

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

CAT NO. CG5023

LOT NO. 259CG

SIZE: 12 x 1 ml

EXPIRY: 2019-11-28

GTIN: 05055273207644

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.

1. 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.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix the contents of the vial thoroughly.

MATERIALS PROVIDED

Coagulation Control - Level 3 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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Cat. No. CG5023 Lot No. 259CG

Size: 12 x 1 ml Expiry: 2019-11-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (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	HemoDiagnostics 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)
Activated Partial Thromboplastin Time (APTT) Ratio	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

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

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Size: 12 x 1 ml Expiry: 2019-11-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	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
Antithrombin III activity	%	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)
Factor II activity	%	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
Factor IX activity	%	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
Factor V activity	%	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
Factor VII activity	%	64.1	51.3	76.9	Stago Neoplastine CI Plus
	%	69.7	55.8	83.6	Siemens/Dade Thromborel S

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Analyte	unit	Target	low	high	methods
Factor VII activity	%	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
Factor VIII activity	%	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
Factor X activity	%	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
Factor XI activity	%	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
Factor XII activity	%	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
Fibrinogen	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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Analyte	unit	Target	low	high	methods
Fibrinogen	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	
Plasminogen activity	%	57.1	45.7	68.5	HemosIL Plasminogen
	%	62.7	50.2	75.2	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	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
Protein S activity	%	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
Prothrombin Time (PT)	Seconds	23.0	18.4	27.6	Tcoag TriniCLOT PT Excel

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Analyte	unit	Target	low	high	methods
Prothrombin Time (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
Prothrombin Time (PT) activity	%	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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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT)	%	41.1	32.9	49.3	Cobas PT Screen
Prothrombin Time (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
Prothrombin Time (PT) ratio	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
Thrombin Time (TT)	ratio	2.11	1.69	2.53	Biodevice PT
	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