

# 凝血质控品

## (COAG CONTROL 3)

货号	CG 5023	批号	304CG
包装:	12 x 1 ml	效期:	2021-11-28
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℃可保存至效期末。

### 使用说明

该凝血质控品为冻干粉。

- 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。
- 参照各个分析仪的质控说明。
- 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](http://www.randox.com) 进行下载。

# 凝血质控品 - LEVEL 3 (COAG CONTROL 3)

货号. CG5023 批号. 304CG 包装: 12 x 1 ml 效期: 2021-11-28

范围					
分析物	单位	靶值	低值	低值	方法学
Activated Partial Thromboplastin Time (APTT)	seconds	56.9	45.5	68.3	Tcoag TriniCLOT aPTT S
	seconds	52.2	41.8	62.6	Tcoag TriniCLOT aPTT HS
	seconds	50.7	40.6	60.8	Siemens/Dade Actin
	seconds	46.7	37.4	56.0	Siemens/Dade Actin FS
	seconds	44.0	35.2	52.8	Siemens/Dade Actin FSL
	seconds	82.7	66.2	99.0	Siemens/Dade Actin SL
	seconds	84.6	67.7	102	Siemens/Dade Pathromtin SL
	seconds	43.5	34.8	52.2	HemosIL APTT-SP Liquid
	seconds	63.2	50.6	75.8	HemosIL Synthasil
	seconds	59.2	47.4	71.0	Pacific Hemostasis APTT-XL
	seconds	55.9	44.7	67.1	Stago aPTT
	seconds	49.4	39.5	59.3	Stago Cephascreen
	seconds	58.9	47.1	70.7	Stago CK-Prest
	seconds	59.4	47.5	71.3	Stago PTT Automate
	seconds	57.5	46.0	69.0	Teco TEClot APTT
	seconds	48.3	38.6	58.0	Human Hemostat APTT
	seconds	47.1	37.7	56.5	Bio-Ksel System APTTs
	seconds	67.6	54.1	81.1	Diagon Dia-PTT
	seconds	48.4	38.7	58.1	Weiner Lab APTT
	seconds	51.6	41.3	61.9	Biolabo Bio-CK APTT
	seconds	54.9	43.9	65.9	Spinreact APTT
	seconds	54.8	43.8	65.8	Technology-Standard aPTT
	seconds	54.2	43.4	65.0	Media IVD aPTT
	seconds	50.1	40.1	60.1	Biomedica QuikCoag aPTT
	seconds	68.5	54.8	82.2	Hemosil aPTT Lyophilised Silica
	seconds	51.8	41.4	62.2	Siemens/Dade Actin Cephaloplastin
	seconds	54.0	43.2	64.8	Labitec aPTT
	seconds	58.1	46.5	69.7	Sclavo APTT-S
	seconds	50.4	40.3	60.5	HemoDiagnostica aPTT
	seconds	59.8	47.8	71.8	Cypress Diagnostics aPTT
seconds	50.9	40.7	61.1	Fortress Diagnostics aPTT	
seconds	68.2	54.6	81.8	Tokra Medikal APTT	
seconds	43.5	34.8	52.2	Coagpia APTT-N	
seconds	84.3	67.4	101	Cobas aPTT MedS	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.80	1.44	2.16	Tcoag TriniCLOT aPTT S
	ratio	1.65	1.32	1.98	Siemens/Dade Actin FSL
	ratio	2.60	2.08	3.12	Siemens/Dade Actin SL
	ratio	1.64	1.31	1.97	Stago Cephascreen
	ratio	1.79	1.43	2.15	Stago PTT Automate
	ratio	1.76	1.41	2.11	Stago aPTT
	ratio	2.67	2.14	3.20	Siemens/Dade Pathromtin SL
	ratio	1.43	1.14	1.72	HemosIL APTT-SP Liquid

## 凝血质控品 - LEVEL 3 (COAG CONTROL 3)

货号: CG5023 批号: 304CG 包装: 12 x 1 ml 效期: 2021-11-28

范围					
分析物	单位	靶值	低值	低值	方法学
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.09	1.67	2.51	HemosIL Synthasil
	ratio	1.93	1.54	2.32	Stago CK-Prest
	ratio	1.66	1.33	1.99	Human Hemostat APTT
	ratio	1.40	1.12	1.68	Bio-Ksel System APTTs
	ratio	1.83	1.46	2.20	Siemens/Dade Actin FS
	ratio	1.90	1.52	2.28	Diagon Dia-PTT
	ratio	1.86	1.49	2.23	Siemens/Dade Actin
	ratio	1.89	1.51	2.27	Media IVD aPTT
	ratio	1.94	1.55	2.33	Biodevice aPTT
	ratio	1.74	1.39	2.09	Labitec aPTT
	ratio	2.05	1.64	2.46	Sclavo APTT-S
ratio	1.36	1.09	1.63	Coagpia APTT-N	
Antithrombin III activity	%	64.1	51.3	76.9	Siemens/Dade Berichrom ATIII
	%	59.7	47.8	71.6	HemosIL Liquid Antithrombin
	%	62.3	49.8	74.8	Roche Chronogenic Thrombin
	%	59.6	47.7	71.5	Hemosil Lyophilised Antithrombin III
	%	64.6	51.7	77.5	STACHrom ATIII
	%	69.2	55.4	83.0	Siemens/Dade Antithrombin III
	%	60.6	48.5	72.7	Diagon ATIII
	%	61.8	49.4	74.2	Siemens Innovance Antithrombin III
	%	60.1	48.1	72.1	Sclavo ATIII
	%	62.0	49.6	74.4	Teco TEChrom AT
Factor II activity	%	65.8	52.6	79.0	Siemens/Dade-Behring Innovin
	%	68.4	54.7	82.1	Siemens/Dade-Behring Thromborel S
	%	64.5	51.6	77.4	HemosIL PT-Fibrinogen HS Plus
	%	63.5	50.8	76.2	HemosIL RecombiPlasTin 2G
	%	58.5	46.8	70.2	HemosIL Factor II deficient plasma
Factor IX activity	%	61.6	49.3	73.9	Stago PTT Automate
	%	57.2	45.8	68.6	Siemens/Dade Actin FS
	%	60.4	48.3	72.5	Siemens/Dade Pathromtin SL
	%	56.7	45.4	68.0	HemosIL Synthasil
	%	62.0	49.6	74.4	Stago CK-Prest
	%	59.1	47.3	70.9	Siemens/Dade Actin FSL
	%	68.7	55.0	82.4	Stago Deficient / ImmunoDef IX
	%	55.9	44.7	67.1	HemosIL Factor IX deficient plasma
Factor V activity	%	51.1	40.9	61.3	Siemens/Dade-Behring Thromborel S
	%	47.5	38.0	57.0	Siemens/Dade-Behring Innovin
	%	44.8	35.8	53.8	HemosIL PT-Fibrinogen HS Plus
	%	49.2	39.4	59.0	HemosIL RecombiPlasTin 2G
	%	40.3	32.2	48.4	Stago Neoplastin R
	%	48.3	38.6	58.0	HemosIL Factor V deficient plasma
Factor VII activity	%	75.0	60.0	90.0	Siemens/Dade-Behring Thromborel S
	%	85.5	68.4	103	Siemens/Dade-Behring Innovin
	%	70.4	56.3	84.5	HemosIL PT-Fibrinogen HS Plus
	%	89.6	71.7	108	HemosIL RecombiPlasTin 2G
	%	75.5	60.4	90.6	Stago Neoplastin R

## 凝血质控品 - LEVEL 3 (COAG CONTROL 3)

货号. CG5023 批号. 304CG 包装: 12 x 1 ml 效期: 2021-11-28

范围					
分析物	单位	靶值	低值	低值	方法学
Factor VII activity	%	85.3	68.2	102	HemosIL Factor VII deficient plasma
Factor VIII activity	%	40.1	32.1	48.1	Stago CK-Prest
	%	36.2	29.0	43.4	Stago PTT Automate
	%	40.7	32.6	48.8	Siemens/Dade Actin FS
	%	38.5	30.8	46.2	Siemens/Dade Pathromtin SL
	%	37.5	30.0	45.0	Siemens/Dade Actin FSL
	%	35.3	28.2	42.4	HemosIL Synthasil
	%	35.9	28.7	43.1	HemosIL APTT-SP Liquid
	%	35.5	28.4	42.6	Stago STA Factor VIII
	%	37.6	30.1	45.1	Stago Deficient / ImmunoDef VIII
	%	36.2	29.0	43.4	HemosIL Factor VIII deficient plasma
Factor X activity	%	70.7	56.6	84.8	Siemens/Dade-Behring Thromborel S
	%	70.0	56.0	84.0	Siemens/Dade-Behring Innovin
	%	66.1	52.9	79.3	HemosIL PT-Fibrinogen HS Plus
	%	72.0	57.6	86.4	Stago Neoplastine CI Plus
	%	66.2	53.0	79.4	HemosIL RecombiPlasTin 2G
	%	66.4	53.1	79.7	HemosIL Factor X deficient plasma
Factor XI activity	%	36.4	29.1	43.7	Siemens/Dade Actin FS
	%	37.2	29.8	44.6	Siemens/Dade Pathromtin SL
	%	34.7	27.8	41.6	HemosIL Synthasil
	%	29.5	23.6	35.4	Siemens/Dade Actin FSL
	%	39.1	31.3	46.9	HemosIL APTT-SP Liquid
	%	32.9	26.3	39.5	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	59.8	47.8	71.8	Siemens/Dade Actin FS
	%	55.0	44.0	66.0	Siemens/Dade Pathromtin SL
	%	60.2	48.2	72.2	HemosIL Synthasil
	%	59.7	47.8	71.6	Siemens/Dade Actin FSL
	%	66.4	53.1	79.7	HemosIL Factor XII deficient plasma
Fibrinogen	g/L	1.89	1.51	2.27	HemosIL PT-Fibrinogen HS Plus
	mg/dL	189	151	227	
	g/L	1.91	1.53	2.29	Stago Fibrinogen / Liquid-Fib
	mg/dL	191	153	229	
	g/L	1.34	1.07	1.61	Siemens/Dade Multifibren U
	mg/dL	134	107	161	
	g/L	1.87	1.50	2.24	HemosIL Fibrinogen C
	mg/dL	187	150	224	
	g/L	1.58	1.26	1.90	Dade Thrombin
	mg/dL	158	126	190	
	g/L	2.21	1.77	2.65	Technoclone Fibrinogen
	mg/dL	221	177	265	
	g/L	1.90	1.52	2.28	Tcoag TriniCLOT Fibrinogen
	mg/dL	190	152	228	
	g/L	1.67	1.34	2.00	Biolabo Bio-Fibri
	mg/dL	167	134	200	
g/L	1.75	1.40	2.10	Teco Teclot Fibrinogen	
mg/dL	175	140	210		

# 凝血质控品 - LEVEL 3 (COAG CONTROL 3)

货号. CG5023 批号. 304CG 包装: 12 x 1 ml 效期: 2021-11-28

范围					
分析物	单位	靶值	低值	低值	方法学
Fibrinogen	g/L	1.71	1.37	2.05	HemosIL QFA (bovine thrombin)
	mg/dL	171	137	205	
	g/L	1.81	1.45	2.17	Human Fibrinogen
	mg/dL	181	145	217	
	g/L	1.96	1.57	2.35	Stago STA Fibri-Prest Automate
	mg/dL	196	157	235	
	g/L	1.88	1.50	2.26	Bio-Ksel Fibrinogen
	mg/dL	188	150	226	
	g/L	1.63	1.30	1.96	Diagon Dia-F
	mg/dL	163	130	196	
	g/L	1.24	0.992	1.49	Dade Innovin Derived Fibrinogen
	mg/dL	124	99.2	149	
	g/L	1.44	1.15	1.73	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	144	115	173	
	g/L	2.21	1.77	2.65	Wiener Lab Fibrinogen
	mg/dL	221	177	265	
	g/L	1.28	1.02	1.54	HemosIL RecombiPlasTin 2G
	mg/dL	128	102	154	
	g/L	1.83	1.46	2.20	Sclavo Fibrinogen
	mg/dL	183	146	220	
g/L	2.08	1.66	2.50	Labitec Fibrinogen	
mg/dL	208	166	250		
g/L	1.75	1.40	2.10	HemoDiagnostica Fibrinogen	
mg/dL	175	140	210		
g/L	1.86	1.49	2.23	Cypress Diagnostics Fibrinogen	
mg/dL	186	149	223		
g/L	1.95	1.56	2.34	Helena Clauss Fibrinogen 100	
mg/dL	195	156	234		
g/L	1.55	1.24	1.86	Tokra Medikal Fibrinogen	
mg/dL	155	124	186		
g/L	1.61	1.29	1.93	Coagpia Fibrinogen	
mg/dL	161	129	193		
g/L	1.84	1.47	2.21	HemosIL PT-Fibrinogen	
mg/dL	184	147	221		
g/L	2.07	1.66	2.48	Beijing Succeder Fibrinogen	
mg/dL	207	166	248		
g/L	1.80	1.44	2.16	Cobas Fibrinogen	
mg/dL	180	144	216		
Plasminogen activity	%	64.5	51.6	77.4	Stago Stachrom Plasminogen
	%	65.0	52.0	78.0	HemosIL Plasminogen
	%	68.2	54.6	81.8	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	66.4	53.1	79.7	Siemens/Dade Berichrom Protein C
	%	64.3	51.4	77.2	Stago StaClot
	%	58.0	46.4	69.6	Biomerieux VIDAS Protein C
	%	63.1	50.5	75.7	IL HemosIL Protein C
	%	68.3	54.6	82.0	Siemens

# 凝血质控品 - LEVEL 3 (COAG CONTROL 3)

货号. CG5023 批号. 304CG 包装: 12 x 1 ml 效期: 2021-11-28

范围					
分析物	单位	靶值	低值	低值	方法学
Protein C activity	%	66.4	53.1	79.7	STACrom Protein C
Protein S activity	%	67.2	47.0	87.4	STA Liatest
	%	64.5	45.2	83.9	Stago StaClot
	%	64.3	45.0	83.6	IL HemosIL Free Protein S
	%	46.2	32.3	60.1	Dade Protein S Ac
	%	63.7	44.6	82.8	Siemens Innovance Free PS Ag
	%	51.0	35.7	66.3	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	20.2	16.2	24.2	Siemens/Dade-Behring Innovin
	Seconds	16.5	13.2	19.8	Siemens/Dade Thromborel IS
	Seconds	16.5	13.2	19.8	Siemens/Dade-Behring Thromborel S
	Seconds	22.7	18.2	27.2	HemosIL PT-Fibrinogen HS Plus
	Seconds	30.1	24.1	36.1	Pacific Thromboplastin DS
	Seconds	21.5	17.2	25.8	Stago Neoplastine CI
	Seconds	19.9	15.9	23.9	Stago Neoplastine CI Plus
	Seconds	31.6	25.3	37.9	R2 Phosphoplastin RL
	Seconds	19.5	15.6	23.4	Teco TEClot PT-S
	Seconds	17.9	14.3	21.5	Stago Neoplastin R
	Seconds	13.8	11.0	16.6	Bio-Ksel System PT
	Seconds	18.5	14.8	22.2	Human Thromboplastin
	Seconds	20.1	16.1	24.1	Diagon PT
	Seconds	25.7	20.6	30.8	Weiner Lab Soluplastin
	Seconds	19.4	15.5	23.3	Spinreact PT
	Seconds	28.1	22.5	33.7	TCoag TriniCLOT PT Excel S
	Seconds	22.2	17.8	26.6	Media IVD PT
	Seconds	17.6	14.1	21.1	Biodevice PT
	Seconds	21.9	17.5	26.3	Biomedica QuikCoag PT-HS
	Seconds	14.5	11.6	17.4	HemosIL RecombiPlasTin 2G
	Seconds	23.5	18.8	28.2	Helena Thromboplastin
	Seconds	20.7	16.6	24.8	Labitec PT
	Seconds	18.2	14.6	21.8	Cypress Diagnostics PT
	Seconds	28.8	23.0	34.6	Fortress Diagnostics PT with Calcium
	Seconds	18.8	15.0	22.6	Tokra Medikal PT
	Seconds	26.5	21.2	31.8	Coagpia PT-N
	Seconds	13.7	11.0	16.4	Bio-Ksel PT Plus
	Seconds	21.8	17.4	26.2	Beijing Succeeder PT
	Seconds	16.3	13.0	19.6	Diagon PT R
	Seconds	17.4	13.9	20.9	Cobas PT Screen
Seconds	27.1	21.7	32.5	Stago STA-NeoPTimal	
Prothrombin Time (PT) activity	%	32.1	25.7	38.5	Siemens/Dade-Behring Innovin
	%	53.6	42.9	64.3	Siemens/Dade-Behring Thromborel S
	%	45.0	36.0	54.0	Stago Neoplastine CI
	%	45.7	36.6	54.8	Stago Neoplastine CI Plus
	%	48.8	39.0	58.6	HemosIL PT-Fibrinogen HS Plus
	%	52.3	41.8	62.8	Teco TEClot PT-S
	%	62.8	50.2	75.4	Stago Neoplastin R
	%	73.7	59.0	88.4	Bio-Ksel System PT

# 凝血质控品 - LEVEL 3 (COAG CONTROL 3)

货号. CG5023 批号. 304CG 包装: 12 x 1 ml 效期: 2021-11-28

范围					
分析物	单位	靶值	低值	低值	方法学
Prothrombin Time (PT) activity	%	50.5	40.4	60.6	Human Thromboplastin
	%	45.4	36.3	54.5	Diagon PT
	%	32.2	25.8	38.6	Weiner Lab Soluplastin
	%	31.5	25.2	37.8	TCoag TriniCLOT PT Excel S
	%	52.3	41.8	62.8	Biodevice PT
	%	69.1	55.3	82.9	HemosIL RecombiPlasTin 2G
	%	40.3	32.2	48.4	Helena Thromboplastin
	%	46.6	37.3	55.9	Labitec PT
	%	52.6	42.1	63.1	Tokra Medikal PT
	%	26.3	21.0	31.6	Coagpia PT-N
	%	79.8	63.8	95.8	Bio-Ksel PT Plus
	%	52.2	41.8	62.6	Beijing Succeeder PT
	%	51.1	40.9	61.3	Diagon PT R
	%	50.3	40.2	60.4	Cobas PT Screen
%	37.2	29.8	44.6	Stago STA-NeoPTimal	
Prothrombin Time (PT) INR	INR	2.01	1.61	2.41	Siemens/Dade-Behring Innovin
	INR	1.39	1.11	1.67	Siemens/Dade Thromborel IS
	INR	1.45	1.16	1.74	Siemens/Dade-Behring Thromborel S
	INR	1.68	1.34	2.02	HemosIL PT-Fibrinogen HS Plus
	INR	2.09	1.67	2.51	Pacific Thromboplastin DS
	INR	1.82	1.46	2.18	Stago Neoplastine CI
	INR	1.73	1.38	2.08	Stago Neoplastine CI Plus
	INR	1.56	1.25	1.87	Human Thromboplastin
	INR	1.51	1.21	1.81	Teco TEClot PT-S
	INR	1.17	0.936	1.40	Stago SPA
	INR	1.29	1.03	1.55	Stago Neoplastin R
	INR	1.36	1.09	1.63	Bio-Ksel System PT
	INR	1.63	1.30	1.96	Diagon PT
	INR	1.74	1.39	2.09	Spinreact PT
	INR	2.09	1.67	2.51	Technology-Standard PT
	INR	2.60	2.08	3.12	TCoag TriniCLOT PT Excel S
	INR	1.63	1.30	1.96	Biodevice PT
	INR	1.74	1.39	2.09	Biomedica QuikCoag PT-HS
	INR	1.27	1.02	1.52	HemosIL RecombiPlasTin 2G
	INR	1.91	1.53	2.29	Helena Thromboplastin
	INR	1.64	1.31	1.97	Labitec PT
	INR	1.46	1.17	1.75	Tokra Medikal PT
	INR	2.27	1.82	2.72	Coagpia PT-N
	INR	1.28	1.02	1.54	Bio-Ksel PT Plus
INR	1.73	1.38	2.08	Beijing Succeeder PT	
INR	1.53	1.22	1.84	Diagon PT R	
INR	1.70	1.36	2.04	Cobas PT Screen	
INR	2.10	1.68	2.52	Stago STA-NeoPTimal	
Prothrombin Time (PT) ratio	ratio	2.05	1.64	2.46	Siemens/Dade-Behring Innovin
	ratio	1.45	1.16	1.74	Siemens/Dade-Behring Thromborel S
	ratio	1.83	1.46	2.20	Stago Neoplastine CI Plus

## 凝血质控品 - LEVEL 3 (COAG CONTROL 3)

货号: CG5023 批号: 304CG 包装: 12 x 1 ml 效期: 2021-11-28

### 范围

分析物	单位	靶值	低值	低值	方法学
Prothrombin Time (PT) ratio	ratio	1.52	1.22	1.82	Diagon PT
	ratio	1.52	1.22	1.82	HemosIL PT-Fibrinogen HS Plus
	ratio	1.27	1.02	1.52	HemosIL RecombiPlasTin 2G
	ratio	1.56	1.25	1.87	Biodevice PT
	ratio	2.07	1.66	2.48	Stago STA-NeoPTimal
Thrombin Time (TT)	Seconds	30.2	24.2	36.2	Dade Thrombin
	Seconds	27.0	21.6	32.4	Siemens/Dade Thromboclotin
	Seconds	32.2	25.8	38.6	Stago Thrombin
	Seconds	28.6	22.9	34.3	Sysmex Thrombin Time
	Seconds	34.5	27.6	41.4	Diagon, Dia-TT
	Seconds	25.8	20.6	31.0	HemosIL Thrombin Time 5ml
	Seconds	34.8	27.8	41.8	HemosIL Thrombin Time 8ml