

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat No. CG5023
Size: 12 x 1 ml

Lot No. 182CG
Expiry: 2018-03

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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COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 182CG Size: 12 x 1 ml Expiry: 2018-03

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	131	105	157	Tcoag TriniCLOT aPTT S
	seconds	138	110	166	Siemens/Dade Actin
	seconds	135	108	162	Siemens/Dade Actin FS
	seconds	97.7	78.2	117	Siemens/Dade Actin FSL
	seconds	139	111	167	Helena aPTT
	seconds	126	101	151	HemosIL APTT-SP Liquid
	seconds	138	110	166	HemosIL Synthasil
	seconds	101	80.8	121	Pacific Hemostasis APTT-XL
	seconds	136	109	163	Stago aPTT
	seconds	131	105	157	Stago Cephascreen
	seconds	136	109	163	Stago CK-Prest
	seconds	143	114	172	Stago PTT Automate
	seconds	148	118	178	Teco TEClot APTT
	seconds	142	114	170	Human Hemostat APTT
	seconds	120	96.0	144	Bio-Ksel System APTTs
	seconds	207	166	248	Grifols DG-APTT
	seconds	147	118	176	Diagon Dia-PTT
	seconds	121	96.8	145	Weiner Lab APTT
	seconds	151	121	181	Biolabo Bio-CK APTT
	seconds	132	106	158	Spinreact APTT
	seconds	53.3	42.6	64.0	Gernon Hemos PTT
	seconds	92.6	74.1	111	Technology-Standard aPTT
	seconds	164	131	197	Tcoag TriniCLOT Automated aPTT
	seconds	87.6	70.1	105	Biomedica QuikCoag aPTT
	seconds	150	120	180	Siemens Dade Actin Cephaloplastin
	seconds	128	102	154	Technoclone Siron aPTT
	seconds	154	123	185	Sclavo APTT-S
	seconds	92.9	74.3	111	Cypress Diagnostics aPTT
	seconds	86.5	69.2	104	Coagpia APTT-N
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	3.61	2.89	4.33	Siemens/Dade Actin FSL
	ratio	4.38	3.50	5.26	Stago Cephascreen
	ratio	4.07	3.26	4.88	Stago PTT Automate
	ratio	4.38	3.50	5.26	Stago aPTT
	ratio	4.12	3.30	4.94	HemosIL APTT-SP Liquid
	ratio	4.58	3.66	5.50	HemosIL Synthasil
	ratio	3.54	2.83	4.25	Pacific Hemostasis APTT-XL
	ratio	4.26	3.41	5.11	Stago CK-Prest
	ratio	3.76	3.01	4.51	Human Hemostat APTT
	ratio	3.90	3.12	4.68	Bio-Ksel System APTTs
	ratio	5.26	4.21	6.31	Siemens/Dade Actin FS
	ratio	4.58	3.66	5.50	Diagon Dia-PTT
	ratio	4.93	3.94	5.92	Siemens/Dade Actin

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COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 182CG

Size: 12 x 1 ml Expiry: 2018-03

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	4.74	3.79	5.69	Siemens Dade Actin Cephaloplastin
	ratio	5.10	4.08	6.12	Sclavo APTT-S
	ratio	2.70	2.16	3.24	Coaggia APTT-N
Antithrombin III activity	%	45.1	36.1	54.1	Siemens/Dade Berichrom ATIII
	%	43.1	34.5	51.7	Helena Chrom-Z
	%	42.1	33.7	50.5	HemosIL Liquid Antithrombin
	%	46.2	37.0	55.4	Roche Chronogenic Thrombin
	%	39.0	31.2	46.8	Hemosil Lyophilised Antithrombin III
	%	47.7	38.2	57.2	STACHrom ATIII
	%	46.7	37.4	56.0	Siemens/Dade Antithrombin III
	%	44.6	35.7	53.5	Siemens Innovance Antithrombin III
	%	45.5	36.4	54.6	Sclavo ATIII
Factor II activity	%	9.84	7.87	11.8	Dade Innovin
	%	10.3	8.24	12.4	Siemens/Dade Thromborel S
	%	9.75	7.80	11.7	Stago Neoplastine CI Plus
	%	10.0	8.00	12.0	Stago Neoplastine CI
	%	9.17	7.34	11.0	HemosIL PT-Fibrinogen HS Plus
	%	7.70	6.16	9.24	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	9.20	7.36	11.0	Stago Neoplastin R
Factor IX activity	%	9.00	7.20	10.8	Stago PTT Automate
	%	9.54	7.63	11.4	Siemens/Dade Actin FS
	%	13.0	10.4	15.6	Siemens/Dade Pathromtin SL
	%	8.39	6.71	10.1	HemosIL Synthasil
	%	10.7	8.56	12.8	Stago CK-Prest
	%	9.68	7.74	11.6	HemosIL APTT-SP Liquid
	%	12.3	9.84	14.8	Stago aPTT
	%	6.10	4.88	7.32	HemosIL Factor IX deficient plasma
Factor V activity	%	24.8	19.8	29.8	Stago Neoplastine CI Plus
	%	26.1	20.9	31.3	Siemens/Dade Thromborel S
	%	23.0	18.4	27.6	Dade Innovin
	%	26.3	21.0	31.6	HemosIL PT-Fibrinogen HS Plus
	%	22.7	18.2	27.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	22.2	17.8	26.6	Stago Neoplastin R
	%	26.2	21.0	31.4	HemosIL Factor V deficient plasma
Factor VII activity	%	11.7	9.36	14.0	Stago Neoplastine CI Plus
	%	11.3	9.04	13.6	Siemens/Dade Thromborel S
	%	13.9	11.1	16.7	Dade Innovin
	%	13.2	10.6	15.8	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	11.7	9.36	14.0	Stago Neoplastin R
Factor VIII activity	%	26.0	20.8	31.2	Stago CK-Prest
	%	25.1	20.1	30.1	Siemens/Dade Actin FS
	%	25.7	20.6	30.8	Siemens/Dade Pathromtin SL
	%	26.2	21.0	31.4	Siemens/Dade Actin FSL
	%	23.1	18.5	27.7	HemosIL Synthasil
	%	27.7	22.2	33.2	HemosIL APTT-SP Liquid
	%	27.7	22.2	33.2	Stago aPTT

%

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 182CG Size: 12 x 1 ml Expiry: 2018-03

Range					
Analyte	unit	Target	low	high	methods
Factor X activity	%	10.6	8.48	12.7	Siemens/Dade Thromborel S
	%	10.6	8.48	12.7	Dade Innovin
	%	10.4	8.32	12.5	HemosIL PT-Fibrinogen HS Plus
	%	9.00	7.20	10.8	Stago Neoplastine CI Plus
	%	8.87	7.10	10.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	9.60	7.68	11.5	Stago Neoplastin R
Factor XI activity	%	22.8	18.2	27.4	Siemens/Dade Actin FSL
	%	25.4	20.3	30.5	Stago aPTT
Factor XII activity	%	38.0	30.4	45.6	Siemens/Dade Actin FS
	%	35.1	28.1	42.1	Siemens/Dade Pathromtin SL
	%	34.3	27.4	41.2	HemosIL Synthasil
	%	41.8	33.4	50.2	Siemens/Dade Actin FSL
	%	37.6	30.1	45.1	HemosIL APTT-SP Liquid
	%	43.0	34.4	51.6	Stago CK-Prest
Fibrinogen	g/L	1.33	1.06	1.60	HemosIL PT-Fibrinogen HS Plus
	mg/dL	133	106	160	
	g/L	1.28	1.02	1.54	Stago Fibrinogen
	mg/dL	128	102	154	
	g/L	1.23	0.984	1.48	Tcoag TriniCLOT Thrombin Time
	mg/dL	123	98.4	148	
	g/L	1.19	0.952	1.43	Dade Multifibrin
	mg/dL	119	95.2	143	
	g/L	1.31	1.05	1.57	HemosIL Fibrinogen C
	mg/dL	131	105	157	
	g/L	1.18	0.944	1.42	Dade Thrombin
	mg/dL	118	94.4	142	
	g/L	1.08	0.864	1.30	Technoclone Fibrinogen
	mg/dL	108	86.4	130	
	g/L	1.31	1.05	1.57	Tcoag TriniCLOT Fibrinogen
	mg/dL	131	105	157	
	g/L	1.24	0.992	1.49	Biolabo Bio-Fibri
	mg/dL	124	99.2	149	
	g/L	1.24	0.992	1.49	Teco Teclot Fibrinogen
	mg/dL	124	99.2	149	
	g/L	1.28	1.02	1.54	HemosIL QFA (bovine thrombin)
	mg/dL	128	102	154	
	g/L	1.52	1.22	1.82	Pacific Hemostasis Fibrinogen
	mg/dL	152	122	182	
	g/L	1.19	0.952	1.43	Human Fibrinogen
	mg/dL	119	95.2	143	
	g/L	1.31	1.05	1.57	Stago STA Fibri-Prest Automate
	mg/dL	131	105	157	
	g/L	1.34	1.07	1.61	Bio-Ksel System PT
	mg/dL	134	107	161	
	g/L	1.24	0.992	1.49	Bio-Ksel Fibrinogen
	mg/dL	124	99.2	149	

%

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Range					
Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	1.26	1.01	1.51	Grifols DG-FIB
	mg/dL	126	101	151	
	g/L	1.15	0.920	1.38	Diagon Dia-FIB
	mg/dL	115	92.0	138	
	g/L	1.10	0.880	1.32	Dade Innovin Derived Fibrinogen
	mg/dL	110	88.0	132	
	g/L	1.21	0.968	1.45	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	121	96.8	145	
	g/L	1.52	1.22	1.82	Liofilchem Fibrinogen
	mg/dL	152	122	182	
	g/L	1.36	1.09	1.63	Biodevice PT
	mg/dL	136	109	163	
	g/L	1.29	1.03	1.55	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	129	103	155	
	g/L	1.36	1.09	1.63	Sclavo Fibrinogen
	mg/dL	136	109	163	
	g/L	1.24	0.992	1.49	Beijing Steelex Fibrinogen
	mg/dL	124	99.2	149	
Plasminogen activity	g/L	1.05	0.840	1.26	Cypress Diagnostics Fibrinogen
	mg/dL	105	84.0	126	
	g/L	1.29	1.03	1.55	Helena Clauss Fibrinogen 100
Protein C activity	mg/dL	129	103	155	
	g/L	1.33	1.06	1.60	Coagpia Fibrinogen
	mg/dL	133	106	160	
Protein S activity	%	52.0	41.6	62.4	Stago Stachrom Plasminogen
	%	47.6	38.1	57.1	HemosIL Plasminogen
	%	56.6	45.3	67.9	Siemens/Dade Berichrom Plasminogen
	%	13.9	11.1	16.7	Siemens/Dade Berichrom Protein C
Prothrombin Time (PT)	%	11.0	8.80	13.2	Biomerieux VIDAS Protein C
	%	9.67	7.74	11.6	IL HemosIL Protein C
	%	14.7	11.8	17.6	STACHrom Protein C
	%	13.2	9.24	17.2	STA Liatest
	%	8.00	5.60	10.4	IL HemosIL ProS
Prothrombin Time (PT)	%	9.35	6.55	12.2	IL HemosIL Free Protein S
	%	11.7	8.19	15.2	Stago Asserachrom Free Protein S
	%	11.8	8.26	15.3	Siemens Innovance Free PS Ag
	Seconds	33.9	27.1	40.7	Tcoag TriniCLOT PT Excel
	Seconds	48.9	39.1	58.7	Tcoag TriniCLOT PT HTF
	Seconds	35.4	28.3	42.5	Dade Innovin
	Seconds	51.9	41.5	62.3	Siemens/Dade Thromborel S
	Seconds	59.9	47.9	71.9	HemosIL PT-Fibrinogen HS Plus
	Seconds	53.0	42.4	63.6	STA Hepato Quick
	Seconds	45.1	36.1	54.1	Stago Neoplastine CI
Prothrombin Time (PT)	Seconds	54.3	43.4	65.2	Stago Neoplastine CI Plus
	Seconds	53.4	42.7	64.1	Biolabo Bio-TP
	Seconds	52.9	42.3	63.5	Stago SPA

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT)	Seconds	59.3	47.4	71.2	Stago Neoplastin R
	Seconds	41.2	33.0	49.4	Bio-Ksel System PT
	Seconds	53.3	42.6	64.0	Human Thromboplastin
	Seconds	53.9	43.1	64.7	Grifols DG-PT
	Seconds	48.3	38.6	58.0	Diagon, Dia-PT
	Seconds	53.5	42.8	64.2	Weiner Lab Soluplastin
	Seconds	62.3	49.8	74.8	Spinreact PT
	Seconds	66.0	52.8	79.2	TCoag TriniCLOT PT Excel S
	Seconds	49.2	39.4	59.0	Biodevice PT
	Seconds	48.3	38.6	58.0	Biomedica QuikCoag PT-HS
	Seconds	45.4	36.3	54.5	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	58.9	47.1	70.7	Helena Thromboplastin LI
	Seconds	52.3	41.8	62.8	Helena Thromboplastin
	Seconds	55.8	44.6	67.0	Labitec PT
	Seconds	43.1	34.5	51.7	Cypress Diagnostics PT
	Seconds	42.5	34.0	51.0	Technoclone Technoclot PT Plus
	Seconds	57.4	45.9	68.9	Coagpia PT-N
	Seconds	42.2	33.8	50.6	Bio-Ksel PT Plus
	Seconds	42.1	33.7	50.5	Beijing Succeeder PT
Prothrombin Time (PT) activity	%	15.1	12.1	18.1	Tcoag TriniCLOT PT Excel
	%	11.3	9.04	13.6	Tcoag TriniCLOT PT HTF
	%	18.0	14.4	21.6	Dade Innovin
	%	14.7	11.8	17.6	Siemens/Dade Thromborel S
	%	16.2	13.0	19.4	Stago Neoplastine CI
	%	13.3	10.6	16.0	Stago Neoplastine CI Plus
	%	13.6	10.9	16.3	HemosIL PT-Fibrinogen
	%	13.0	10.4	15.6	HemosIL PT-Fibrinogen HS Plus
	%	13.5	10.8	16.2	Biolabo Bio-TP
	%	9.67	7.74	11.6	Stago SPA
	%	15.1	12.1	18.1	Stago Neoplastin R
	%	24.8	19.8	29.8	Bio-Ksel System PT
	%	13.3	10.6	16.0	Human Thromboplastin
	%	18.0	14.4	21.6	Biomedica QuikCoag PT-HS
	%	16.0	12.8	19.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	29.2	23.4	35.0	Technoclone Technoclot PT Plus
	%	10.6	8.48	12.7	Coagpia PT-N
	%	24.5	19.6	29.4	Bio-Ksel PT Plus
Prothrombin Time (PT) INR	INR	8.17	6.54	9.80	Tcoag TriniCLOT PT Excel
	INR	4.19	3.35	5.03	Tcoag TriniCLOT PT HTF
	INR	3.24	2.59	3.89	Dade Innovin
	INR	4.80	3.84	5.76	Siemens/Dade Thromborel IS
	INR	4.52	3.62	5.42	Siemens/Dade Thromborel S
	INR	4.02	3.22	4.82	HemosIL PT-Fibrinogen
	INR	5.40	4.32	6.48	HemosIL PT-Fibrinogen HS Plus
	INR	6.19	4.95	7.43	STA Hepato Quick
	INR	5.80	4.64	6.96	Stago Neoplastine CI

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Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) INR	INR	6.08	4.86	7.30	Stago Neoplastine CI Plus
	INR	4.74	3.79	5.69	Human Thromboplastin
	INR	4.36	3.49	5.23	Teco TEClot PT-S
	INR	6.14	4.91	7.37	Biolabo Bio-TP
	INR	4.89	3.91	5.87	Stago SPA
	INR	3.99	3.19	4.79	Stago Neoplastin R
	INR	3.76	3.01	4.51	Bio-Ksel System PT
	INR	4.97	3.98	5.96	Grifols DG-PT
	INR	4.91	3.93	5.89	Diagon, Dia-PT
	INR	4.26	3.41	5.11	Futura System Thromboplastin S
	INR	4.24	3.39	5.09	SGM Italia Thromboplastin
	INR	6.61	5.29	7.93	TCoag TriniCLOT PT Excel S
	INR	4.37	3.50	5.24	Biomedica QuikCoag PT-HS
	INR	4.07	3.26	4.88	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	4.56	3.65	5.47	Helena Thromboplastin LI
	INR	3.29	2.63	3.95	Technoclone Technoclot PT Plus
	INR	4.60	3.68	5.52	Coagpia PT-N
	INR	3.97	3.18	4.76	Bio-Ksel PT Plus
	INR	3.63	2.90	4.36	Beijing Succeder PT
Prothrombin Time (PT) ratio	ratio	3.37	2.70	4.04	Dade Innovin
	ratio	4.45	3.56	5.34	Siemens/Dade Thromborel S
	ratio	4.37	3.50	5.24	Stago Neoplastine CI Plus
	ratio	4.41	3.53	5.29	Stago Neoplastin R
	ratio	3.66	2.93	4.39	Diagon, Dia-PT
	ratio	4.46	3.57	5.35	HemosIL PT-Fibrinogen HS Plus
	ratio	3.96	3.17	4.75	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	5.09	4.07	6.11	Biodevice PT
Thrombin Time (TT)	Seconds	35.8	28.6	43.0	Siemens/Dade Thromboclotin
	Seconds	24.5	19.6	29.4	Technology-Standard Thrombin
	Seconds	39.9	31.9	47.9	Technoclone Thrombin Reagent
	Seconds	44.6	35.7	53.5	HemosIL Thrombin Time 8ml