

凝血质控品

货号: CG5021
批号: 348CG

包装: 12 x 1 ml
效期: 2022-09-28

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。

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

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。

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 348CG Size 12 x 1ml Expiry 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
活化部分凝血活酶时间 (APTT)	seconds	41.8	33.4	50.2	Tcoag TriniCLOT aPTT S
	seconds	41.9	33.5	50.3	Tcoag TriniCLOT aPTT HS
	seconds	39.9	31.9	47.9	Siemens/Dade Actin
	seconds	36.1	28.9	43.3	Siemens/Dade Actin FS
	seconds	34.3	27.4	41.2	Siemens/Dade Actin FSL
	seconds	49.3	39.4	59.2	Siemens/Dade Actin SL
	seconds	50.8	40.6	61.0	Siemens/Dade Pathromtin SL
	seconds	35.1	28.1	42.1	HemosIL APTT-SP Liquid
	seconds	42.4	33.9	50.9	HemosIL Synthasil
	seconds	45.1	36.1	54.1	Stago aPTT
	seconds	41.4	33.1	49.7	Stago Cephascreen
	seconds	45.3	36.2	54.4	Stago CK-Prest
	seconds	45.1	36.1	54.1	Stago PTT Automate
	seconds	45.4	36.3	54.5	Teco TEClot APTT
	seconds	38.4	30.7	46.1	Human Hemostat APTT
	seconds	40.5	32.4	48.6	Bio-Ksel System APTTs
	seconds	48.5	38.8	58.2	Diagon Dia-PTT
	seconds	35.5	28.4	42.6	Weiner Lab APTT
	seconds	44.6	35.7	53.5	Futura System APTT
	seconds	42.3	33.8	50.8	Biolabo Bio-CK APTT
	seconds	43.3	34.6	52.0	Spinreact APTT
	seconds	55.5	44.4	66.6	Shanghai Changdao Biotech APTT
	seconds	41.1	32.9	49.3	Tcoag TriniCLOT Automated aPTT
	seconds	38.1	30.5	45.7	Media IVD aPTT
	seconds	38.2	30.6	45.8	Biodevice aPTT
	seconds	37.2	29.8	44.6	Biomedica QuikCoag aPTT
	seconds	43.2	34.6	51.8	Hemosil aPTT Lyophilised Silica
	seconds	38.9	31.1	46.7	Siemens/Dade Actin Cephaloplastin
	seconds	42.2	33.8	50.6	Labitec aPTT
	seconds	43.5	34.8	52.2	Dutch Diagnostics aPTT
	seconds	38.7	31.0	46.4	Technoclone Siron aPTT
	seconds	38.6	30.9	46.3	Sclavo APTT-S
	seconds	40.8	32.6	49.0	HemoDiagnostics aPTT
	seconds	55.7	44.6	66.8	Fortress Diagnostics aPTT
	seconds	44.1	35.3	52.9	Tokra Medikal APTT
	seconds	37.3	29.8	44.8	Coagpia APTT-N
	seconds	49.3	39.4	59.2	Cobas aPTT MedS
	seconds	42.7	34.2	51.2	Biolabo Bio-Sil (APTT)
活化部分凝血活酶时间 (APTT) 比	ratio	1.37	1.10	1.64	Tcoag TriniCLOT aPTT S
	ratio	1.30	1.04	1.56	Siemens/Dade Actin FSL
	ratio	1.37	1.10	1.64	Stago Cephascreen
	ratio	1.37	1.10	1.64	Stago PTT Automate

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 348CG Size 12 x 1ml Expiry 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
活化部分凝血活酶时间 (APTT) 比	ratio	1.47	1.18	1.76	Stago aPTT
	ratio	1.60	1.28	1.92	Siemens/Dade Pathromtin SL
	ratio	1.18	0.944	1.42	HemosIL APTT-SP Liquid
	ratio	1.39	1.11	1.67	HemosIL Synthasil
	ratio	1.44	1.15	1.73	Stago CK-Prest
	ratio	1.49	1.19	1.79	Human Hemostat APTT
	ratio	1.20	0.960	1.44	Bio-Ksel System APTTs
	ratio	1.40	1.12	1.68	Siemens/Dade Actin FS
	ratio	1.38	1.10	1.66	Diagon Dia-PTT
	ratio	1.47	1.18	1.76	Biolabo Bio-CK APTT
	ratio	1.44	1.15	1.73	Spinreact APTT
	ratio	1.23	0.984	1.48	Technology-Standard aPTT
	ratio	1.45	1.16	1.74	Media IVD aPTT
	ratio	1.49	1.19	1.79	Biodevice aPTT
	ratio	1.39	1.11	1.67	Labitec aPTT
	ratio	1.33	1.06	1.60	Sclavo APTT-S
	ratio	1.18	0.944	1.42	Coagpia APTT-N
抗凝血酶 (AT) 活性	%	79.6	63.7	95.5	Siemens/Dade Berichrom ATIII
	%	80.9	64.7	97.1	HemosIL Liquid Antithrombin
	%	80.8	64.6	97.0	Roche Chronogenic Thrombin
	%	82.6	66.1	99.0	STACHrom ATIII
	%	80.1	64.1	96.1	Siemens/Dade Antithrombin III
	%	79.3	63.4	95.2	Diagon ATIII
	%	80.3	64.2	96.4	Siemens Innovance Antithrombin III
	%	76.1	60.9	91.3	Sclavo ATIII
	%	76.8	61.4	92.2	HemoDiagnostica Antithrombin III (Fxa)
II 因子活性	%	83.2	66.6	100	Siemens/Dade-Behring Innovin
	%	90.8	72.6	109	Siemens/Dade-Behring Thromborel S
	%	86.6	69.3	104	HemosIL PT-Fibrinogen HS Plus
	%	88.8	71.0	107	HemosIL RecombiPlasTin 2G
	%	87.1	69.7	105	HemosIL Factor II deficient plasma
	%	90.8	72.6	109	Stago STA-NeoPTimal
IX 因子活性	%	73.2	58.6	87.8	Siemens/Dade Actin FS
	%	81.0	64.8	97.2	Siemens/Dade Pathromtin SL
	%	79.7	63.8	95.6	HemosIL Synthasil
	%	77.0	61.6	92.4	Stago CK-Prest
	%	74.5	59.6	89.4	Siemens/Dade Actin FSL
	%	79.4	63.5	95.3	HemosIL APTT-SP Liquid
	%	82.7	66.2	99.0	Stago Deficient / ImmunoDef IX
	%	74.4	59.5	89.3	HemosIL Factor IX deficient plasma
V 因子活性	%	66.0	52.8	79.2	Stago Neoplastine CI Plus
	%	74.5	59.6	89.4	Siemens/Dade-Behring Thromborel S
	%	66.3	53.0	79.6	Siemens/Dade-Behring Innovin
	%	62.1	49.7	74.5	HemosIL PT-Fibrinogen HS Plus
	%	63.9	51.1	76.7	HemosIL RecombiPlasTin 2G
	%	64.0	51.2	76.8	Stago Neoplastin R

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 348CG Size 12 x 1ml Expiry 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
V 因子活性	%	62.1	49.7	74.5	HemosIL Factor V deficient plasma
	%	57.0	45.6	68.4	Stago STA-NeoPTimal
VII 因子活性	%	118	94.4	142	Stago Neoplastine CI Plus
	%	118	94.4	142	Siemens/Dade-Behring Thromborel S
	%	128	102	154	Siemens/Dade-Behring Innovin
	%	158	126	190	HemosIL PT-Fibrinogen HS Plus
	%	150	120	180	HemosIL RecombiPlasTin 2G
	%	148	118	178	HemosIL Factor VII deficient plasma
	%	119	95.2	143	Stago STA-NeoPTimal
VIII 因子活性	%	53.2	42.6	63.8	Stago CK-Prest
	%	54.4	43.5	65.3	Siemens/Dade Actin FS
	%	56.3	45.0	67.6	Siemens/Dade Pathromtin SL
	%	54.7	43.8	65.6	Siemens/Dade Actin FSL
	%	50.1	40.1	60.1	HemosIL Synthasil
	%	52.1	41.7	62.5	HemosIL APTT-SP Liquid
	%	55.0	44.0	66.0	Stago STA Factor VIII
	%	53.6	42.9	64.3	Stago Deficient / ImmunoDef VIII
	%	49.6	39.7	59.5	HemosIL Factor VIII deficient plasma
X 因子活性	%	97.8	78.2	117	Siemens/Dade-Behring Thromborel S
	%	97.3	77.8	117	Siemens/Dade-Behring Innovin
	%	89.8	71.8	108	HemosIL PT-Fibrinogen HS Plus
	%	91.3	73.0	110	Stago Neoplastine CI Plus
	%	84.2	67.4	101	HemosIL RecombiPlasTin 2G
	%	87.6	70.1	105	HemosIL Factor X deficient plasma
	%	80.5	64.4	96.6	Stago STA-NeoPTimal
XI 因子活性	%	47.5	38.0	57.0	Siemens/Dade Actin FS
	%	52.8	42.2	63.4	Siemens/Dade Pathromtin SL
	%	44.7	35.8	53.6	HemosIL Synthasil
	%	37.9	30.3	45.5	Siemens/Dade Actin FSL
	%	50.1	40.1	60.1	HemosIL APTT-SP Liquid
	%	51.6	41.3	61.9	Stago CK-Prest
XII 因子活性	%	80.6	64.5	96.7	Siemens/Dade Actin FS
	%	82.2	65.8	98.6	Siemens/Dade Pathromtin SL
	%	74.6	59.7	89.5	HemosIL Synthasil
	%	74.3	59.4	89.2	Siemens/Dade Actin FSL
	%	91.3	73.0	110	HemosIL APTT-SP Liquid
	%	83.8	67.0	101	HemosIL Factor XII deficient plasma
纤维蛋白原	g/L	2.29	1.83	2.75	HemosIL PT-Fibrinogen HS Plus
	mg/dL	229	183	275	
	g/L	2.35	1.88	2.82	Helena Fibrinogen
	mg/dL	235	188	282	
	g/L	2.44	1.95	2.93	Stago Fibrinogen / Liquid-Fib
	mg/dL	244	195	293	
	g/L	2.02	1.62	2.42	Siemens/Dade Multifibren U
	mg/dL	202	162	242	
	g/L	2.22	1.78	2.66	HemosIL Fibrinogen C
	mg/dL	222	178	266	

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 348CG Size 12 x 1ml Expiry 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
纤维蛋白原	g/L	2.13	1.70	2.56	Dade Thrombin
	mg/dL	213	170	256	
	g/L	2.80	2.24	3.36	Technoclone Fibrinogen
	mg/dL	280	224	336	
	g/L	2.35	1.88	2.82	Tcoag TriniCLOT Fibrinogen
	mg/dL	235	188	282	
	g/L	2.36	1.89	2.83	Biolabo Bio-Fibri
	mg/dL	236	189	283	
	g/L	2.13	1.70	2.56	Teco Teclot Fibrinogen
	mg/dL	213	170	256	
	g/L	2.07	1.66	2.48	HemosIL QFA (bovine thrombin)
	mg/dL	207	166	248	
	g/L	2.31	1.85	2.77	Human Fibrinogen
	mg/dL	231	185	277	
	g/L	2.38	1.90	2.86	Stago STA Fibri-Prest Automate
	mg/dL	238	190	286	
	g/L	1.88	1.50	2.26	Bio-Ksel System PT
	mg/dL	188	150	226	
	g/L	2.32	1.86	2.78	Bio-Ksel Fibrinogen
	mg/dL	232	186	278	
	g/L	2.05	1.64	2.46	Diagon Dia-F
	mg/dL	205	164	246	
	g/L	1.60	1.28	1.92	Dade Innovin Derived Fibrinogen
	mg/dL	160	128	192	
	g/L	2.00	1.60	2.40	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	200	160	240	
	g/L	2.02	1.62	2.42	HemosIL RecombiPlasTin 2G
	mg/dL	202	162	242	
	g/L	2.29	1.83	2.75	Sclavo Fibrinogen
	mg/dL	229	183	275	
	g/L	2.31	1.85	2.77	Labitec Fibrinogen
	mg/dL	231	185	277	
	g/L	2.30	1.84	2.76	HemoDiagnostica Fibrinogen
	mg/dL	230	184	276	
	g/L	2.36	1.89	2.83	Helena Clauss Fibrinogen 100
	mg/dL	236	189	283	
	g/L	2.05	1.64	2.46	Tokra Medikal Fibrinogen
	mg/dL	205	164	246	
	g/L	2.34	1.87	2.81	Coagpia Fibrinogen
	mg/dL	234	187	281	
	g/L	2.03	1.62	2.44	Beijing Succeeder Fibrinogen
	mg/dL	203	162	244	
	g/L	2.01	1.61	2.41	BioApex Fibrinogen
	mg/dL	201	161	241	
	g/L	2.23	1.78	2.68	Cobas Fibrinogen
	mg/dL	223	178	268	

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 348CG Size 12 x 1ml Expiry 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
血浆酶原活性	%	84.3	67.4	101	Stago Stachrom Plasminogen
	%	83.1	66.5	100	HemosIL Plasminogen
	%	92.2	73.8	111	Siemens/Dade Berichrom Plasminogen
C 蛋白	%	88.6	70.9	106	Siemens/Dade Berichrom Protein C
	%	87.1	69.7	105	Stago StaClot
	%	85.4	68.3	102	IL HemosIL Protein C
	%	76.7	61.4	92.0	Siemens
	%	89.4	71.5	107	STACHrom Protein C
S 蛋白	%	74.9	52.4	97.4	STA Liatest
	%	66.5	46.6	86.5	Stago StaClot
	%	85.7	60.0	111	IL HemosIL ProS
	%	81.2	56.8	106	IL HemosIL Free Protein S
	%	55.5	38.9	72.2	Dade Protein S Ac
	%	78.1	54.7	102	Siemens Innovance Free PS Ag
	%	61.9	43.3	80.5	IL HemosIL Protein S Activity
凝血酶原时间 (PT)	Seconds	12.2	9.76	14.6	Siemens/Dade-Behring Innovin
	Seconds	12.1	9.68	14.5	Siemens/Dade Thromborel IS
	Seconds	12.1	9.68	14.5	Siemens/Dade-Behring Thromborel S
	Seconds	14.6	11.7	17.5	HemosIL PT-Fibrinogen HS Plus
	Seconds	14.3	11.4	17.2	Stago Neoplastine CI Plus
	Seconds	13.6	10.9	16.3	Teco TEClot PT-S
	Seconds	14.6	11.7	17.5	Biolabo Bio-TP
	Seconds	13.3	10.6	16.0	Stago Neoplastin R
	Seconds	11.3	9.04	13.6	Bio-Ksel System PT
	Seconds	12.9	10.3	15.5	Human Thromboplastin
	Seconds	13.4	10.7	16.1	Diagon PT
	Seconds	15.3	12.2	18.4	Weiner Lab Soluplastin
	Seconds	13.7	11.0	16.4	Spinreact PT
	Seconds	11.8	9.44	14.2	Shanghai Changdao Biotech PT
	Seconds	15.1	12.1	18.1	TCoag TriniCLOT PT Excel S
	Seconds	14.9	11.9	17.9	Media IVD PT
	Seconds	11.7	9.36	14.0	Biodevice PT
	Seconds	13.6	10.9	16.3	Biomedica QuikCoag PT-HS
	Seconds	11.2	8.96	13.4	HemosIL RecombiPlasTin 2G
	Seconds	13.6	10.9	16.3	Helena Thromboplastin LI
	Seconds	13.4	10.7	16.1	Helena Thromboplastin
	Seconds	13.4	10.7	16.1	Labitec PT
	Seconds	15.0	12.0	18.0	Dutch Diagnostics PT
	Seconds	11.9	9.52	14.3	Fortress Diagnostics PT with Calcium
	Seconds	13.1	10.5	15.7	Tokra Medikal PT
	Seconds	12.7	10.2	15.2	Coagpia PT-N
	Seconds	10.6	8.48	12.7	Bio-Ksel PT Plus
	Seconds	12.7	10.2	15.2	Beijing Succeder PT
	Seconds	10.2	8.16	12.2	Diagon PT R
	Seconds	12.1	9.68	14.5	Cobas PT Screen

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 348CG Size 12 x 1ml Expiry 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
凝血酶原时间 (PT)	Seconds	15.6	12.5	18.7	Stago STA-NeoPTimal
凝血酶原时间 (PT) 活性	%	69.6	55.7	83.5	Siemens/Dade-Behring Innovin
	%	93.1	74.5	112	Siemens/Dade-Behring Thromborel S
	%	83.1	66.5	100	Stago Neoplastine CI Plus
	%	90.3	72.2	108	HemosIL PT-Fibrinogen
	%	101	80.8	121	HemosIL PT-Fibrinogen HS Plus
	%	89.0	71.2	107	Teco TEClot PT-S
	%	76.1	60.9	91.3	Biolabo Bio-TP
	%	98.2	78.6	118	Stago Neoplastin R
	%	83.5	66.8	100	Human Thromboplastin
	%	97.5	78.0	117	Diagon PT
	%	69.3	55.4	83.2	TCoag TriniCLOT PT Excel S
	%	81.0	64.8	97.2	Media IVD PT
	%	100	80.0	120	Biodevice PT
	%	103	82.4	124	HemosIL RecombiPlasTin 2G
	%	96.3	77.0	116	Helena Thromboplastin
	%	92.5	74.0	111	Labitec PT
	%	97.2	77.8	117	Tokra Medikal PT
	%	91.5	73.2	110	Coagpia PT-N
	%	106	84.8	127	Bio-Ksel PT Plus
	%	100	80.0	120	Diagon PT R
	%	89.1	71.3	107	Cobas PT Screen
	%	78.3	62.6	94.0	Stago STA-NeoPTimal
凝血酶原时间 (PT) INR	INR	1.19	0.952	1.43	Siemens/Dade-Behring Innovin
	INR	1.03	0.824	1.24	Siemens/Dade Thromborel IS
	INR	1.03	0.824	1.24	Siemens/Dade-Behring Thromborel S
	INR	1.00	0.800	1.20	HemosIL PT-Fibrinogen
	INR	1.01	0.808	1.21	HemosIL PT-Fibrinogen HS Plus
	INR	1.10	0.880	1.32	Stago Neoplastine CI Plus
	INR	1.03	0.824	1.24	Human Thromboplastin
	INR	1.01	0.808	1.21	Teco TEClot PT-S
	INR	1.20	0.960	1.44	Biolabo Bio-TP
	INR	0.950	0.760	1.14	Stago SPA
	INR	1.00	0.800	1.20	Stago Neoplastin R
	INR	1.03	0.824	1.24	Diagon PT
	INR	1.28	1.02	1.54	Weiner Lab Soluplastin
	INR	0.980	0.784	1.18	Spinreact PT
	INR	1.26	1.01	1.51	TCoag TriniCLOT PT Excel S
	INR	1.11	0.888	1.33	Media IVD PT
	INR	1.00	0.800	1.20	Biodevice PT
	INR	1.11	0.888	1.33	Biomedica QuikCoag PT-HS
	INR	0.980	0.784	1.18	HemosIL RecombiPlasTin 2G
	INR	1.05	0.840	1.26	Helena Thromboplastin LI
	INR	1.04	0.832	1.25	Helena Thromboplastin
	INR	1.05	0.840	1.26	Labitec PT
	INR	1.21	0.968	1.45	Dutch Diagnostics PT

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 348CG Size 12 x 1ml Expiry 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
凝血酶原时间 (PT) INR	INR	0.950	0.760	1.14	Tokra Medikal PT
	INR	1.06	0.848	1.27	Coagpia PT-N
	INR	0.980	0.784	1.18	Bio-Ksel PT Plus
	INR	0.970	0.776	1.16	Beijing Succeder PT
	INR	0.970	0.776	1.16	Diagon PT R
	INR	1.14	0.912	1.37	Cobas PT Screen
	INR	1.18	0.944	1.42	Stago STA-NeoPTimal
凝血酶原时间 (PT) 比率	ratio	1.17	0.936	1.40	Siemens/Dade-Behring Innovin
	ratio	1.04	0.832	1.25	Siemens/Dade-Behring Thromborel S
	ratio	1.08	0.864	1.30	Stago Neoplastine CI Plus
	ratio	1.02	0.816	1.22	Diagon PT
	ratio	0.980	0.784	1.18	HemosIL PT-Fibrinogen HS Plus
	ratio	0.970	0.776	1.16	HemosIL RecombiPlasTin 2G
	ratio	1.16	0.928	1.39	Stago STA-NeoPTimal
凝血酶时间 (TT)	Seconds	24.8	19.8	29.8	Dade Thrombin
	Seconds	24.2	19.4	29.0	Siemens/Dade Thromboclotin
	Seconds	25.1	20.1	30.1	Stago Thrombin
	Seconds	24.6	19.7	29.5	Sysmex Thrombin Time
	Seconds	28.0	22.4	33.6	Diagon, Dia-TT
	Seconds	22.8	18.2	27.4	HemosIL Thrombin Time 5ml
	Seconds	28.3	22.6	34.0	HemosIL Thrombin Time 8ml