

COAGULATION CONTROL - LEVEL I (COAG CONTROL I)

CAT. NO. CG 502I

LOT NO. 271CG

SIZE: 12 x 1 ml

EXPIRY: 2020-10-28

GTIN: 05055273207620

INTENDED USE

This product is intended for *in vitro* diagnostic use, and in the quality control of coagulation systems. The Coagulation Controls are for the control of accuracy and precision.

DEVICE DESCRIPTION

The Coagulation Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values section.

SAFETY PRECAUTIONS AND WARNINGS

The controls are intended for *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents and controls.

Human source material, which has been added, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and was found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). APTT, TT, PT, Fibrinogen and Antithrombin III in reconstituted serum are stable for 24 hours at +2°C to +8°C, if kept capped in original container and free from contamination. Protein C, Protein S, Plasminogen, and Factors II, V, VII, VIII, IX, X, XI, XII are stable for 8 hours at +2°C to +8°C. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

PREPARATION FOR USE

The Coagulation Controls are supplied lyophilised.

- Carefully reconstitute each vial of lyophilised control with exactly 1 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid the formation of foam. Do not shake the vial.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix the contents of the vial thoroughly.

MATERIALS PROVIDED

Coagulation Control - Level I 12 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Each batch of Coagulation Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its test methods.

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COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 271CG Size: 12 x 1 ml Expiry: 2020-10-28

Analyte	unit	Target	Range		methods
			low	high	
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	HemoDiagnostica 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

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 271CG Size: 12 x 1 ml Expiry: 2020-10-28

Analyte	unit	Target	Range		methods
			low	high	
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

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 271CG Size: 12 x 1 ml Expiry: 2020-10-28

Range					
Analyte	unit	Target	low	high	methods
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
Factor X activity	%	42.0	33.6	50.4	HemosIL Factor VIII deficient plasma
	%	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
Factor XI activity	%	83.5	66.8	100	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	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
Factor XII activity	%	38.9	31.1	46.7	HemosIL Factor XI Deficient Plasma
	%	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
Fibrinogen	%	89.7	71.8	108	HemosIL APTT-SP Liquid
	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		

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 271CG Size: 12 x 1 ml Expiry: 2020-10-28

Analyte	unit	Target	Range		methods
			low	high	
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 Fibri-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 Succeeder 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

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 271CG Size: 12 x 1 ml Expiry: 2020-10-28

Range					
Analyte	unit	Target	low	high	methods
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	

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 271CG Size: 12 x 1 ml Expiry: 2020-10-28

Range						
Analyte	unit	Target	low	high	methods	
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	

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 271CG Size: 12 x 1 ml Expiry: 2020-10-28

Range					
Analyte	unit	Target	low	high	methods
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