	79.8	63.8	95.8	HemoDiagnostica Antithrombin III (Fxa)
Factor II activity	%	88.4	70.7	106	Dade Innovin
	%	87.9	70.3	105	Siemens/Dade Thromborel S
	%	77.0	61.6	92.4	Stago Neoplastine CI Plus
	%	82.8	66.2	99.0	HemosIL PT-Fibrinogen HS Plus
	%	83.4	66.7	100	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	74.9	59.9	89.9	Siemens/Dade Actin FS
	%	77.7	62.2	93.2	Siemens/Dade Pathromtin SL
	%	72.0	57.6	86.4	HemosIL Synthasil
	%	86.4	69.1	104	Stago CK-Prest
	%	74.0	59.2	88.8	Siemens/Dade Actin FSL
	%	80.5	64.4	96.6	HemosIL APTT-SP Liquid
	%	92.7	74.2	111	Stago Deficient / ImmunoDef IX
	%	74.8	59.8	89.8	HemosIL Factor IX deficient plasma
Factor V activity	%	70.8	56.6	85.0	Stago Neoplastine CI Plus
	%	69.5	55.6	83.4	Siemens/Dade Thromborel S
	%	64.8	51.8	77.8	Dade Innovin
	%	59.6	47.7	71.5	HemosIL PT-Fibrinogen HS Plus
	%	64.7	51.8	77.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	63.0	50.4	75.6	HemosIL Factor V deficient plasma
Factor VII activity	%	104	83.2	125	Stago Neoplastine CI Plus
	%	102	81.6	122	Siemens/Dade Thromborel S
	%	101	80.8	121	Dade Innovin
	%	107	85.6	128	HemosIL PT-Fibrinogen HS Plus
	%	111	88.8	133	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	93.8	75.0	113	Stago Neoplastin R

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Factor VII activity	%	114	91.2	137	HemosIL Factor VII deficient plasma
Factor VIII activity	%	44.3	35.4	53.2	Stago PTT Automate
	%	48.7	39.0	58.4	Siemens/Dade Actin FS
	%	46.7	37.4	56.0	Siemens/Dade Pathromtin SL
	%	43.8	35.0	52.6	Siemens/Dade Actin FSL
	%	42.0	33.6	50.4	HemosIL Synthasil
	%	42.6	34.1	51.1	HemosIL APTT-SP Liquid
	%	54.4	43.5	65.3	Stago STA Factor VIII
	%	48.4	38.7	58.1	Stago Deficient / ImmunoDef VIII
	%	42.0	33.6	50.4	HemosIL Factor VIII deficient plasma
Factor X activity	%	92.7	74.2	111	Siemens/Dade Thromborel S
	%	83.5	66.8	100	Dade Innovin
	%	85.1	68.1	102	HemosIL PT-Fibrinogen HS Plus
	%	75.5	60.4	90.6	Stago Neoplastine CI Plus
	%	83.5	66.8	100	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	45.0	36.0	54.0	Siemens/Dade Actin FS
	%	48.2	38.6	57.8	Siemens/Dade Pathromtin SL
	%	41.9	33.5	50.3	HemosIL Synthasil
	%	30.9	24.7	37.1	Siemens/Dade Actin FSL
	%	48.7	39.0	58.4	HemosIL APTT-SP Liquid
	%	38.9	31.1	46.7	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	71.5	57.2	85.8	Siemens/Dade Actin FS
	%	76.0	60.8	91.2	Siemens/Dade Pathromtin SL
	%	71.3	57.0	85.6	Siemens/Dade Actin FSL
	%	89.7	71.8	108	HemosIL APTT-SP Liquid
Fibrinogen	g/L	2.22	1.78	2.66	HemosIL PT-Fibrinogen HS Plus
	mg/dL	222	178	266	
	g/L	2.29	1.83	2.75	Helena Fibrinogen
	mg/dL	229	183	275	
	g/L	2.38	1.90	2.86	Stago Fibrinogen / Liquid-Fib
	mg/dL	238	190	286	
	g/L	2.07	1.66	2.48	Siemens/Dade Multifibren U
	mg/dL	207	166	248	
	g/L	2.22	1.78	2.66	HemosIL Fibrinogen C
	mg/dL	222	178	266	
	g/L	2.02	1.62	2.42	Dade Thrombin
	mg/dL	202	162	242	
	g/L	2.48	1.98	2.98	Technoclone Fibrinogen
	mg/dL	248	198	298	
	g/L	2.31	1.85	2.77	Tcoag TriniCLOT Fibrinogen
	mg/dL	231	185	277	
	g/L	1.97	1.58	2.36	Biolabo Bio-Fibri
	mg/dL	197	158	236	
	g/L	2.15	1.72	2.58	Teco Teclot Fibrinogen
	mg/dL	215	172	258	
	g/L	2.09	1.67	2.51	HemosIL QFA (bovine thrombin)
	mg/dL	209	167	251	

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Fibrinogen	g/L	2.15	1.72	2.58	Human Fibrinogen
	mg/dL	215	172	258	
	g/L	2.34	1.87	2.81	Stago STA Fibrin-Prest Automate
	mg/dL	234	187	281	
	g/L	1.93	1.54	2.32	Bio-Ksel System PT
	mg/dL	193	154	232	
	g/L	2.25	1.80	2.70	Bio-Ksel Fibrinogen
	mg/dL	225	180	270	
	g/L	2.07	1.66	2.48	Diagon Dia-F
	mg/dL	207	166	248	
	g/L	1.71	1.37	2.05	Dade Innovin Derived Fibrinogen
	mg/dL	171	137	205	
	g/L	1.93	1.54	2.32	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	193	154	232	
	g/L	2.20	1.76	2.64	Spinreact Fibrinogen
	mg/dL	220	176	264	
	g/L	2.10	1.68	2.52	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	210	168	252	
	g/L	2.19	1.75	2.63	Sclavo Fibrinogen
	mg/dL	219	175	263	
	g/L	2.10	1.68	2.52	Labitec Fibrinogen
	mg/dL	210	168	252	
	g/L	2.34	1.87	2.81	HemoDiagnostica Fibrinogen
	mg/dL	234	187	281	
	g/L	2.32	1.86	2.78	Helena Clauss Fibrinogen 100
	mg/dL	232	186	278	
	g/L	2.00	1.60	2.40	Tokra Medikal Fibrinogen
	mg/dL	200	160	240	
	g/L	2.21	1.77	2.65	Coagpia Fibrinogen
	mg/dL	221	177	265	
	g/L	2.12	1.70	2.54	HemosIL PT-Fibrinogen
	mg/dL	212	170	254	
	g/L	2.20	1.76	2.64	Beijing Succeder Fibrinogen
	mg/dL	220	176	264	
	g/L	2.11	1.69	2.53	Cobas Fibrinogen
	mg/dL	211	169	253	
Plasminogen activity	%	84.0	67.2	101	Stago Stachrom Plasminogen
	%	80.9	64.7	97.1	HemosIL Plasminogen
	%	85.2	68.2	102	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	88.5	70.8	106	Siemens/Dade Berichrom Protein C
	%	87.0	69.6	104	Stago StaClot
	%	81.8	65.4	98.2	IL HemosIL Protein C
	%	88.6	70.9	106	Siemens
	%	88.0	70.4	106	STACHrom Protein C
Protein S activity	%	71.8	50.3	93.3	STA Liatest

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Protein S activity	%	68.6	48.0	89.2	Stago StaClot
	%	75.5	52.9	98.2	IL HemosIL ProS
	%	79.7	55.8	104	IL HemosIL Free Protein S
	%	55.1	38.6	71.6	Dade Protein S Ac
	%	78.3	54.8	102	Siemens Innovance Free PS Ag
	%	59.6	41.7	77.5	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	12.0	9.60	14.4	Dade Innovin
	Seconds	13.0	10.4	15.6	Siemens/Dade Thromborel IS
	Seconds	12.5	10.0	15.0	Siemens/Dade Thromborel S
	Seconds	14.9	11.9	17.9	HemosIL PT-Fibrinogen HS Plus
	Seconds	16.0	12.8	19.2	Pacific Thromboplastin DS
	Seconds	14.9	11.9	17.9	Stago Neoplastine CI
	Seconds	14.9	11.9	17.9	Stago Neoplastine CI Plus
	Seconds	16.0	12.8	19.2	R2 Phosphoplastin RL
	Seconds	14.7	11.8	17.6	Teco TEClot PT-S
	Seconds	14.4	11.5	17.3	Biolabo Bio-TP
	Seconds	14.7	11.8	17.6	Stago Neoplastin R
	Seconds	11.0	8.80	13.2	Bio-Ksel System PT
	Seconds	14.0	11.2	16.8	Human Thromboplastin
	Seconds	14.2	11.4	17.0	Diagon PT
	Seconds	14.8	11.8	17.8	Weiner Lab Soluplastin
	Seconds	13.3	10.6	16.0	Spinreact PT
	Seconds	15.8	12.6	19.0	TCoag TriniCLOT PT Excel S
	Seconds	13.0	10.4	15.6	Media IVD PT
	Seconds	12.1	9.68	14.5	Biodevice PT
	Seconds	14.1	11.3	16.9	Biomedica QuikCoag PT-HS
	Seconds	12.0	9.60	14.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	14.5	11.6	17.4	Helena Thromboplastin
	Seconds	13.0	10.4	15.6	Labitec PT
	Seconds	13.4	10.7	16.1	Cypress Diagnostics PT
	Seconds	14.5	11.6	17.4	Tokra Medikal PT
	Seconds	13.2	10.6	15.8	Coagpia PT-N
	Seconds	11.2	8.96	13.4	Bio-Ksel PT Plus
	Seconds	14.0	11.2	16.8	Beijing Succeeder PT
	Seconds	10.5	8.40	12.6	Diagon PT R
	Seconds	12.1	9.68	14.5	Cobas PT Screen
Prothrombin Time (PT) activity	%	69.9	55.9	83.9	Dade Innovin
	%	87.9	70.3	105	Siemens/Dade Thromborel S
	%	77.1	61.7	92.5	Stago Neoplastine CI
	%	79.7	63.8	95.6	Stago Neoplastine CI Plus
	%	88.8	71.0	107	HemosIL PT-Fibrinogen HS Plus
	%	63.5	50.8	76.2	Pacific Thromboplastin DS
	%	87.4	69.9	105	Teco TEClot PT-S
	%	81.5	65.2	97.8	Biolabo Bio-TP
	%	89.0	71.2	107	Stago Neoplastin R
	%	98.7	79.0	118	Bio-Ksel System PT

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Prothrombin Time (PT) activity	%	80.3	64.2	96.4	Human Thromboplastin
	%	88.6	70.9	106	Diagon PT
	%	67.0	53.6	80.4	TCoag TriniCLOT PT Excel S
	%	79.1	63.3	94.9	Media IVD PT
	%	85.0	68.0	102	Biodevice PT
	%	90.2	72.2	108	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	81.3	65.0	97.6	Helena Thromboplastin
	%	85.5	68.4	103	Labitec PT
	%	78.8	63.0	94.6	Tokra Medikal PT
	%	83.7	67.0	100	Coagpia PT-N
	%	96.6	77.3	116	Bio-Ksel PT Plus
	%	91.2	73.0	109	Beijing Succeeder PT
	%	103	82.4	124	Diagon PT R
Prothrombin Time (PT) INR	INR	1.18	0.944	1.42	Dade Innovin
	INR	1.08	0.864	1.30	Siemens/Dade Thromborel IS
	INR	1.07	0.856	1.28	Siemens/Dade Thromborel S
	INR	1.08	0.864	1.30	HemosIL PT-Fibrinogen HS Plus
	INR	1.19	0.952	1.43	Pacific Thromboplastin DS
	INR	1.20	0.960	1.44	Stago Neoplastine CI
	INR	1.16	0.928	1.39	Stago Neoplastine CI Plus
	INR	1.10	0.880	1.32	Human Thromboplastin
	INR	1.10	0.880	1.32	Teco TEClot PT-S
	INR	1.25	1.00	1.50	Biolabo Bio-TP
	INR	1.07	0.856	1.28	Stago Neoplastin R
	INR	1.00	0.800	1.20	Bio-Ksel System PT
	INR	1.09	0.872	1.31	Diagon PT
	INR	1.23	0.984	1.48	Weiner Lab Soluplastin
	INR	1.08	0.864	1.30	Spinreact PT
	INR	1.26	1.01	1.51	TCoag TriniCLOT PT Excel S
	INR	1.15	0.920	1.38	Media IVD PT
	INR	1.09	0.872	1.31	Biodevice PT
	INR	1.11	0.888	1.33	Biomedica QuikCoag PT-HS
	INR	1.05	0.840	1.26	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.14	0.912	1.37	Helena Thromboplastin
	INR	1.09	0.872	1.31	Labitec PT
	INR	1.06	0.848	1.27	Tokra Medikal PT
	INR	1.10	0.880	1.32	Coagpia PT-N
	INR	1.02	0.816	1.22	Bio-Ksel PT Plus
	INR	1.07	0.856	1.28	Beijing Succeeder PT
	INR	0.943	0.754	1.13	Diagon PT R
	INR	1.10	0.880	1.32	Cobas PT Screen
Prothrombin Time (PT) ratio	ratio	1.25	1.00	1.50	Dade Innovin
	ratio	1.07	0.856	1.28	Siemens/Dade Thromborel S
	ratio	1.13	0.904	1.36	Stago Neoplastine CI
	ratio	1.13	0.904	1.36	Stago Neoplastine CI Plus
	ratio	1.05	0.840	1.26	Stago Neoplastin R

凝血质控品- LEVEL 1 (COAG CONTROL 1)

货号: CG5021 批号: 271CG 包装: 12 x 1 ml 效期: 2020-10-28

范围					
分析物	单位	靶值	低值	高值	方法学
Prothrombin Time (PT) ratio	ratio	1.10	0.880	1.32	Diagon PT
	ratio	1.05	0.840	1.26	HemosIL PT-Fibrinogen HS Plus
	ratio	1.06	0.848	1.27	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	25.0	20.0	30.0	Dade Thrombin
	Seconds	20.1	16.1	24.1	Siemens/Dade Thromboclotin
	Seconds	22.3	17.8	26.8	Stago Thrombin
	Seconds	24.0	19.2	28.8	HemosIL Thrombin Time 5ml
	Seconds	32.0	25.6	38.4	HemosIL Thrombin Time 8ml