

COAGULATION CONTROL – LEVEL 2 (COAG CONTROL 2)

Cat No: CG 5022 **Lot No:** 158CG
Size: 12 x 1 ml **Expiry:** 2016-06

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 2 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 and 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. CG 5022 Lot No. 158CG Size: 12 x 1 ml Expiry: 2016-06

Range					
Analyte	unit	target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	57.6	46.1	69.1	Trinity/Biomerieux Platelin LS/APTT HS
	seconds	69.2	55.4	83.0	Siemens/Dade Actin
	seconds	75.8	60.6	91.0	Siemens/Dade Actin FS
	seconds	52.4	41.9	62.9	Siemens/Dade Actin FSL
	seconds	110	88.0	132	Siemens/Dade Actin SL
	seconds	108	86.4	130	Siemens/Dade Pathromtin SL
	seconds	70.4	56.3	84.5	Helena aPTT
	seconds	52.6	42.1	63.1	HemosIL APTT-SP Liquid
	seconds	61.0	48.8	73.2	HemosIL Synthasil
	seconds	51.6	41.3	61.9	HemosIL Synthafax
	seconds	61.3	46.0	76.6	Pacific Hemostasis APTT-XL
	seconds	64.3	51.4	77.2	Stago aPTT
	seconds	62.2	49.8	74.6	Stago Cephascreen
	seconds	62.3	49.8	74.8	Stago CK-Prest
	seconds	66.4	53.1	79.7	Stago PTT Automate
	seconds	82.5	66.0	99.0	Teco TEClot APTT
	seconds	66.7	53.4	80.0	Trinity/Biopool aPTT-P
	seconds	59.4	47.5	71.3	Bio-Ksel System APTTs
	seconds	74.7	59.8	89.6	Diagon Dia-PTT
	seconds	52.6	42.1	63.1	Weiner Lab APTT
	seconds	53.0	42.4	63.6	Futura System APTT
	seconds	60.8	48.6	73.0	Biolabo Bio-CK APTT
	seconds	53.4	42.7	64.1	Gernon Hemos PTT
	seconds	77.0	61.6	92.4	Technology-Standard aPTT
	seconds	85.8	68.6	103	SGM Italia aPTT
	seconds	46.1	36.9	55.3	Pokler Italia aPTT
	seconds	66.4	53.1	79.7	Trinity/Biomerieux Triniclot aPTT
	seconds	63.6	50.9	76.3	Biodevice aPTT
	seconds	66.4	53.1	79.7	Siemens Dade Actin Cephaloplastin
	seconds	67.2	53.8	80.6	Technoclone Siron aPTT
	seconds	74.4	59.5	89.3	Sclavo APTT-S
	seconds	85.7	68.6	103	HemoDiagnostics aPTT
	seconds	65.9	52.7	79.1	Tokra Medikal APTT
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.04	1.63	2.45	Siemens/Dade Actin FSL
	ratio	3.58	2.86	4.30	Siemens/Dade Actin SL
	ratio	2.09	1.67	2.51	Stago Cephascreen
	ratio	1.93	1.54	2.32	Stago PTT Automate
	ratio	2.03	1.62	2.44	Stago aPTT
	ratio	3.19	2.55	3.83	Siemens/Dade Pathromtin SL
	ratio	1.74	1.39	2.09	HemosIL APTT-SP Liquid
	ratio	2.03	1.62	2.44	HemosIL Synthasil
	ratio	1.94	1.55	2.33	Stago CK-Prest

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG 5022 Lot No. 158CG Size: 12 x 1 ml Expiry: 2016-06

Range					
Analyte	unit	target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.91	2.33	3.49	Human Hemostat APTT
	ratio	1.79	1.43	2.15	Bio-Ksel System APTTs
	ratio	2.78	2.22	3.34	Siemens/Dade Actin FS
	ratio	2.92	2.34	3.50	Siemens/Dade Actin
	ratio	2.42	1.94	2.90	Trinity/Biomerieux Triniclot aPTT
	ratio	2.85	2.28	3.42	Siemens Dade Actin Cephaloplastin
	ratio	2.35	1.88	2.82	Sclavo APTT-S
Antithrombin III activity	%	95.8	76.6	115	Siemens/Dade Berichrom ATIII
	%	100	80.0	120	HemosIL Liquid Antithrombin
	%	101	80.8	121	Hyphen BioMed BioPhen ATIII
	%	95.4	76.3	114	Roche Chronogenic Thrombin
	%	100	80.0	120	Hemosil Lyophilised Antithrombin III
	%	99.0	79.2	119	STACHrom ATIII
	%	92.7	74.2	111	Siemens/Dade Antithrombin III
	%	91.3	73.0	110	Siemens Innovance Antithrombin III
	%	94.7	75.8	114	Sclavo ATIII
Factor II activity	%	15.3	12.2	18.4	Siemens/Dade Thromborel S
	%	13.8	11.0	16.6	HemosIL RecombiPlasTin
	%	15.0	12.0	18.0	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	17.4	13.9	20.9	Stago PTT Automate
	%	12.2	9.76	14.6	Siemens/Dade Actin FS
	%	15.5	12.4	18.6	HemosIL Synthasil
	%	13.6	10.9	16.3	Siemens/Dade Actin FSL
Factor V activity	%	59.7	47.8	71.6	Stago Neoplastine CI Plus
	%	62.2	49.8	74.6	Siemens/Dade Thromborel S
	%	56.2	45.0	67.4	Dade Innovin
	%	57.5	46.0	69.0	HemosIL RecombiPlasTin
	%	54.8	43.8	65.8	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	75.0	60.0	90.0	Stago Neoplastin R
Factor VII activity	%	19.0	15.2	22.8	Stago Neoplastine CI Plus
	%	19.4	15.5	23.3	Siemens/Dade Thromborel S
	%	18.8	15.0	22.6	Dade Innovin
	%	18.0	14.4	21.6	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VIII activity	%	46.6	37.3	55.9	Stago PTT Automate
	%	42.2	33.8	50.6	Siemens/Dade Actin FS
	%	40.0	32.0	48.0	Siemens/Dade Pathromtin SL
	%	37.7	30.2	45.2	Siemens/Dade Actin FSL
	%	41.6	33.3	49.9	HemosIL Synthasil
	%	50.6	40.5	60.7	HemosIL APTT-SP Liquid
	%	42.7	34.2	51.2	Stago aPTT
Factor X activity	%	15.1	12.1	18.1	Siemens/Dade Thromborel S
	%	15.3	12.2	18.4	Dade Innovin
	%	15.3	12.2	18.4	HemosIL RecombiPlasTin
	%	15.6	12.5	18.7	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	14.5	11.6	17.4	Stago Neoplastin R
Factor XI activity	%	48.3	41.9	54.7	Stago PTT Automate

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Analyte	unit	target	low	high	methods
Factor XI activity	%	41.4	33.1	49.7	Siemens/Dade Pathromtin SL
	%	32.2	25.8	38.6	Siemens/Dade Actin FSL
Factor XII activity	%	54.8	43.8	65.8	Siemens/Dade Pathromtin SL
	%	56.1	44.9	67.3	HemosIL Synthasil
	%	54.9	43.9	65.9	Siemens/Dade Actin FSL
Fibrinogen	g/L	3.00	2.40	3.60	HemosIL PT-Fibrinogen Recombinant
	mg/dL	300	240	360	
	g/L	3.40	2.72	4.08	HemosIL PT-Fibrinogen HS Plus
	mg/dL	340	272	408	
	g/L	2.80	2.24	3.36	Stago Fibrinogen
	mg/dL	280	224	336	
	g/L	2.75	2.20	3.30	Dade Multifibrin
	mg/dL	275	220	330	
	g/L	2.65	2.12	3.18	HemosIL Fibrinogen C
	mg/dL	265	212	318	
	g/L	2.47	1.98	2.96	Dade Thrombin
	mg/dL	247	198	296	
	g/L	2.76	2.21	3.31	Technoclone Fibrinogen
	mg/dL	276	221	331	
	g/L	2.62	2.10	3.14	Trinity/Biopool Fibrinogen
	mg/dL	262	210	314	
	g/L	2.79	2.23	3.35	Biolabo Bio-Fibri
	mg/dL	279	223	335	
	g/L	2.88	2.30	3.46	Teco Teclot Fibrinogen
	mg/dL	288	230	346	
	g/L	2.57	2.06	3.08	HemosIL QFA (bovine thrombin)
	mg/dL	257	206	308	
	g/L	2.24	1.79	2.69	Pacific Hemostasis Fibrinogen
	mg/dL	224	179	269	
	g/L	2.65	2.12	3.18	Human Fibrinogen
	mg/dL	265	212	318	
	g/L	2.78	2.22	3.34	Stago STA Fibri-Prest Automate
	mg/dL	278	222	334	
	g/L	3.46	2.77	4.15	Bio-Ksel System PT
	mg/dL	346	277	415	
	g/L	2.34	1.87	2.81	Bio-Ksel Fibrinogen
	mg/dL	234	187	281	
	g/L	2.49	1.99	2.99	Grifols DG-FIB
	mg/dL	249	199	299	
	g/L	2.61	2.09	3.13	Diagon Dia-FIB
	mg/dL	261	209	313	
	g/L	3.20	2.56	3.84	Dade Innovin Derived Fibrinogen
	mg/dL	320	256	384	
	g/L	2.86	2.29	3.43	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	286	229	343	
	g/L	2.56	2.05	3.07	Trinity/Biopool Bovine Thrombin
	mg/dL	256	205	307	

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Range					
Analyte	unit	target	low	high	methods
Fibrinogen	g/L	3.13	2.50	3.76	Liofilchem Fibrinogen
	mg/dL	313	250	376	
	g/L	2.88	2.30	3.46	SGM Italia Fibrinogen
	mg/dL	288	230	346	
	g/L	2.95	2.36	3.54	Biodevice PT
	mg/dL	295	236	354	
	g/L	2.73	2.18	3.28	Spinreact Fibrinogen
	mg/dL	273	218	328	
	g/L	3.21	2.57	3.85	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	321	257	385	
	g/L	2.66	2.13	3.19	Sclavo Fibrinogen
	mg/dL	266	213	319	
Plasminogen activity	g/L	2.71	2.17	3.25	Labitec Fibrinogen
	mg/dL	271	217	325	
Protein C activity	g/L	2.29	1.83	2.75	HemoDiagnostica Fibrinogen
	mg/dL	229	183	275	
Plasminogen activity	%	97.5	78.0	117	Stago Stachrom Plasminogen
	%	84.8	67.8	102	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	21.7	17.4	26.0	Siemens/Dade Berichrom Protein C
	%	16.7	13.4	20.0	IL HemosIL Protein C
Protein S activity	%	10.8	7.56	14.0	IL HemosIL Free Protein S
	%	9.15	6.41	11.9	Dade Protein S Ac
Prothrombin Time (PT)	Seconds	27.7	22.2	33.2	Trinity/Biomerieux Simplastin/PT HTF
	Seconds	25.7	20.6	30.8	Dade Innovin
	Seconds	30.6	24.5	36.7	Siemens/Dade Thromborel S
	Seconds	36.3	29.0	43.6	HemosIL PT-Fibrinogen HS Plus
	Seconds	29.7	23.8	35.6	HemosIL RecombiPlasTin
	Seconds	24.8	19.8	29.8	Stago Neoplastine CI
	Seconds	34.3	27.4	41.2	Stago Neoplastine CI Plus
	Seconds	35.5	28.4	42.6	Trinity/Biopool Thromboplastin S
	Seconds	33.8	27.0	40.6	Teco TEClot PT-S
	Seconds	29.9	23.9	35.9	Biolabo Bio-TP
	Seconds	37.2	29.8	44.6	Stago Neoplastin R
	Seconds	33.8	27.0	40.6	Bio-Ksel System PT
	Seconds	36.4	29.1	43.7	Human Thromboplastin
	Seconds	31.3	25.0	37.6	Diagon, Dia-PT
	Seconds	31.6	25.3	37.9	Weiner Lab Soluplastin
	Seconds	30.3	24.2	36.4	Vital Diagnostics ElectaLab PT
	Seconds	24.3	19.4	29.2	Gernon Hemoplastin PT
	Seconds	37.1	29.7	44.5	Trinity/Biomerieux Simplastin/PT Excel S
	Seconds	28.6	22.9	34.3	Biodevice PT
	Seconds	29.6	23.7	35.5	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	34.6	27.7	41.5	Helena Thromboplastin LI
	Seconds	29.7	23.8	35.6	SGM Italia Thromboplastin
	Seconds	29.1	23.3	34.9	Technoclone Technoclot PT Plus

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Range					
Analyte	unit	target	low	high	methods
Prothrombin Time (PT)	Seconds	31.9	25.5	38.3	Tokra Medikal PT
Prothrombin Time (PT) activity	%	24.0	19.2	28.8	Trinity/Biomerieux Simplastin/PT HTF
	%	26.2	21.0	31.4	Dade Innovin
	%	25.2	20.2	30.2	Siemens/Dade Thromborel S
	%	27.8	22.2	33.4	Stago Neoplastine CI
	%	22.2	17.8	26.6	Stago Neoplastine CI Plus
	%	22.8	18.2	27.4	HemosIL PT-Fibrinogen
	%	23.9	19.1	28.7	HemosIL PT-Fibrinogen HS Plus
	%	25.3	20.2	30.4	HemosIL RecombiPlasTin
	%	25.4	20.3	30.5	Biolabo Bio-TP
	%	14.5	11.6	17.4	Stago SPA
	%	25.8	20.6	31.0	Stago Neoplastin R
	%	44.2	35.4	53.0	Bio-Ksel System PT
	%	28.6	22.9	34.3	Diagon, Dia-PT
	%	19.7	15.8	23.6	Futura System Thromboplastin S
	%	29.8	23.8	35.8	Gernon Hemoplastin PT
	%	26.3	21.0	31.6	SGM Italia Thromboplastin
	%	24.4	19.5	29.3	Trinity/Biomerieux Simplastin/PT Excel S
	%	37.5	30.0	45.0	Pokler Italia Thromboplastin
	%	24.0	19.2	28.8	Biodevice PT
	%	26.3	21.0	31.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	23.7	19.0	28.4	Technoclone Technoclot PT Plus
Prothrombin Time (PT) INR	INR	2.71	2.17	3.25	Trinity/Biomerieux Simplastin/PT HTF
	INR	2.35	1.88	2.82	Dade Innovin
	INR	2.62	2.10	3.14	Siemens/Dade Thromborel S
	INR	2.93	2.34	3.52	HemosIL PT-Fibrinogen HS Plus
	INR	2.42	1.94	2.90	HemosIL PT-Fibrinogen Recombinant
	INR	2.63	2.10	3.16	HemosIL RecombiPlasTin
	INR	3.06	2.45	3.67	Stago Neoplastine CI
	INR	3.50	2.80	4.20	Stago Neoplastine CI Plus
	INR	3.28	2.62	3.94	Human Thromboplastin
	INR	2.64	2.11	3.17	Teco TEClot PT-S
	INR	3.37	2.70	4.04	Biolabo Bio-TP
	INR	3.41	2.73	4.09	Stago SPA
	INR	2.65	2.12	3.18	Stago Neoplastin R
	INR	2.29	1.83	2.75	Bio-Ksel System PT
	INR	2.75	2.20	3.30	Diagon, Dia-PT
	INR	2.91	2.33	3.49	Weiner Lab Soluplastin
	INR	3.02	2.42	3.62	Futura System Thromboplastin S
	INR	2.31	1.85	2.77	Gernon Hemoplastin PT
	INR	2.50	2.00	3.00	SGM Italia Thromboplastin
	INR	2.76	2.21	3.31	Trinity/Biomerieux Simplastin/PT Excel S
	INR	2.36	1.89	2.83	Pokler Italia Thromboplastin
	INR	2.54	2.03	3.05	Biodevice PT
	INR	2.63	2.10	3.16	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	3.20	2.56	3.84	Helena Thromboplastin LI

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Analyte	unit	target	low	high	methods
Prothrombin Time (PT) INR	INR	2.80	2.24	3.36	Technoclone Technoplastin HIS
	INR	2.29	1.83	2.75	LTA PT Calcium Thromboplastin
	INR	2.44	1.95	2.93	Technoclone Technoclot PT Plus
	INR	2.85	2.28	3.42	Tokra Medikal PT
Prothrombin Time (PT) ratio	ratio	2.61	2.09	3.13	Dade Innovin
	ratio	2.66	2.13	3.19	Siemens/Dade Thromborel S
	ratio	1.97	1.58	2.36	Stago Neoplastine CI
	ratio	2.68	2.14	3.22	Stago Neoplastine CI Plus
	ratio	2.68	2.14	3.22	HemosIL RecombiPlasTin
	ratio	2.23	1.78	2.68	Diagon, Dia-PT
	ratio	2.59	2.07	3.11	HemosIL PT-Fibrinogen HS Plus
	ratio	2.75	2.20	3.30	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	2.61	2.09	3.13	Technoclone Technoplastin HIS
Thrombin Time (TT)	Seconds	23.0	18.4	27.6	Dade Thrombin
	Seconds	19.2	15.4	23.0	Siemens/Dade Thromboclotin
	Seconds	22.4	17.9	26.9	HemosIL Thrombin Time
	Seconds	20.1	16.1	24.1	Stago Thrombin
	Seconds	22.9	18.3	27.5	Sysmex Thrombin Time
	Seconds	23.1	18.5	27.7	Diagon, Dia-TT
	Seconds	16.7	13.4	20.0	Technology-Standard Thrombin