

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

CAT. NO. CG5023

SIZE: 12 x 1 ml

LOT NO. 267CG

EXPIRY: 2020-04-28

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.

LIMITATION

The Randox Level 3 Coagulation Control may not be suitable for the control of aPTT on some analysers, due to a slow clotting time.

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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Size: 12 x 1 ml Expiry: 2020-04-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	64.3	51.4	77.2	Tcoag TriniCLOT aPTT S
	seconds	57.1	45.7	68.5	Tcoag TriniCLOT aPTT HS
	seconds	57.0	45.6	68.4	Siemens/Dade Actin
	seconds	51.2	41.0	61.4	Siemens/Dade Actin FS
	seconds	49.8	39.8	59.8	Siemens/Dade Actin FSL
	seconds	85.4	68.3	102	Siemens/Dade Actin SL
	seconds	89.7	71.8	108	Siemens/Dade Pathromtin SL
	seconds	56.9	45.5	68.3	Helena aPTT
	seconds	48.1	38.5	57.7	HemosIL APTT-SP Liquid
	seconds	69.4	55.5	83.3	HemosIL Synthasil
	seconds	59.9	47.9	71.9	Pacific Hemostasis APTT-XL
	seconds	59.7	47.8	71.6	Stago aPTT
	seconds	52.7	42.2	63.2	Stago Cephascreen
	seconds	64.2	51.4	77.0	Stago CK-Prest
	seconds	63.8	51.0	76.6	Stago PTT Automate
	seconds	60.6	48.5	72.7	Teco TEClot APTT
	seconds	57.1	45.7	68.5	Human Hemostat APTT
	seconds	51.6	41.3	61.9	Bio-Ksel System APTTs
	seconds	72.1	57.7	86.5	Diagon Dia-PTT
	seconds	52.1	41.7	62.5	Weiner Lab APTT
	seconds	61.8	49.4	74.2	Biolabo Bio-CK APTT
	seconds	63.2	50.6	75.8	Spinreact APTT
	seconds	44.0	35.2	52.8	Technology-Standard aPTT
	seconds	64.8	51.8	77.8	Tcoag TriniCLOT Automated aPTT
	seconds	43.9	35.1	52.7	Media IVD aPTT
	seconds	61.3	49.0	73.6	Siemens Dade Actin Cephaloplastin
	seconds	60.0	48.0	72.0	Sclavo APTT-S
	seconds	60.1	48.1	72.1	HemoDiagnostica aPTT
	seconds	60.7	48.6	72.8	Cypress Diagnostics aPTT
	seconds	65.5	52.4	78.6	Tokra Medikal APTT
	seconds	49.0	39.2	58.8	Coagpia APTT-N
	seconds	83.2	66.6	100	Cobas aPTT MedS
	seconds	58.5	46.8	70.2	Biolabo Bio-Sil (APTT)
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.31	1.85	2.77	Tcoag TriniCLOT aPTT S
	ratio	1.94	1.55	2.33	Siemens/Dade Actin FSL
	ratio	2.55	2.04	3.06	Siemens/Dade Actin SL
	ratio	1.77	1.42	2.12	Stago Cephascreen
	ratio	1.97	1.58	2.36	Stago PTT Automate
	ratio	1.95	1.56	2.34	Stago aPTT
	ratio	2.92	2.34	3.50	Siemens/Dade Pathromtin SL
	ratio	1.56	1.25	1.87	HemosIL APTT-SP Liquid
	ratio	2.33	1.86	2.80	HemosIL Synthasil

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Size: 12 x 1 ml Expiry: 2020-04-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.90	1.52	2.28	Pacific Hemostasis APTT-XL
	ratio	1.90	1.52	2.28	Helena aPTT
	ratio	2.13	1.70	2.56	Stago CK-Prest
	ratio	2.25	1.80	2.70	Human Hemostat APTT
	ratio	1.51	1.21	1.81	Bio-Ksel System APTTs
	ratio	1.96	1.57	2.35	Siemens/Dade Actin FS
	ratio	2.18	1.74	2.62	Diagon Dia-PTT
	ratio	1.97	1.58	2.36	Biodevice aPTT
	ratio	2.06	1.65	2.47	Sclavo APTT-S
	ratio	1.54	1.23	1.85	Coagpia APTT-N
Antithrombin III activity	%	57.2	45.8	68.6	Siemens/Dade Berichrom ATIII
	%	54.5	43.6	65.4	Helena Chrom-Z
	%	51.6	41.3	61.9	HemosIL Liquid Antithrombin
	%	55.1	44.1	66.1	Roche Chronogenic Thrombin
	%	50.5	40.4	60.6	Hemosil Lyophilised Antithrombin III
	%	59.1	47.3	70.9	STACHrom ATIII
	%	61.2	49.0	73.4	Siemens/Dade Antithrombin III
	%	58.4	46.7	70.1	Diagon ATIII
	%	57.6	46.1	69.1	Siemens Innovance Antithrombin III
	%	54.4	43.5	65.3	Sclavo ATIII
	%	49.7	39.8	59.6	Teco TEChrom AT
	%	63.7	51.0	76.4	HemoDiagnostics Antithrombin III (Fxa)
Factor II activity	%	55.8	44.6	67.0	Dade Innovin
	%	60.3	48.2	72.4	Siemens/Dade Thromborel S
	%	56.4	45.1	67.7	Stago Neoplastine CI Plus
	%	51.8	41.4	62.2	HemosIL PT-Fibrinogen HS Plus
	%	51.7	41.4	62.0	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	65.4	52.3	78.5	Stago PTT Automate
	%	56.2	45.0	67.4	Siemens/Dade Actin FS
	%	59.2	47.4	71.0	Siemens/Dade Pathromtin SL
	%	50.4	40.3	60.5	HemosIL Synthasil
	%	55.0	44.0	66.0	Stago CK-Prest
	%	52.8	42.2	63.4	Siemens/Dade Actin FSL
	%	57.9	46.3	69.5	HemosIL APTT-SP Liquid
	%	57.9	46.3	69.5	Stago Deficient / ImmunoDef IX
	%	52.0	41.6	62.4	HemosIL Factor IX deficient plasma
Factor V activity	%	42.2	33.8	50.6	Stago Neoplastine CI Plus
	%	45.7	36.6	54.8	Siemens/Dade Thromborel S
	%	37.1	29.7	44.5	Dade Innovin
	%	36.4	29.1	43.7	HemosIL PT-Fibrinogen HS Plus
	%	41.6	33.3	49.9	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	39.5	31.6	47.4	Stago Neoplastin R
	%	39.0	31.2	46.8	HemosIL Factor V deficient plasma
Factor VII activity	%	66.6	53.3	79.9	Stago Neoplastine CI Plus
	%	71.2	57.0	85.4	Siemens/Dade Thromborel S
	%	75.2	60.2	90.2	Dade Innovin

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Analyte	unit	Target	low	high	methods
Factor VII activity	%	71.6	57.3	85.9	HemosIL PT-Fibrinogen HS Plus
	%	78.3	62.6	94.0	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	75.7	60.6	90.8	HemosIL Factor VII deficient plasma
Factor VIII activity	%	37.0	29.6	44.4	Stago PTT Automate
	%	36.2	29.0	43.4	Siemens/Dade Actin FS
	%	34.5	27.6	41.4	Siemens/Dade Pathromtin SL
	%	33.0	26.4	39.6	Siemens/Dade Actin FSL
	%	35.2	28.2	42.2	HemosIL Synthasil
	%	36.6	29.3	43.9	HemosIL APTT-SP Liquid
	%	32.8	26.2	39.4	Stago STA Factor VIII
	%	33.8	27.0	40.6	Stago Deficient / ImmunoDef VIII
	%	33.7	27.0	40.4	HemosIL Factor VIII deficient plasma
Factor X activity	%	62.0	49.6	74.4	Siemens/Dade Thromborel S
	%	57.0	45.6	68.4	Dade Innovin
	%	60.7	48.6	72.8	HemosIL PT-Fibrinogen HS Plus
	%	60.0	48.0	72.0	Stago Neoplastine CI Plus
	%	59.3	47.4	71.2	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	35.1	28.1	42.1	HemosIL Synthasil
	%	27.9	22.3	33.5	Siemens/Dade Actin FSL
Factor XII activity	%	55.1	44.1	66.1	Siemens/Dade Actin FS
	%	53.0	42.4	63.6	Siemens/Dade Pathromtin SL
	%	56.6	45.3	67.9	HemosIL Synthasil
	%	49.7	39.8	59.6	Siemens/Dade Actin FSL
	%	59.6	47.7	71.5	HemosIL APTT-SP Liquid
Fibrinogen	g/L	1.78	1.42	2.14	HemosIL PT-Fibrinogen HS Plus
	mg/dL	178	142	214	
	g/L	1.72	1.38	2.06	Helena Fibrinogen
	mg/dL	172	138	206	
	g/L	1.66	1.33	1.99	Stago Fibrinogen / Liquid-Fib
	mg/dL	166	133	199	
	g/L	1.19	0.952	1.43	Siemens/Dade Multifibren U
	mg/dL	119	95.2	143	
	g/L	1.58	1.26	1.90	HemosIL Fibrinogen C
	mg/dL	158	126	190	
	g/L	1.36	1.09	1.63	Dade Thrombin
	mg/dL	136	109	163	
	g/L	1.69	1.35	2.03	Technoclone Fibrinogen
	mg/dL	169	135	203	
	g/L	1.56	1.25	1.87	Tcoag TriniCLOT Fibrinogen
	mg/dL	156	125	187	
	g/L	1.58	1.26	1.90	Biolabo Bio-Fibri
	mg/dL	158	126	190	
	g/L	1.53	1.22	1.84	HemosIL QFA (bovine thrombin)
	mg/dL	153	122	184	
	g/L	2.02	1.62	2.42	Pacific Hemostasis Fibrinogen
	mg/dL	202	162	242	

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Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	1.52	1.22	1.82	Human Fibrinogen
	mg/dL	152	122	182	
	g/L	1.66	1.33	1.99	Stago STA Fibri-Prest Automate
	mg/dL	166	133	199	
	g/L	1.11	0.888	1.33	Bio-Ksel System PT
	mg/dL	111	88.8	133	
	g/L	1.70	1.36	2.04	Bio-Ksel Fibrinogen
	mg/dL	170	136	204	
	g/L	1.45	1.16	1.74	Diagon Dia-F
	mg/dL	145	116	174	
	g/L	1.20	0.960	1.44	Dade Innovin Derived Fibrinogen
	mg/dL	120	96.0	144	
	g/L	1.14	0.912	1.37	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	114	91.2	137	
	g/L	1.47	1.18	1.76	Technology-Standard Fibrinogen
	mg/dL	147	118	176	
	g/L	1.13	0.904	1.36	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	113	90.4	136	
	g/L	1.44	1.15	1.73	Sclavo Fibrinogen
	mg/dL	144	115	173	
	g/L	1.38	1.10	1.66	Labitec Fibrinogen
	mg/dL	138	110	166	
	g/L	1.56	1.25	1.87	HemoDiagnostica Fibrinogen
	mg/dL	156	125	187	
Plasminogen activity	g/L	1.60	1.28	1.92	Beijing Steelex Fibrinogen
	mg/dL	160	128	192	
	g/L	1.65	1.32	1.98	Helena Clauss Fibrinogen 100
Protein C activity	mg/dL	165	132	198	
	g/L	1.37	1.10	1.64	Coagpia Fibrinogen
	mg/dL	137	110	164	
	g/L	1.68	1.34	2.02	Cobas Fibrinogen
	mg/dL	168	134	202	
	g/L	1.70	1.36	2.04	HemosIL PT-Fibrinogen
Protein S activity	mg/dL	170	136	204	
	%	59.4	47.5	71.3	Stago Stachrom Plasminogen
	%	58.3	46.6	70.0	HemosIL Plasminogen
Protein C activity	%	64.4	51.5	77.3	Siemens/Dade Berichrom Plasminogen
	%	57.9	46.3	69.5	Siemens/Dade Berichrom Protein C
	%	63.8	51.0	76.6	Stago StaClot
	%	55.2	44.2	66.2	Biomerieux VIDAS Protein C
	%	53.3	42.6	64.0	IL HemosIL Protein C
	%	61.5	49.2	73.8	Siemens
Protein S activity	%	61.4	49.1	73.7	STACHrom Protein C
	%	53.8	37.7	69.9	STA Liatest
	%	57.5	40.3	74.8	Stago StaClot
Protein S activity	%	63.5	44.5	82.6	IL HemosIL ProS

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Protein S activity	%	60.0	42.0	78.0	IL HemosIL Free Protein S
	%	39.3	27.5	51.1	Dade Protein S Ac
	%	54.6	38.2	71.0	Siemens Innovance Free PS Ag
	%	46.1	32.3	59.9	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	24.2	19.4	29.0	Tcoag TriniCLOT PT Excel
	Seconds	26.3	21.0	31.6	Dade Innovin
	Seconds	18.1	14.5	21.7	Siemens/Dade Thromborel IS
	Seconds	18.1	14.5	21.7	Siemens/Dade Thromborel S
	Seconds	28.2	22.6	33.8	HemosIL PT-Fibrinogen HS Plus
	Seconds	40.2	32.2	48.2	Pacific Thromboplastin DS
	Seconds	21.3	17.0	25.6	STA Hepato Quick
	Seconds	21.0	16.8	25.2	Stago Neoplastine CI
	Seconds	21.6	17.3	25.9	Stago Neoplastine CI Plus
	Seconds	24.8	19.8	29.8	R2 Phosphoplastin RL
	Seconds	26.1	20.9	31.3	Teco TEClot PT-S
	Seconds	19.4	15.5	23.3	Stago Neoplastin R
	Seconds	15.5	12.4	18.6	Bio-Ksel System PT
	Seconds	22.7	18.2	27.2	Human Thromboplastin
	Seconds	25.3	20.2	30.4	Diagon PT
	Seconds	33.1	26.4	39.7	Weiner Lab Soluplastin
	Seconds	26.1	20.9	31.3	Spinreact PT
	Seconds	25.8	20.6	31.0	Technology-Standard PT
	Seconds	45.1	36.1	54.1	TCoag TriniCLOT PT Excel S
	Seconds	21.5	17.2	25.8	Biodevice PT
	Seconds	27.0	21.6	32.4	Biomedica QuikCoag PT-HS
	Seconds	16.2	13.0	19.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	29.0	23.2	34.8	Helena Thromboplastin
	Seconds	19.9	15.9	23.9	Cypress Diagnostics PT
	Seconds	23.3	18.6	28.0	Tokra Medikal PT
	Seconds	36.4	29.1	43.7	Coagpia PT-N
	Seconds	15.3	12.2	18.4	Bio-Ksel PT Plus
	Seconds	25.0	20.0	30.0	Beijing Succeeder PT
	Seconds	21.9	17.5	26.3	Diagon PT R
	Seconds	18.7	15.0	22.4	Cobas PT Screen
Prothrombin Time (PT) activity	%	21.6	17.3	25.9	Dade Innovin
	%	47.1	37.7	56.5	Siemens/Dade Thromborel S
	%	37.7	30.2	45.2	Stago Neoplastine CI
	%	41.9	33.5	50.3	Stago Neoplastine CI Plus
	%	32.6	26.1	39.1	HemosIL PT-Fibrinogen HS Plus
	%	38.1	30.5	45.7	Biolabo Bio-TP
	%	62.9	50.3	75.5	Stago SPA
	%	56.2	45.0	67.4	Stago Neoplastin R
	%	69.6	55.7	83.5	Bio-Ksel System PT
	%	34.0	27.2	40.8	Diagon PT
	%	17.8	14.2	21.3	TCoag TriniCLOT PT Excel S
	%	34.2	27.4	41.0	Media IVD PT

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Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	43.1	34.5	51.7	Biodevice PT
	%	22.1	17.7	26.5	Biomedica QuikCoag PT-HS
	%	57.9	46.3	69.5	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	27.4	21.9	32.9	Helena Thromboplastin
	%	24.0	19.2	28.8	Tokra Medikal PT
	%	16.9	13.5	20.3	Coagpia PT-N
	%	71.5	57.2	85.8	Bio-Ksel PT Plus
	%	26.4	21.1	31.7	Diagon PT R
	%	38.3	30.6	46.0	Cobas PT Screen
Prothrombin Time (PT) INR	INR	2.64	2.11	3.17	Dade Innovin
	INR	1.50	1.20	1.80	Siemens/Dade Thromborel IS
	INR	1.59	1.27	1.91	Siemens/Dade Thromborel S
	INR	2.21	1.77	2.65	HemosIL PT-Fibrinogen HS Plus
	INR	3.28	2.62	3.94	Pacific Thromboplastin DS
	INR	1.85	1.48	2.22	STA Hepato Quick
	INR	2.16	1.73	2.59	Stago Neoplastine CI
	INR	1.92	1.54	2.30	Stago Neoplastine CI Plus
	INR	1.95	1.56	2.34	Human Thromboplastin
	INR	2.03	1.62	2.44	Teco TEClot PT-S
	INR	2.40	1.92	2.88	Biolabo Bio-TP
	INR	1.21	0.968	1.45	Stago SPA
	INR	1.39	1.11	1.67	Stago Neoplastin R
	INR	1.41	1.13	1.69	Bio-Ksel System PT
	INR	2.13	1.70	2.56	Diagon PT
	INR	1.95	1.56	2.34	Technology-Standard PT
	INR	4.34	3.47	5.21	TCoag TriniCLOT PT Excel S
	INR	1.88	1.50	2.26	Biodevice PT
	INR	2.36	1.89	2.83	Biomedica QuikCoag PT-HS
	INR	1.43	1.14	1.72	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.87	1.50	2.24	Technoclon Technoplastin HIS
	INR	2.52	2.02	3.02	Helena Thromboplastin
	INR	1.81	1.45	2.17	Tokra Medikal PT
	INR	2.96	2.37	3.55	Coagpia PT-N
	INR	1.39	1.11	1.67	Bio-Ksel PT Plus
	INR	1.88	1.50	2.26	Beijing Succeeder PT
	INR	2.13	1.70	2.56	Diagon PT R
	INR	1.81	1.45	2.17	Cobas PT Screen
Prothrombin Time (PT) ratio	ratio	2.78	2.22	3.34	Dade Innovin
	ratio	1.56	1.25	1.87	Siemens/Dade Thromborel S
	ratio	1.78	1.42	2.14	Stago Neoplastine CI
	ratio	1.63	1.30	1.96	Stago Neoplastine CI Plus
	ratio	1.36	1.09	1.63	Stago Neoplastin R
	ratio	2.02	1.62	2.42	Diagon PT
	ratio	2.03	1.62	2.44	HemosIL PT-Fibrinogen HS Plus
	ratio	1.43	1.14	1.72	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	31.5	25.2	37.8	Dade Thrombin

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Analyte	unit	Target	low	high	methods
Thrombin Time (TT)	Seconds	25.5	20.4	30.6	Siemens/Dade Thromboclotin
	Seconds	34.2	27.4	41.0	Stago Thrombin
	Seconds	29.7	23.8	35.6	Sysmex Thrombin Time
	Seconds	31.1	24.9	37.3	Pacific Hemostasis Thrombin Time
	Seconds	27.5	22.0	33.0	HemosIL Thrombin Time 5ml
	Seconds	39.1	31.3	46.9	HemosIL Thrombin Time 8ml