

凝血质控品

货号：CG5023

包装：12 x 1 ml

批号：259CG

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 °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-水平3

货号: CG5023		批号: 259CG			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	61.1	48.9	73.3	Tcoag TriniCLOT aPTT S	
	seconds	55.9	44.7	67.1	Tcoag TriniCLOT aPTT HS	
	seconds	57.1	45.7	68.5	Siemens/Dade Actin	
	seconds	52.5	42.0	63.0	Siemens/Dade Actin FS	
	seconds	49.2	39.4	59.0	Siemens/Dade Actin FSL	
	seconds	101	80.8	121	Siemens/Dade Pathromtin SL	
	seconds	63.2	50.6	75.8	Helena aPTT	
	seconds	47.2	37.8	56.6	HemosIL APTT-SP Liquid	
	seconds	72.9	58.3	87.5	HemosIL Synthasil	
	seconds	49.4	39.5	59.3	HemosIL Synthafax	
	seconds	59.5	47.6	71.4	Pacific Hemostasis APTT-XL	
	seconds	62.2	49.8	74.6	Stago aPTT	
	seconds	54.4	43.5	65.3	Stago Cephascreen	
	seconds	64.9	51.9	77.9	Stago CK-Prest	
	seconds	64.5	51.6	77.4	Stago PTT Automate	
	seconds	67.3	53.8	80.8	Teco TEClot APTT	
	seconds	55.0	44.0	66.0	Human Hemostat APTT	
	seconds	51.5	41.2	61.8	Bio-Ksel System APTTs	
	seconds	60.8	48.6	73.0	Grifols DG-APTT	
	seconds	67.5	54.0	81.0	Diagon Dia-PTT	
	seconds	55.5	44.4	66.6	Futura System APTT	
	seconds	61.2	49.0	73.4	Biolabo Bio-CK APTT	
	seconds	58.8	47.0	70.6	Spinreact APTT	
	seconds	52.1	41.7	62.5	Technology-Standard aPTT	
	seconds	60.5	48.4	72.6	SGM Italia aPTT	
	seconds	60.7	48.6	72.8	Tcoag TriniCLOT Automated aPTT	
	seconds	54.4	43.5	65.3	Media IVD aPTT	
	seconds	58.3	46.6	70.0	Siemens Dade Actin Cephaloplastin	
	seconds	48.5	38.8	58.2	Labitec aPTT	
	seconds	65.4	52.3	78.5	Sclavo APTT-S	
	seconds	62.8	50.2	75.4	HemoDiagnostica aPTT	
	seconds	59.5	47.6	71.4	Cypress Diagnostics aPTT	
seconds	62.5	50.0	75.0	Tokra Medikal APTT		
seconds	49.1	39.3	58.9	Coagpia APTT-N		
seconds	89.2	71.4	107	Cobas aPTT MedS		
seconds	59.9	47.9	71.9	Biolabo Bio-Sil (APTT)		
活化部分凝血活酶时间 (APTT) 比	ratio	2.05	1.64	2.46	Tcoag TriniCLOT aPTT S	
	ratio	1.88	1.50	2.26	Siemens/Dade Actin FSL	
	ratio	2.56	2.05	3.07	Siemens/Dade Actin SL	
	ratio	1.82	1.46	2.18	Stago Cephascreen	
	ratio	2.07	1.66	2.48	Stago PTT Automate	
	ratio	1.96	1.57	2.35	Stago aPTT	

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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	3.24	2.59	3.89	Siemens/Dade Pathromtin SL	
	ratio	1.55	1.24	1.86	HemosIL APTT-SP Liquid	
	ratio	2.49	1.99	2.99	HemosIL Synthasil	
	ratio	2.06	1.65	2.47	Pacific Hemostasis APTT-XL	
	ratio	2.18	1.74	2.62	Stago CK-Prest	
	ratio	1.55	1.24	1.86	Bio-Ksel System APTTs	
	ratio	2.02	1.62	2.42	Siemens/Dade Actin FS	
	ratio	2.18	1.74	2.62	Diagon Dia-PTT	
	ratio	2.03	1.62	2.44	Siemens/Dade Actin	
	ratio	2.02	1.62	2.42	Siemens Dade Actin Cephaloplastin	
	ratio	2.17	1.74	2.60	Biodevice aPTT	
	ratio	1.72	1.38	2.06	Labitec aPTT	
	ratio	2.29	1.83	2.75	Sclavo APTT-S	
	ratio	1.55	1.24	1.86	Coagpia APTT-N	
抗凝血酶III (AT) 活圖	%	56.7	45.4	68.0	Siemens/Dade Berichrom ATIII	
	%	52.6	42.1	63.1	HemosIL Liquid Antithrombin	
	%	55.0	44.0	66.0	Chromogenix Coamatic LR	
	%	55.4	44.3	66.5	Roche Chronogenic Thrombin	
	%	55.5	44.4	66.6	Hemosil Lyophilised Antithrombin III	
	%	57.5	46.0	69.0	STACHrom ATIII	
	%	57.8	46.2	69.4	Siemens/Dade Antithrombin III	
	%	53.2	42.6	63.8	Diagon ATIII	
	%	57.7	46.2	69.2	Siemens Innovance Antithrombin III	
	%	50.8	40.6	61.0	Sclavo ATIII	
	%	57.9	46.3	69.5	HemoDiagnostica Antithrombin III (Fxa)	
II. 子活性	%	58.7	47.0	70.4	Dade Innovin	
	%	58.0	46.4	69.6	Siemens/Dade Thromborel S	
	%	52.0	41.6	62.4	Stago Neoplastine CI Plus	
	%	48.0	38.4	57.6	HemosIL PT-Fibrinogen HS Plus	
	%	51.4	41.1	61.7	HemosIL PT-Fibrinogen Recombiplastin 2G	
IX 因子活性	%	56.6	45.3	67.9	Stago PTT Automate	
	%	53.8	43.0	64.6	Siemens/Dade Actin FS	
	%	54.7	43.8	65.6	Siemens/Dade Pathromtin SL	
	%	48.7	39.0	58.4	HemosIL Synthasil	
	%	51.0	40.8	61.2	Siemens/Dade Actin FSL	
	%	46.9	37.5	56.3	HemosIL APTT-SP Liquid	
	%	56.6	45.3	67.9	Stago Deficient / ImmunoDef IX	
	%	45.2	36.2	54.2	HemosIL Factor IX deficient plasma	
V 因子活性	%	35.0	28.0	42.0	Stago Neoplastine CI Plus	
	%	45.1	36.1	54.1	Siemens/Dade Thromborel S	
	%	32.2	25.8	38.6	Dade Innovin	
	%	32.9	26.3	39.5	HemosIL PT-Fibrinogen HS Plus	
	%	38.5	30.8	46.2	HemosIL PT-Fibrinogen Recombiplastin 2G	
	%	41.4	33.1	49.7	HemosIL Factor V deficient plasma	
VII 因子活性	%	64.1	51.3	76.9	Stago Neoplastine CI Plus	
	%	69.7	55.8	83.6	Siemens/Dade Thromborel S	

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VII 因子活性	%	72.5	58.0	87.0	Dade Innovin	
	%	63.6	50.9	76.3	HemosIL PT-Fibrinogen HS Plus	
	%	79.7	63.8	95.6	HemosIL PT-Fibrinogen Recombiplastin 2G	
	%	74.7	59.8	89.6	HemosIL Factor VII deficient plasma	
VIII 因子活性	%	31.3	25.0	37.6	Stago CK-Prest	
	%	36.7	29.4	44.0	Siemens/Dade Actin FS	
	%	34.3	27.4	41.2	Siemens/Dade Pathromtin SL	
	%	32.9	26.3	39.5	Siemens/Dade Actin FSL	
	%	33.8	27.0	40.6	HemosIL Synthasil	
	%	32.4	25.9	38.9	HemosIL APTT-SP Liquid	
	%	39.0	31.2	46.8	Stago STA Factor VIII	
	%	31.0	24.8	37.2	Stago Deficient / ImmunoDef VIII	
	%	32.3	25.8	38.8	HemosIL Factor VIII deficient plasma	
X 因子活性	%	62.2	49.8	74.6	Siemens/Dade Thromborel S	
	%	56.6	45.3	67.9	Dade Innovin	
	%	56.5	45.2	67.8	HemosIL PT-Fibrinogen HS Plus	
	%	53.0	42.4	63.6	Stago Neoplastine CI Plus	
	%	60.7	48.6	72.8	HemosIL PT-Fibrinogen Recombiplastin 2G	
XI 因子活性	%	33.5	26.8	40.2	Siemens/Dade Actin FS	
	%	38.4	30.7	46.1	Siemens/Dade Pathromtin SL	
	%	34.7	27.8	41.6	HemosIL Synthasil	
	%	40.7	32.6	48.8	HemosIL APTT-SP Liquid	
XII 因子活性	%	59.8	47.8	71.8	Siemens/Dade Actin FS	
	%	49.2	39.4	59.0	Siemens/Dade Pathromtin SL	
	%	57.5	46.0	69.0	HemosIL Synthasil	
	%	49.3	39.4	59.2	Siemens/Dade Actin FSL	
	%	59.4	47.5	71.3	HemosIL APTT-SP Liquid	
纤维蛋白原	g/L	1.59	1.27	1.91	HemosIL PT-Fibrinogen HS Plus	
	mg/dL	159	127	191		
	g/L	1.54	1.23	1.85	Stago Fibrinogen / Liquid-Fib	
	mg/dL	154	123	185		
	g/L	1.08	0.864	1.30	Siemens/Dade Multifibren U	
	mg/dL	108	86.4	130		
	g/L	1.49	1.19	1.79	HemosIL Fibrinogen C	
	mg/dL	149	119	179		
	g/L	1.26	1.01	1.51	Dade Thrombin	
	mg/dL	126	101	151		
	g/L	1.43	1.14	1.72	Tcoag TriniCLOT Fibrinogen	
	mg/dL	143	114	172		
	g/L	1.54	1.23	1.85	Biolabo Bio-Fibri	
	mg/dL	154	123	185		
	g/L	1.46	1.17	1.75	Teco Teclot Fibrinogen	
mg/dL	146	117	175			
g/L	1.44	1.15	1.73	HemosIL QFA (bovine thrombin)		
mg/dL	144	115	173			
g/L	1.65	1.32	1.98	Pacific Hemostasis Fibrinogen		
mg/dL	165	132	198			

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分析物	单位	靶值	低值	高值		
纤维蛋白原	g/L	1.37	1.10	1.64	Human Fibrinogen	
	mg/dL	137	110	164		
	g/L	1.54	1.23	1.85	Stago STA Fibri-Prest Automate	
	mg/dL	154	123	185		
	g/L	0.860	0.688	1.03	Bio-Ksel System PT	
	mg/dL	86.0	68.8	103		
	g/L	1.56	1.25	1.87	Bio-Ksel Fibrinogen	
	mg/dL	156	125	187		
	g/L	1.38	1.10	1.66	Diagon Dia-F	
	mg/dL	138	110	166		
	g/L	1.08	0.864	1.30	Dade Innovin Derived Fibrinogen	
	mg/dL	108	86.4	130		
	g/L	1.16	0.928	1.39	Siemens/Dade Thromboplastin Derived Fibrinogen	
	mg/dL	116	92.8	139		
	g/L	1.49	1.19	1.79	Liofilchem Fibrinogen	
	mg/dL	149	119	179		
	g/L	1.35	1.08	1.62	Sclavo Fibrinogen	
	mg/dL	135	108	162		
	g/L	1.23	0.984	1.48	Labitec Fibrinogen	
	mg/dL	123	98.4	148		
g/L	1.59	1.27	1.91	HemoDiagnostica Fibrinogen		
mg/dL	159	127	191			
g/L	1.40	1.12	1.68	Beijing Steelex Fibrinogen		
mg/dL	140	112	168			
g/L	1.57	1.26	1.88	Helena Clauss Fibrinogen 100		
mg/dL	157	126	188			
g/L	1.50	1.20	1.80	Tokra Medikal Fibrinogen		
mg/dL	150	120	180			
g/L	1.24	0.992	1.49	Coagpia Fibrinogen		
mg/dL	124	99.2	149			
g/L	1.39	1.11	1.67	Cobas Fibrinogen		
mg/dL	139	111	167			
血浆酶原活性	%	57.1	45.7	68.5	HemosIL Plasminogen	
	%	62.7	50.2	75.2	Siemens/Dade Berichrom Plasminogen	
C 蛋白	%	55.5	44.4	66.6	Siemens/Dade Berichrom Protein C	
	%	50.3	40.2	60.4	Biomerieux VIDAS Protein C	
	%	53.1	42.5	63.7	IL HemosIL Protein C	
	%	57.3	45.8	68.8	Siemens	
	%	60.2	48.2	72.2	STACHrom Protein C	
S 蛋白	%	51.3	35.9	66.7	STA Liatest	
	%	45.8	32.1	59.5	Stago StaClot	
	%	58.9	41.2	76.6	IL HemosIL Free Protein S	
	%	52.1	36.5	67.7	Siemens Innovance Free PS Ag	
	%	42.1	29.5	54.7	IL HemosIL Protein S Activity	
凝血酶原时间 (PT)	Seconds	23.0	18.4	27.6	Tcoag TriniCLOT PT Excel	

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分析物	单位	靶值	低值	高值		
凝血酶原时间 (PT)	Seconds	28.1	22.5	33.7	Dade Innovin	
	Seconds	17.6	14.1	21.1	Siemens/Dade Thromborel IS	
	Seconds	18.7	15.0	22.4	Siemens/Dade Thromborel S	
	Seconds	28.9	23.1	34.7	HemosIL PT-Fibrinogen HS Plus	
	Seconds	23.4	18.7	28.1	Stago Neoplastine CI	
	Seconds	23.1	18.5	27.7	Stago Neoplastine CI Plus	
	Seconds	33.7	27.0	40.4	Teco TEClot PT-S	
	Seconds	29.7	23.8	35.6	Biolabo Bio-TP	
	Seconds	20.6	16.5	24.7	Stago Neoplastin R	
	Seconds	17.3	13.8	20.8	Bio-Ksel System PT	
	Seconds	23.6	18.9	28.3	Human Thromboplastin	
	Seconds	26.8	21.4	32.2	Diagon PT	
	Seconds	26.1	20.9	31.3	Spinreact PT	
	Seconds	47.0	37.6	56.4	Technology-Standard PT	
	Seconds	48.5	38.8	58.2	TCoag TriniCLOT PT Excel S	
	Seconds	23.8	19.0	28.6	Biodevice PT	
	Seconds	27.5	22.0	33.0	Biomedica QuikCoag PT-HS	
	Seconds	17.3	13.8	20.8	HemosIL PT-Fibrinogen Recombiplastin 2G	
	Seconds	25.5	20.4	30.6	SGM Italia Thromboplastin	
	Seconds	22.0	17.6	26.4	Cypress Diagnostics PT	
	Seconds	25.2	20.2	30.2	Tokra Medikal PT	
	Seconds	39.5	31.6	47.4	Coagpia PT-N	
	Seconds	16.3	13.0	19.6	Bio-Ksel PT Plus	
	Seconds	20.2	16.2	24.2	Diagon PT R	
Seconds	19.0	15.2	22.8	Cobas PT Screen		
凝血酶原时间 (PT) 活性	%	27.0	21.6	32.4	Tcoag TriniCLOT PT Excel	
	%	20.8	16.6	25.0	Dade Innovin	
	%	45.0	36.0	54.0	Siemens/Dade Thromborel S	
	%	33.7	27.0	40.4	Stago Neoplastine CI	
	%	38.6	30.9	46.3	Stago Neoplastine CI Plus	
	%	31.5	25.2	37.8	HemosIL PT-Fibrinogen HS Plus	
	%	18.0	14.4	21.6	Pacific Thromboplastin DS	
	%	62.4	49.9	74.9	Stago SPA	
	%	52.4	41.9	62.9	Stago Neoplastin R	
	%	63.0	50.4	75.6	Bio-Ksel System PT	
	%	33.7	27.0	40.4	Human Thromboplastin	
	%	30.5	24.4	36.6	Diagon PT	
	%	16.5	13.2	19.8	TCoag TriniCLOT PT Excel S	
	%	28.9	23.1	34.7	Media IVD PT	
	%	35.1	28.1	42.1	Biodevice PT	
	%	24.5	19.6	29.4	Biomedica QuikCoag PT-HS	
	%	51.9	41.5	62.3	HemosIL PT-Fibrinogen Recombiplastin 2G	
	%	25.5	20.4	30.6	Helena Thromboplastin	
	%	15.3	12.2	18.4	Coagpia PT-N	
	%	66.0	52.8	79.2	Bio-Ksel PT Plus	
	%	35.1	28.1	42.1	Diagon PT R	

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凝血酶原时间 (PT) 活性	%	41.1	32.9	49.3	Cobas PT Screen	
凝血酶原时间 (PT) INR	INR	2.84	2.27	3.41	Tcoag TriniCLOT PT Excel	
	INR	2.72	2.18	3.26	Dade Innovin	
	INR	1.64	1.31	1.97	Siemens/Dade Thromborel IS	
	INR	1.64	1.31	1.97	Siemens/Dade Thromborel S	
	INR	2.28	1.82	2.74	HemosIL PT-Fibrinogen HS Plus	
	INR	2.27	1.82	2.72	Stago Neoplastine CI	
	INR	2.07	1.66	2.48	Stago Neoplastine CI Plus	
	INR	1.94	1.55	2.33	Human Thromboplastin	
	INR	2.90	2.32	3.48	Teco TEClot PT-S	
	INR	2.17	1.74	2.60	Biolabo Bio-TP	
	INR	1.26	1.01	1.51	Stago SPA	
	INR	1.45	1.16	1.74	Stago Neoplastin R	
	INR	1.58	1.26	1.90	Bio-Ksel System PT	
	INR	2.31	1.85	2.77	Diagon PT	
	INR	4.60	3.68	5.52	TCoag TriniCLOT PT Excel S	
	INR	2.06	1.65	2.47	Media IVD PT	
	INR	2.17	1.74	2.60	Biodevice PT	
	INR	2.37	1.90	2.84	Biomedica QuikCoag PT-HS	
	INR	1.53	1.22	1.84	HemosIL PT-Fibrinogen Recombiplastin 2G	
	INR	2.59	2.07	3.11	Helena Thromboplastin	
INR	2.09	1.67	2.51	Tokra Medikal PT		
INR	3.15	2.52	3.78	Coagpia PT-N		
INR	1.49	1.19	1.79	Bio-Ksel PT Plus		
INR	1.86	1.49	2.23	Diagon PT R		
INR	1.80	1.44	2.16	Cobas PT Screen		
凝血酶原时间 (PT) 比率	ratio	2.96	2.37	3.55	Dade Innovin	
	ratio	1.64	1.31	1.97	Siemens/Dade Thromborel S	
	ratio	2.02	1.62	2.42	Stago Neoplastine CI	
	ratio	1.76	1.41	2.11	Stago Neoplastine CI Plus	
	ratio	1.46	1.17	1.75	Stago Neoplastin R	
	ratio	2.10	1.68	2.52	Diagon PT	
	ratio	2.03	1.62	2.44	HemosIL PT-Fibrinogen HS Plus	
	ratio	1.53	1.22	1.84	HemosIL PT-Fibrinogen Recombiplastin 2G	
凝血酶时间 (TT)	Seconds	34.0	27.2	40.8	Dade Thrombin	
	Seconds	27.8	22.2	33.4	Siemens/Dade Thromboclotin	
	Seconds	37.1	29.7	44.5	Stago Thrombin	
	Seconds	31.6	25.3	37.9	Sysmex Thrombin Time	
	Seconds	30.4	24.3	36.5	Human - Hemostat	
	Seconds	35.6	28.5	42.7	Pacific Hemostasis Thrombin Time	
	Seconds	29.1	23.3	34.9	HemosIL Thrombin Time 5ml	
	Seconds	40.0	32.0	48.0	HemosIL Thrombin Time 8ml	