

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 **Lot No.** 160CG
Size: 12 x 1ml **Expiry:** 2016-07

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 1ml 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 1ml

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	107	85.6	128	Trinity/Biomerieux Platelin LS/APTT HS
	seconds	127	102	152	Siemens/Dade Actin
	seconds	142	100	184	Siemens/Dade Actin FS
	seconds	88.1	68.3	108	Siemens/Dade Actin FSL
	seconds	90.6	70.2	111	HemosIL APTT-SP Liquid
	seconds	104	83.2	125	HemosIL Synthasil
	seconds	89.1	66.1	112	Pacific Hemostasis APTT-XL
	seconds	105	79.8	130	Stago aPTT
	seconds	101	80.8	121	Stago Cephascreen
	seconds	102	81.6	122	Stago CK-Prest
	seconds	112	89.6	134	Stago PTT Automate
	seconds	116	92.8	139	Human Hemostat APTT
	seconds	101	80.0	122	Bio-Ksel System APTTs
	seconds	95.4	76.3	114	Biolabo Bio-CK APTT
	seconds	94.7	75.8	114	Gernon Hemos PTT
	seconds	79.6	63.7	95.5	Technology-Standard aPTT
	seconds	160	128	192	SGM Italia aPTT
	seconds	110	82.7	137	Trinity/Biomerieux Triniclot aPTT
	seconds	91.7	73.4	110	Biomedica QuikCoag aPTT
	seconds	134	95.9	172	Siemens Dade Actin Cephaloplastin
	seconds	87.3	69.8	105	Technoclone Siron aPTT
	seconds	162	120	204	Sclavo APTT-S
	seconds	136	104	168	HemoDiagnostics aPTT
	seconds	124	95.6	152	Tokra Medikal APTT
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	3.49	2.61	4.37	Siemens/Dade Actin FSL
	ratio	3.39	2.71	4.07	Stago Cephascreen
	ratio	3.25	2.60	3.90	Stago PTT Automate
	ratio	3.23	2.58	3.88	Stago aPTT
	ratio	7.09	5.67	8.51	Siemens/Dade Pathromtin SL
	ratio	3.00	2.40	3.60	HemosIL APTT-SP Liquid
	ratio	3.43	2.67	4.19	HemosIL Synthasil
	ratio	3.22	2.58	3.86	Stago CK-Prest
	ratio	3.37	2.70	4.04	Human Hemostat APTT
	ratio	3.02	2.42	3.62	Bio-Ksel System APTTs
	ratio	5.48	4.22	6.74	Siemens/Dade Actin FS
	ratio	2.91	2.33	3.49	Biolabo Bio-CK APTT
	ratio	5.13	4.10	6.16	Siemens/Dade Actin
	ratio	5.24	4.19	6.29	Siemens Dade Actin Cephaloplastin
	ratio	3.26	2.61	3.91	Biodevice aPTT
	ratio	5.56	4.45	6.67	Sclavo APTT-S
Antithrombin III activity	%	93.2	74.6	112	Siemens/Dade Berichrom ATIII
	%	115	92.0	138	Helena Chrom-Z

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Analyte	unit	target	low	high	methods
Antithrombin III activity	%	100	80.0	120	HemosIL Liquid Antithrombin
	%	103	78.1	128	Hyphen BioMed BioPhen ATIII
	%	96.9	77.5	116	Roche Chronogenic Thrombin
	%	98.3	78.6	118	Hemosil Lyophilised Antithrombin III
	%	97.5	78.0	117	STACHrom ATIII
	%	95.0	76.0	114	Siemens/Dade Antithrombin III
	%	94.3	75.4	113	Biodevice ATIII
	%	91.9	73.5	110	Siemens Innovance Antithrombin III
	%	99.0	79.2	119	Sclavo ATIII
Factor II activity	%	7.04	5.43	8.65	Siemens/Dade Thromborel S
	%	6.59	5.27	7.91	HemosIL RecombiPlasTin
	%	6.34	5.07	7.61	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	7.37	5.90	8.84	Siemens/Dade Actin FS
	%	7.32	5.86	8.78	HemosIL Synthasil
	%	6.67	5.34	8.00	Stago CK-Prest
	%	8.33	6.66	10.0	Stago aPTT
Factor V activity	%	68.2	53.4	83.0	Siemens/Dade Thromborel S
	%	56.8	40.9	72.7	Dade Innovin
	%	57.0	45.6	68.4	HemosIL RecombiPlasTin
	%	53.0	41.9	64.1	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	69.8	55.8	83.8	Stago Neoplastin R
Factor VII activity	%	8.00	6.37	9.63	Stago Neoplastine CI Plus
	%	9.56	7.65	11.5	Siemens/Dade Thromborel S
	%	7.98	5.62	10.3	Dade Innovin
	%	8.39	6.71	10.1	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	7.90	6.32	9.48	Stago Neoplastin R
Factor VIII activity	%	43.3	34.6	52.0	Stago PTT Automate
	%	38.5	30.8	46.2	Siemens/Dade Actin FS
	%	44.1	33.8	54.4	Siemens/Dade Pathromtin SL
	%	41.1	32.9	49.3	Siemens/Dade Actin FSL
	%	40.9	32.7	49.1	HemosIL Synthasil
	%	47.2	37.8	56.6	HemosIL APTT-SP Liquid
	%	45.8	36.6	55.0	Stago aPTT
Factor X activity	%	6.58	5.15	8.01	Dade Innovin
	%	6.63	5.29	7.97	HemosIL RecombiPlasTin
	%	6.67	5.34	8.00	Stago Neoplastine CI Plus
	%	6.55	5.24	7.86	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	8.00	6.40	9.60	Stago Neoplastin R
Factor XI activity	%	11.6	9.28	13.9	Stago PTT Automate
	%	8.07	6.26	9.88	HemosIL Synthasil
	%	12.0	9.60	14.4	Stago aPTT
Factor XII activity	%	58.3	46.6	70.0	Siemens/Dade Pathromtin SL
	%	67.6	54.1	81.1	Siemens/Dade Actin FSL
	%	66.6	53.3	79.9	HemosIL APTT-SP Liquid
Fibrinogen	g/L	3.74	2.78	4.70	HemosIL PT-Fibrinogen HS Plus
	mg/dL	374	278	470	

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Analyte	unit	target	low	high	methods
Fibrinogen	g/L	2.86	2.11	3.61	Helena Fibrinogen
	mg/dL	286	211	361	
	g/L	3.01	2.41	3.61	Stago Fibrinogen
	mg/dL	301	241	361	
	g/L	3.25	2.59	3.91	Dade Multifibrin
	mg/dL	325	259	391	
	g/L	2.82	2.26	3.38	HemosIL Fibrinogen C
	mg/dL	282	226	338	
	g/L	2.75	2.20	3.30	Dade Thrombin
	mg/dL	275	220	330	
	g/L	2.60	1.88	3.32	Technoclone Fibrinogen
	mg/dL	260	188	332	
	g/L	2.88	2.30	3.46	Trinity/Biopool Fibrinogen
	mg/dL	288	230	346	
	g/L	2.85	2.28	3.42	Biolabo Bio-Fibri
	mg/dL	285	228	342	
	g/L	2.71	2.17	3.25	Teco Teclot Fibrinogen
	mg/dL	271	217	325	
	g/L	2.70	2.16	3.24	HemosIL QFA (bovine thrombin)
	mg/dL	270	216	324	
	g/L	2.66	2.13	3.19	Human Fibrinogen
	mg/dL	266	213	319	
	g/L	3.03	2.42	3.64	Stago STA Fibri-Prest Automate
	mg/dL	303	242	364	
	g/L	3.82	3.06	4.58	Bio-Ksel System PT
	mg/dL	382	306	458	
	g/L	2.75	2.20	3.30	Bio-Ksel Fibrinogen
	mg/dL	275	220	330	
	g/L	2.67	2.14	3.20	Grifols DG-FIB
	mg/dL	267	214	320	
	g/L	2.77	2.22	3.32	Diagon Dia-FIB
	mg/dL	277	222	332	
	g/L	4.13	3.30	4.96	Dade Innovin Derived Fibrinogen
	mg/dL	413	330	496	
	g/L	2.84	2.27	3.41	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	284	227	341	
	g/L	2.53	2.02	3.04	Gernon Hemofibrin
	mg/dL	253	202	304	
	g/L	2.84	2.08	3.60	Technology-Standard Fibrinogen
	mg/dL	284	208	360	
	g/L	2.85	2.23	3.47	SGM Italia Fibrinogen
	mg/dL	285	223	347	
	g/L	2.79	2.23	3.35	Renam Fibrinogen
	mg/dL	279	223	335	
	g/L	3.06	2.37	3.75	Sclavo Fibrinogen
	mg/dL	306	237	375	

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Analyte	unit	target	low	high	methods
Fibrinogen	g/L	2.86	2.29	3.43	HemoDiagnostica Fibrinogen
	mg/dL	286	229	343	
	g/L	3.05	2.44	3.66	Beijing Steelex Fibrinogen
	mg/dL	305	244	366	
Plasminogen activity	%	85.5	68.4	103	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	13.9	10.7	17.1	Siemens/Dade Berichrom Protein C
	%	14.8	11.2	18.4	STACHrom Protein C
Protein S activity	%	5.67	3.97	7.37	IL HemosIL Free Protein S
Prothrombin Time (PT)	Seconds	43.4	34.7	52.1	Trinity/Biomerieux Simplastin/PT HTF
	Seconds	41.0	32.8	49.2	Dade Innovin
	Seconds	55.0	44.0	66.0	Siemens/Dade Thromborel S
	Seconds	61.9	49.5	74.3	HemosIL PT-Fibrinogen HS
	Seconds	61.4	49.1	73.7	HemosIL PT-Fibrinogen HS Plus
	Seconds	48.9	39.1	58.7	HemosIL RecombiPlasTin
	Seconds	54.7	43.8	65.6	STA Hepato Quick
	Seconds	41.2	33.0	49.4	Stago Neoplastine CI
	Seconds	54.4	43.5	65.3	Stago Neoplastine CI Plus
	Seconds	54.5	43.2	65.8	Teco TEClot PT-S
	Seconds	63.0	50.4	75.6	Stago Neoplastin R
	Seconds	47.8	38.2	57.4	Bio-Ksel System PT
	Seconds	59.0	47.2	70.8	Human Thromboplastin
	Seconds	52.5	42.0	63.0	Diagon, Dia-PT
	Seconds	53.5	42.8	64.2	Weiner Lab Soluplastin
	Seconds	61.0	48.8	73.2	Trinity/Biomerieux Simplastin/PT Excel S
	Seconds	48.1	38.5	57.7	Biodevice PT
	Seconds	50.3	38.8	61.8	Biomedica QuikCoag PT-HS
	Seconds	48.9	39.1	58.7	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	53.5	42.8	64.2	Helena Thromboplastin LI
	Seconds	48.7	39.0	58.4	SGM Italia Thromboplastin
	Seconds	43.3	34.6	52.0	Technoclone Technoclot PT Plus
	Seconds	45.1	34.5	55.7	Tokra Medikal PT
Prothrombin Time (PT) activity	%	12.8	10.2	15.4	Trinity/Biomerieux Simplastin/PT HTF
	%	15.1	11.1	19.1	Dade Innovin
	%	13.5	10.8	16.2	Siemens/Dade Thromborel S
	%	15.8	12.6	19.0	Stago Neoplastine CI
	%	12.7	10.2	15.2	Stago Neoplastine CI Plus
	%	14.4	10.8	18.0	HemosIL PT-Fibrinogen
	%	12.7	9.33	16.1	HemosIL PT-Fibrinogen HS Plus
	%	25.1	20.0	30.2	HemosIL PT-Fibrinogen Recombinant
	%	14.8	11.5	18.1	HemosIL RecombiPlasTin
	%	9.78	7.82	11.7	Pacific Thromboplastin DS
	%	18.9	15.1	22.7	R2 Phosphoplastin RL
	%	5.73	4.58	6.88	Stago SPA
	%	13.9	11.0	16.8	Stago Neoplastin R
	%	31.6	25.3	37.9	Bio-Ksel System PT
	%	14.9	11.2	18.6	Diagon, Dia-PT

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Analyte	unit	target	low	high	methods
Prothrombin Time (PT) activity	%	13.2	10.6	15.8	Trinity/Biomerieux Simplastin/PT Excel S
	%	15.2	11.5	18.9	Biodevice PT
	%	14.5	11.6	17.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	20.8	16.6	25.0	Technoclone Technoclot PT Plus
Prothrombin Time (PT) INR	INR	4.71	3.42	6.00	Trinity/Biomerieux Simplastin/PT HTF
	INR	3.64	2.91	4.37	Dade Innovin
	INR	4.68	3.74	5.62	Siemens/Dade Thromborel S
	INR	5.83	4.66	7.00	HemosIL PT-Fibrinogen HS
	INR	5.30	4.13	6.47	HemosIL PT-Fibrinogen HS Plus
	INR	3.77	3.02	4.52	HemosIL PT-Fibrinogen Recombinant
	INR	4.30	3.44	5.16	HemosIL RecombiPlasTin
	INR	5.84	4.67	7.01	STA Hepato Quick
	INR	6.30	4.85	7.75	Stago Neoplastine CI
	INR	6.42	5.14	7.70	Stago Neoplastine CI Plus
	INR	3.14	2.51	3.77	R2 Phosphoplastin RL
	INR	5.22	4.18	6.26	Human Thromboplastin
	INR	6.78	4.84	8.72	Biolabo Bio-TP
	INR	6.91	5.53	8.29	Stago SPA
	INR	4.39	3.51	5.27	Stago Neoplastin R
	INR	3.17	2.54	3.80	Bio-Ksel System PT
	INR	4.88	3.67	6.09	Diagon, Dia-PT
	INR	5.16	4.13	6.19	Futura System Thromboplastin S
	INR	4.65	3.72	5.58	SGM Italia Thromboplastin
	INR	5.02	3.66	6.38	Trinity/Biomerieux Simplastin/PT Excel S
	INR	4.03	2.90	5.16	Biodevice PT
	INR	4.78	3.82	5.74	Biomedica QuikCoag PT-HS
	INR	4.30	3.44	5.16	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	5.81	4.65	6.97	Technoclone Technoplastin HIS
	INR	3.63	2.90	4.36	Technoclone Technoclot PT Plus
Prothrombin Time (PT) ratio	ratio	3.95	3.16	4.74	Dade Innovin
	ratio	4.69	3.75	5.63	Siemens/Dade Thromborel S
	ratio	2.83	2.26	3.40	Stago Neoplastine CI
	ratio	4.19	3.35	5.03	Stago Neoplastine CI Plus
	ratio	4.53	3.62	5.44	HemosIL PT-Fibrinogen
	ratio	4.42	3.54	5.30	HemosIL RecombiPlasTin
	ratio	3.54	2.56	4.52	Diagon, Dia-PT
	ratio	2.68	2.14	3.22	Gernon Hemoplastin PT
	ratio	4.58	3.66	5.50	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	ratio	4.01	2.99	5.03	Biodevice PT
	Seconds	21.0	16.8	25.2	Dade Thrombin
	Seconds	16.3	13.0	19.6	Siemens/Dade Thromboclotin
	Seconds	22.3	17.8	26.8	HemosIL Thrombin Time
	Seconds	19.0	15.2	22.8	Stago Thrombin
	Seconds	22.0	17.6	26.4	Bio-Ksel System TT
	Seconds	15.4	12.3	18.5	Technology-Standard Thrombin