

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat No. CG5023
Size: 12 x 1 ml

Lot No. 165CG
Expiry: 2017-09

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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Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	133	101	165	Siemens/Dade Actin
	seconds	122	93.7	150	Siemens/Dade Actin FS
	seconds	81.6	62.7	101	Siemens/Dade Actin FSL
	seconds	129	103	155	Helena aPTT
	seconds	94.6	75.7	114	HemosIL APTT-SP Liquid
	seconds	108	86.4	130	HemosIL Synthasil
	seconds	94.0	75.2	113	Pacific Hemostasis APTT-XL
	seconds	119	95.2	143	Stago aPTT
	seconds	113	90.4	136	Stago Cephascreen
	seconds	115	92.0	138	Stago CK-Prest
	seconds	122	97.6	146	Stago PTT Automate
	seconds	120	96.0	144	Teco TEClot APTT
	seconds	89.3	71.4	107	Bio-Ksel System APTTs
	seconds	103	82.4	124	Grifols DG-APTT
	seconds	102	81.6	122	Weiner Lab APTT
	seconds	124	93.5	155	Biolabo Bio-CK APTT
	seconds	102	81.6	122	Spinreact APTT
	seconds	130	104	156	Trinity/Biomerieux Triniclot aPTT
	seconds	88.3	70.6	106	Biomedica QuikCoag aPTT
	seconds	130	97.0	163	Siemens Dade Actin Cephaloplastin
	seconds	96.6	77.3	116	Technoclone Siron aPTT
	seconds	126	101	151	Sclavo APTT-S
	seconds	127	102	152	Tokra Medikal APTT
	seconds	77.6	62.1	93.1	Coagpia APTT-N
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	3.07	2.40	3.74	Siemens/Dade Actin FSL
	ratio	3.83	3.06	4.60	Stago Cephascreen
	ratio	3.26	2.61	3.91	Stago PTT Automate
	ratio	3.84	3.07	4.61	Stago aPTT
	ratio	6.77	5.42	8.12	Siemens/Dade Pathromtin SL
	ratio	3.09	2.44	3.74	HemosIL APTT-SP Liquid
	ratio	3.64	2.86	4.42	HemosIL Synthasil
	ratio	2.87	2.12	3.62	Pacific Hemostasis APTT-XL
	ratio	3.47	2.78	4.16	Stago CK-Prest
	ratio	2.58	1.92	3.24	Human Hemostat APTT
	ratio	2.71	2.17	3.25	Bio-Ksel System APTTs
	ratio	4.58	3.66	5.50	Siemens/Dade Actin FS
	ratio	3.75	3.00	4.50	Diagon Dia-PTT
	ratio	4.43	3.54	5.32	Siemens/Dade Actin
	ratio	2.79	2.23	3.35	Hemosil aPTT Lyophilised Silica
	ratio	4.31	3.45	5.17	Trinity/Biomerieux Triniclot aPTT
	ratio	4.53	3.52	5.54	Siemens Dade Actin Cephaloplastin
	ratio	4.25	3.40	5.10	Sclavo APTT-S

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

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Range					
Analyte	unit	Target	low	high	methods
APTT Ratio	ratio	2.49	1.99	2.99	Coaggia APTT-N
Antithrombin III activity	%	39.4	30.6	48.2	Siemens/Dade Berichrom ATIII
	%	44.8	35.8	53.8	Helena Chrom-Z
	%	35.9	25.6	46.2	HemosIL Liquid Antithrombin
	%	40.0	32.0	48.0	Hyphen BioMed BioPhen ATIII
	%	42.2	33.8	50.6	Roche Chronogenic Thrombin
	%	38.0	30.4	45.6	Hemosil Lyophilised Antithrombin III
	%	42.6	32.9	52.3	STACHrom ATIII
	%	41.3	33.0	49.6	Siemens/Dade Antithrombin III
	%	41.0	29.1	52.9	Siemens Innovance Antithrombin III
Factor II activity	%	39.0	31.2	46.8	Sclavo ATIII
	%	8.27	6.62	9.92	Dade Innovin
	%	10.0	8.00	12.0	Siemens/Dade Thromborel S
	%	11.0	8.80	13.2	Stago Neoplastine CI Plus
	%	8.76	7.01	10.5	HemosIL PT-Fibrinogen HS Plus
	%	8.36	6.69	10.0	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	8.33	6.66	10.0	Stago Neoplastin R
	%	9.70	7.20	12.2	Stago PTT Automate
	%	11.4	9.12	13.7	Siemens/Dade Pathromtin SL
	%	8.94	6.97	10.9	HemosIL Synthasil
	%	10.2	8.01	12.4	Stago CK-Prest
Factor V activity	%	11.1	8.88	13.3	Stago aPTT
	%	27.3	20.6	34.0	Stago Neoplastine CI Plus
	%	28.0	20.1	35.9	Siemens/Dade Thromborel S
	%	24.5	19.6	29.4	HemosIL PT-Fibrinogen HS Plus
	%	26.2	21.0	31.4	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VII activity	%	25.6	20.5	30.7	Stago Neoplastin R
	%	9.33	6.60	12.1	Stago Neoplastine CI Plus
	%	11.3	9.04	13.6	Siemens/Dade Thromborel S
	%	12.1	9.16	15.0	Dade Innovin
	%	12.2	9.76	14.6	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VIII activity	%	11.3	8.07	14.5	Stago Neoplastin R
	%	18.8	15.0	22.6	Stago CK-Prest
	%	19.6	15.7	23.5	Stago PTT Automate
	%	19.4	15.5	23.3	Siemens/Dade Actin FS
	%	21.4	17.1	25.7	Siemens/Dade Pathromtin SL
	%	19.4	14.6	24.2	Siemens/Dade Actin FSL
	%	16.9	13.5	20.3	HemosIL Synthasil
	%	21.4	17.1	25.7	HemosIL APTT-SP Liquid
Factor X activity	%	20.9	16.7	25.1	Stago aPTT
	%	9.50	7.60	11.4	Siemens/Dade Thromborel S
	%	9.63	7.70	11.6	Dade Innovin
	%	9.00	7.20	10.8	Stago Neoplastine CI Plus
	%	9.60	7.56	11.6	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	9.50	7.60	11.4	Stago Neoplastin R
	%	13.9	11.1	16.7	Siemens/Dade Pathromtin SL

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Factor XI activity	%	10.7	7.56	13.8	HemosIL Synthasil
	%	10.6	8.48	12.7	HemosIL APTT-SP Liquid
	%	12.1	9.68	14.5	Siemens Dade Actin Cephaloplastin
Factor XII activity	%	31.3	25.0	37.6	Siemens/Dade Actin FS
	%	35.2	27.6	42.8	Siemens/Dade Pathromtin SL
	%	33.7	27.0	40.4	HemosIL Synthasil
	%	37.0	29.6	44.4	Siemens/Dade Actin FSL
	%	37.4	29.9	44.9	HemosIL APTT-SP Liquid
	%	40.5	32.4	48.6	Stago CK-Prest
	%	32.5	26.0	39.0	Stago aPTT
Fibrinogen	g/L	1.22	0.976	1.46	HemosIL PT-Fibrinogen HS Plus
	mg/dL	122	97.6	146	
	g/L	1.28	0.948	1.61	HemosIL PT-Fibrinogen HS
	mg/dL	128	94.8	161	
	g/L	1.26	1.01	1.51	Stago Fibrinogen
	mg/dL	126	101	151	
	g/L	1.16	0.878	1.44	Dade Multifibrin
	mg/dL	116	87.8	144	
	g/L	1.20	0.960	1.44	HemosIL Fibrinogen C
	mg/dL	120	96.0	144	
	g/L	1.17	0.936	1.40	Dade Thrombin
	mg/dL	117	93.6	140	
	g/L	1.19	0.952	1.43	Trinity/Biopool Fibrinogen
	mg/dL	119	95.2	143	
	g/L	1.19	0.952	1.43	Biolabo Bio-Fibri
	mg/dL	119	95.2	143	
	g/L	1.16	0.928	1.39	Teco Teclot Fibrinogen
	mg/dL	116	92.8	139	
	g/L	1.24	0.917	1.56	HemosIL QFA (bovine thrombin)
	mg/dL	124	91.7	156	
	g/L	1.29	1.03	1.55	Pacific Hemostasis Fibrinogen
	mg/dL	129	103	155	
	g/L	1.50	1.20	1.80	Human Fibrinogen
	mg/dL	150	120	180	
	g/L	1.25	1.00	1.50	Stago STA Fibrin-Prest Automate
	mg/dL	125	100	150	
	g/L	1.15	0.920	1.38	Bio-Ksel System PT
	mg/dL	115	92.0	138	
	g/L	1.10	0.835	1.37	Bio-Ksel Fibrinogen
	mg/dL	110	83.5	137	
	g/L	1.18	0.839	1.52	Diagon Dia-FIB
	mg/dL	118	83.9	152	
	g/L	0.982	0.786	1.18	Dade Innovin Derived Fibrinogen
	mg/dL	98.2	78.6	118	
	g/L	1.12	0.896	1.34	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	112	89.6	134	

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Fibrinogen	g/L	1.30	1.04	1.56	Wiener Lab Fibrinogen
	mg/dL	130	104	156	
	g/L	1.09	0.806	1.37	SGM Italia Fibrinogen
	mg/dL	109	80.6	137	
	g/L	1.50	1.20	1.80	Helena Thrombin
	mg/dL	150	120	180	
	g/L	1.42	1.14	1.70	Spinreact Fibrinogen
	mg/dL	142	114	170	
	g/L	1.07	0.791	1.35	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	107	79.1	135	
	g/L	1.27	1.01	1.53	Sclavo Fibrinogen
	mg/dL	127	101	153	
	g/L	1.12	0.896	1.34	HemoDiagnostica Fibrinogen
	mg/dL	112	89.6	134	
	g/L	1.25	1.00	1.50	Beijing Steelex Fibrinogen
	mg/dL	125	100	150	
Plasminogen activity	g/L	1.28	1.02	1.54	Helena Clauss Fibrinogen 100
	mg/dL	128	102	154	
	g/L	1.38	1.10	1.66	Coaggpia Fibrinogen
Plasminogen activity	mg/dL	138	110	166	
	%	53.3	42.6	64.0	Stago Stachrom Plasminogen
	%	42.5	34.0	51.0	HemosIL Plasminogen
Protein C activity	%	51.5	39.8	63.2	Siemens/Dade Berichrom Plasminogen
	%	13.3	10.6	16.0	Siemens/Dade Berichrom Protein C
	%	11.1	8.88	13.3	Biomerieux VIDAS Protein C
	%	12.8	9.53	16.1	STACHrom Protein C
Protein S activity	%	11.5	9.20	13.8	Chromogenix Coatest APC
	%	12.5	8.75	16.3	STA Liatest
	%	11.1	7.77	14.4	IL HemosIL Free Protein S
Prothrombin Time (PT)	%	11.9	8.33	15.5	Siemens Innovance Free PS Ag
	Seconds	44.3	35.4	53.2	Trinity/Biomerieux Simplastin/PT HTF
	Seconds	37.3	29.8	44.8	Dade Innovin
	Seconds	47.4	37.9	56.9	Siemens/Dade Thromborel IS
	Seconds	49.3	39.4	59.2	Siemens/Dade Thromborel S
	Seconds	59.8	47.8	71.8	HemosIL PT-Fibrinogen HS Plus
	Seconds	59.6	47.7	71.5	STA Hepato Quick
	Seconds	55.7	44.6	66.8	Stago Neoplastine CI Plus
	Seconds	53.5	42.8	64.2	Teco TEClot PT-S
	Seconds	59.0	47.2	70.8	Biolabo Bio-TP
	Seconds	49.5	35.7	63.3	Stago SPA
	Seconds	62.1	49.7	74.5	Stago Neoplastin R
	Seconds	47.5	36.1	58.9	Bio-Ksel System PT
	Seconds	54.9	41.8	68.0	Human Thromboplastin
	Seconds	52.0	41.6	62.4	Diagon, Dia-PT
	Seconds	56.6	45.3	67.9	Weiner Lab Soluplastin
	Seconds	51.3	41.0	61.6	Spinreact PT

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Analyte	unit	Target	low	high	methods
Prothrombin Time (PT)	Seconds	60.6	48.5	72.7	Trinity/Biomerieux Simplastin/PT Excel S
	Seconds	50.0	36.8	63.2	Biodevice PT
	Seconds	45.6	36.5	54.7	Biomedica QuikCoag PT-HS
	Seconds	47.6	38.1	57.1	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	54.2	43.4	65.0	Helena Thromboplastin LI
	Seconds	56.3	45.0	67.6	Technoclone Technoplastin HIS
	Seconds	54.6	43.7	65.5	Helena Thromboplastin
	Seconds	54.9	43.9	65.9	SGM Italia Thromboplastin
	Seconds	48.2	38.6	57.8	Technoclone Technoclot PT Plus
	Seconds	53.7	43.0	64.4	Tokra Medikal PT
	Seconds	56.4	45.1	67.7	Coaggia PT-N
Prothrombin Time (PT) activity	%	9.63	6.92	12.3	Trinity/Biomerieux Simplastin/PT HTF
	%	16.2	13.0	19.4	Dade Innovin
	%	15.1	11.3	18.9	Siemens/Dade Thromborel S
	%	15.4	12.3	18.5	Stago Neoplastine CI
	%	12.8	10.2	15.4	Stago Neoplastine CI Plus
	%	15.1	12.1	18.1	HemosIL PT-Fibrinogen
	%	12.8	9.50	16.1	HemosIL PT-Fibrinogen HS Plus
	%	8.51	6.81	10.2	Pacific Thromboplastin DS
	%	10.8	8.64	13.0	R2 Phosphoplastin RL
	%	8.74	6.99	10.5	Stago SPA
	%	14.4	11.5	17.3	Stago Neoplastin R
	%	24.8	19.8	29.8	Bio-Ksel System PT
	%	16.5	12.6	20.4	Diagon, Dia-PT
	%	13.1	10.5	15.7	Trinity/Biomerieux Simplastin/PT Excel S
	%	15.2	12.1	18.3	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	15.4	12.3	18.5	Technoclone Technoclot PT Plus
	%	10.9	8.72	13.1	Coaggia PT-N
Prothrombin Time (PT) INR	INR	4.50	3.60	5.40	Trinity/Biomerieux Simplastin/PT HTF
	INR	3.31	2.65	3.97	Dade Innovin
	INR	3.74	2.99	4.49	Siemens/Dade Thromborel IS
	INR	4.25	3.40	5.10	Siemens/Dade Thromborel S
	INR	5.31	4.25	6.37	HemosIL PT-Fibrinogen HS Plus
	INR	8.74	6.99	10.5	Pacific Thromboplastin DS
	INR	6.87	5.50	8.24	STA Hepato Quick
	INR	6.48	5.18	7.78	Stago Neoplastine CI
	INR	6.45	5.16	7.74	Stago Neoplastine CI Plus
	INR	4.73	3.78	5.68	Human Thromboplastin
	INR	4.27	3.17	5.37	Teco TEClot PT-S
	INR	6.23	4.98	7.48	Biolabo Bio-TP
	INR	5.22	3.76	6.68	Stago SPA
	INR	4.25	3.40	5.10	Stago Neoplastin R
	INR	3.92	3.14	4.70	Bio-Ksel System PT
	INR	4.86	3.43	6.29	Diagon, Dia-PT
	INR	5.01	4.01	6.01	Futura System Thromboplastin S
	INR	3.86	3.09	4.63	Vital Diagnostics ElectaLab PT

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Prothrombin Time (PT) INR	INR	4.13	3.30	4.96	Gernon Hemoplastin PT
	INR	4.57	3.66	5.48	SGM Italia Thromboplastin
	INR	4.70	3.76	5.64	Biodevice PT
	INR	4.90	3.89	5.91	Biomedica QuikCoag PT-HS
	INR	4.16	3.33	4.99	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	5.05	4.04	6.06	Technoclone Technoplastin HIS
	INR	3.74	2.99	4.49	Labitec PT
	INR	3.71	2.97	4.45	Technoclone Technoclot PT Plus
	INR	4.64	3.71	5.57	Tokra Medikal PT
	INR	5.11	4.09	6.13	Coaggia PT-N
Prothrombin Time (PT) ratio	ratio	3.41	2.70	4.12	Dade Innovin
	ratio	4.30	3.44	5.16	Siemens/Dade Thromborel S
	ratio	4.28	3.42	5.14	Stago Neoplastine CI Plus
	ratio	4.53	3.62	5.44	Stago Neoplastin R
	ratio	3.94	2.89	4.99	Diagon, Dia-PT
	ratio	4.22	3.38	5.06	HemosIL PT-Fibrinogen HS Plus
	ratio	4.29	3.43	5.15	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	4.33	3.46	5.20	Technoclone Technoplastin HIS
Thrombin Time (TT)	Seconds	40.9	28.6	53.2	Dade Thrombin
	Seconds	23.1	18.5	27.7	Siemens/Dade Thromboclotin
	Seconds	33.6	26.9	40.3	HemosIL Thrombin Time
	Seconds	28.6	22.9	34.3	Stago Thrombin
	Seconds	35.8	28.6	43.0	Sysmex Thrombin Time
	Seconds	28.6	21.4	35.8	Human - Hemostat