

COAGULATION CONTROL - LEVEL I (COAG CONTROL I)

Cat. No: CG 502I **Lot No:** I56CG
Size: 12 x 1ml **Expiry:** 2016-03

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 I, 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 I 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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COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 156CG Size: 12 x 1ml Expiry: 2016-03

Range					
Analyte	unit	target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	34.5	26.7	42.3	Trinity/Biomerieux Platelin LS/APTT HS
	seconds	31.2	25.0	37.4	Siemens/Dade Actin
	seconds	31.3	25.0	37.6	Siemens/Dade Actin FS
	seconds	29.2	23.4	35.0	Siemens/Dade Actin FSL
	seconds	38.9	31.1	46.7	Siemens/Dade Actin SL
	seconds	38.6	30.9	46.3	Siemens/Dade Pathromtin SL
	seconds	32.1	25.7	38.5	HemosIL APTT-SP Liquid
	seconds	31.6	25.3	37.9	HemosIL Synthasil
	seconds	32.5	26.0	39.0	Pacific Hemostasis APTT-XL
	seconds	36.0	28.8	43.2	Stago aPTT
	seconds	35.2	28.2	42.2	Stago Cephascreen
	seconds	35.8	28.6	43.0	Stago CK-Prest
	seconds	37.2	29.8	44.6	Stago PTT Automate
	seconds	34.1	27.3	40.9	Teco TEClot APTT
	seconds	34.0	27.2	40.8	Human Hemostat APTT
	seconds	33.7	27.0	40.4	Bio-Ksel System APTTs
	seconds	34.3	27.4	41.2	Grifols DG-APTT
	seconds	38.0	29.0	47.0	Diagon Dia-PTT
	seconds	32.5	23.2	41.8	Weiner Lab APTT
	seconds	34.7	27.8	41.6	Futura System APTT
	seconds	34.5	27.6	41.4	Biolabo Bio-CK APTT
	seconds	36.6	27.8	45.4	Spinreact APTT
	seconds	33.6	26.9	40.3	Gernon Hemos PTT
	seconds	35.0	28.0	42.0	Technology-Standard aPTT
	seconds	36.4	29.1	43.7	SGM Italia aPTT
	seconds	35.1	28.1	42.1	Trinity/Biomerieux Triniclot aPTT
	seconds	32.6	26.1	39.1	Biodevice aPTT
	seconds	31.9	25.5	38.3	Biomedica QuikCoag aPTT
	seconds	30.2	24.2	36.2	Hemosil aPTT Lyophilised Silica
	seconds	31.4	25.1	37.7	Siemens Dade Actin Cephaloplastin
	seconds	36.5	29.2	43.8	Labitec aPTT
	seconds	37.4	29.9	44.9	Technoclone Siron aPTT
	seconds	31.4	25.1	37.7	Sclavo APTT-S
	seconds	33.1	26.5	39.7	HemoDiagnostica aPTT
	seconds	35.0	27.8	42.2	Tokra Medikal APTT
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.10	0.880	1.32	Siemens/Dade Actin FSL
	ratio	1.21	0.968	1.45	Siemens/Dade Actin SL
	ratio	1.18	0.944	1.42	Stago Cephascreen
	ratio	1.09	0.872	1.31	Stago PTT Automate
	ratio	1.12	0.896	1.34	Stago aPTT
	ratio	1.18	0.944	1.42	Siemens/Dade Pathromtin SL
	ratio	1.05	0.840	1.26	HemosIL APTT-SP Liquid

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 156CG Size: 12 x 1ml Expiry: 2016-03

Range					
Analyte	unit	target	low	high	methods
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.05	0.840	1.26	HemosIL Synthasil
	ratio	0.960	0.768	1.15	Pacific Hemostasis APTT-XL
	ratio	1.08	0.864	1.30	Stago CK-Prest
	ratio	1.11	0.888	1.33	Human Hemostat APTT
	ratio	0.990	0.792	1.19	Bio-Ksel System APTTs
	ratio	1.17	0.936	1.40	Siemens/Dade Actin FS
	ratio	1.12	0.807	1.43	Diagon Dia-PTT
	ratio	1.16	0.928	1.39	Siemens/Dade Actin
	ratio	1.19	0.952	1.43	Trinity/Biomerieux Triniclot aPTT
	ratio	1.13	0.855	1.41	Siemens Dade Actin Cephaloplastin
	ratio	1.12	0.896	1.34	Biodevice aPTT
	ratio	1.06	0.848	1.27	Sclavo APTT-S
Antithrombin III activity	%	93.8	75.0	113	Siemens/Dade Berichrom ATIII
	%	100	80.0	120	HemosIL Liquid Antithrombin
	%	103	82.4	124	Hyphen BioMed BioPhen ATIII
	%	92.4	73.9	111	Roche Chronogenic Thrombin
	%	97.0	77.6	116	Bio-Ksel Antithrombin III
	%	98.2	78.6	118	Hemosil Lyophilised Antithrombin III
	%	98.4	78.7	118	STACHrom ATIII
	%	93.3	74.6	112	Siemens/Dade Antithrombin III
	%	92.7	74.2	111	Siemens Innovance Antithrombin III
	%	96.1	76.9	115	Sclavo ATIII
Factor II activity	%	103	82.4	124	Siemens/Dade Thromborel S
	%	119	95.2	143	HemosIL RecombiPlasTin
	%	107	85.6	128	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	148	118	178	Stago PTT Automate
	%	110	84.0	136	Siemens/Dade Pathromtin SL
	%	103	78.0	128	HemosIL Synthasil
	%	92.9	74.3	111	Siemens/Dade Actin FSL
	%	106	84.8	127	HemosIL APTT-SP Liquid
	%	113	90.4	136	Stago aPTT
Factor V activity	%	84.8	64.9	105	Stago Neoplastine CI Plus
	%	97.3	75.2	119	Siemens/Dade Thromborel S
	%	97.5	78.0	117	Dade Innovin
	%	86.0	68.8	103	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VII activity	%	164	130	198	Stago Neoplastine CI Plus
	%	152	117	187	Siemens/Dade Thromborel S
	%	183	146	220	Dade Innovin
	%	174	139	209	HemosIL RecombiPlasTin
	%	169	135	203	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VIII activity	%	84.6	67.7	102	Stago PTT Automate
	%	76.1	60.9	91.3	Siemens/Dade Actin FS
	%	73.6	58.9	88.3	Siemens/Dade Pathromtin SL
	%	70.6	56.5	84.7	Siemens/Dade Actin FSL
	%	69.7	55.8	83.6	HemosIL Synthasil
	%	77.1	59.3	94.9	HemosIL APTT-SP Liquid

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 156CG Size: 12 x 1ml Expiry: 2016-03

Range					
Analyte	unit	target	low	high	methods
Factor VIII activity	%	78.1	59.3	96.9	Stago aPTT
Factor X activity	%	114	91.2	137	Siemens/Dade Thromborel S
	%	113	90.4	136	Dade Innovin
	%	103	82.4	124	HemosIL RecombiPlasTin
	%	102	81.6	122	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	103	82.4	124	Stago Neoplastin R
Factor XI activity	%	77.2	61.8	92.6	Siemens/Dade Pathromtin SL
	%	62.6	50.1	75.1	Siemens/Dade Actin FSL
Factor XII activity	%	83.1	63.6	103	Siemens/Dade Actin FS
	%	96.3	77.0	116	Siemens/Dade Pathromtin SL
	%	93.8	75.0	113	Siemens/Dade Actin FSL
	%	99.9	71.6	128	HemosIL APTT-SP Liquid
Fibrinogen	g/L	2.86	2.29	3.43	HemosIL PT-Fibrinogen Recombinant
	mg/dL	286	229	343	
	g/L	3.00	2.40	3.60	HemosIL PT-Fibrinogen HS Plus
	mg/dL	300	240	360	
	g/L	2.67	2.14	3.20	HemosIL PT-Fibrinogen HS
	mg/dL	267	214	320	
	g/L	3.01	2.41	3.61	Stago Fibrinogen
	mg/dL	301	241	361	
	g/L	2.88	2.30	3.46	Dade Multifibrin
	mg/dL	288	230	346	
	g/L	2.83	2.26	3.40	HemosIL Fibrinogen C
	mg/dL	283	226	340	
	g/L	2.70	2.16	3.24	Dade Thrombin
	mg/dL	270	216	324	
	g/L	2.96	2.36	3.56	Technoclone Fibrinogen
	mg/dL	296	236	356	
	g/L	2.71	2.17	3.25	Trinity/Biopool Fibrinogen
	mg/dL	271	217	325	
	g/L	2.66	2.13	3.19	Biolabo Bio-Fibri
	mg/dL	266	213	319	
	g/L	2.74	2.19	3.29	HemosIL QFA (bovine thrombin)
	mg/dL	274	219	329	
	g/L	2.73	2.18	3.28	Pacific Hemostasis Fibrinogen
	mg/dL	273	218	328	
	g/L	3.09	2.47	3.71	Human Fibrinogen
	mg/dL	309	247	371	
	g/L	3.10	2.48	3.72	Stago STA Fibri-Prest Automate
	mg/dL	310	248	372	
	g/L	2.88	2.30	3.46	Bio-Ksel System PT
	mg/dL	288	230	346	
	g/L	2.53	1.89	3.17	Bio-Ksel Fibrinogen
	mg/dL	253	189	317	
	g/L	2.63	2.07	3.19	Diagon Dia-FIB
	mg/dL	263	207	319	

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 156CG Size: 12 x 1ml Expiry: 2016-03

Range					
Analyte	unit	target	low	high	methods
Fibrinogen	g/L	2.06	1.65	2.47	Dade Innovin Derived Fibrinogen
	mg/dL	206	165	247	
	g/L	3.05	2.44	3.66	Gernon Hemofibrin
	mg/dL	305	244	366	
	g/L	2.78	2.22	3.34	Technology-Standard Fibrinogen
	mg/dL	278	222	334	
	g/L	2.74	2.19	3.29	Trinity/Biopool Bovine Thrombin
	mg/dL	274	219	329	
	g/L	2.65	1.86	3.44	Liofilchem Fibrinogen
	mg/dL	265	186	344	
	g/L	3.03	2.42	3.64	SGM Italia Fibrinogen
	mg/dL	303	242	364	
	g/L	3.00	2.40	3.60	Futura System Fibrinogen
	mg/dL	300	240	360	
	g/L	2.79	2.23	3.35	Biodevice PT
	mg/dL	279	223	335	
	g/L	2.93	2.34	3.52	Spinreact Fibrinogen
	mg/dL	293	234	352	
	g/L	2.63	2.10	3.16	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	263	210	316	
Plasminogen activity	g/L	3.01	2.23	3.79	Sclavo Fibrinogen
	mg/dL	301	223	379	
Protein C activity	g/L	2.70	2.16	3.24	HemoDiagnostica Fibrinogen
	mg/dL	270	216	324	
	g/L	3.08	2.46	3.70	Beijing Steelex Fibrinogen
	mg/dL	308	246	370	
Protein S activity	%	102	81.6	122	Stago Stachrom Plasminogen
	%	93.5	74.8	112	Siemens/Dade Berichrom Plasminogen
	%	104	83.2	125	Siemens/Dade Berichrom Protein C
	%	98.0	78.4	118	Stago StaClot
	%	101	80.8	121	IL HemosIL Protein C
Prothrombin Time (PT)	%	98.2	72.3	124	Siemens
	%	105	84.0	126	STACHrom Protein C
	%	91.0	63.7	118	STA Liatest
	%	88.0	61.6	114	Helena Elisa
	%	62.6	43.8	81.4	Stago StaClot
	%	81.4	57.0	106	Siemens/Dade Protein S
	%	91.2	63.8	119	IL HemosIL Free Protein S
Prothrombin Time (PT)	%	64.6	45.2	84.0	Dade Protein S Ac
	Seconds	11.8	9.44	14.2	Trinity/Biomerieux Simplastin/PT HTF
	Seconds	9.85	7.88	11.8	Dade Innovin
	Seconds	10.9	8.72	13.1	Siemens/Dade Thromborel S
	Seconds	10.9	8.46	13.3	HemosIL PT-Fibrinogen
	Seconds	11.7	9.36	14.0	HemosIL PT-Fibrinogen HS
	Seconds	11.7	9.36	14.0	HemosIL PT-Fibrinogen HS Plus
Prothrombin Time (PT)	Seconds	10.5	8.40	12.6	HemosIL PT-Fibrinogen Recombinant

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 156CG Size: 12 x 1ml Expiry: 2016-03

Range					
Analyte	unit	target	low	high	methods
Prothrombin Time (PT)	Seconds	9.78	7.82	11.7	HemosIL RecombiPlasTin
	Seconds	13.0	10.4	15.6	Pacific Thromboplastin DS
	Seconds	11.8	9.44	14.2	Stago Neoplastine CI
	Seconds	12.1	9.68	14.5	Stago Neoplastine CI Plus
	Seconds	12.3	9.84	14.8	Teco TEClot PT-S
	Seconds	12.0	9.60	14.4	Biolabo Bio-TP
	Seconds	12.4	9.92	14.9	Stago Neoplastin R
	Seconds	12.6	10.1	15.1	Bio-Ksel System PT
	Seconds	12.5	10.0	15.0	Human Thromboplastin
	Seconds	11.0	8.80	13.2	Grifols DG-PT
	Seconds	12.2	9.76	14.6	Diagon, Dia-PT
	Seconds	12.4	9.60	15.2	Weiner Lab Soluplastin
	Seconds	13.7	11.0	16.4	Spinreact PT
	Seconds	12.6	10.1	15.1	Gernon Hemoplastin PT
	Seconds	12.0	8.94	15.1	Technology-Standard PT
	Seconds	13.1	10.5	15.7	Trinity/Biomerieux Simplastin/PT Excel S
	Seconds	11.5	9.20	13.8	Biodevice PT
	Seconds	12.4	9.92	14.9	Biomedica QuikCoag PT-HS
	Seconds	9.85	7.88	11.8	Siemens/Dade Thromboplastin CL
	Seconds	9.83	7.86	11.8	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	13.4	10.3	16.5	Helena Thromboplastin LI
	Seconds	12.3	9.56	15.0	Teco Teclot PT
	Seconds	13.1	10.5	15.7	SGM Italia Thromboplastin
	Seconds	11.0	8.80	13.2	Technoclon Technoclot PT Plus
	Seconds	11.6	9.28	13.9	Tokra Medikal PT
Prothrombin Time (PT) activity	%	108	86.4	130	Trinity/Biomerieux Simplastin/PT HTF
	%	114	91.2	137	Dade Innovin
	%	105	84.0	126	Siemens/Dade Thromborel S
	%	100	80.0	120	Stago Neoplastine CI
	%	111	84.4	138	Stago Neoplastine CI Plus
	%	135	97.2	173	HemosIL PT-Fibrinogen HS Plus
	%	125	96.8	153	HemosIL RecombiPlasTin
	%	95.2	76.2	114	Pacific Thromboplastin DS
	%	124	99.0	149	Teco TEClot PT-S
	%	109	79.5	139	Biolabo Bio-TP
	%	137	108	166	Stago SPA
	%	100	80.0	120	Stago Neoplastin R
	%	122	97.6	146	Bio-Ksel System PT
	%	102	81.6	122	Human Thromboplastin
	%	113	90.4	136	Diagon, Dia-PT
	%	98.0	76.4	120	Spinreact PT
	%	136	109	163	Gernon Hemoplastin PT
	%	102	81.6	122	SGM Italia Thromboplastin
	%	104	83.2	125	Trinity/Biomerieux Simplastin/PT Excel S
	%	105	84.0	126	Pokler Italia Thromboplastin
	%	109	87.2	131	Biodevice PT

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 156CG Size: 12 x 1ml Expiry: 2016-03

Range					
Analyte	unit	target	low	high	methods
Prothrombin Time (PT) activity	%	132	106	158	Siemens/Dade Thromboplastin CL
	%	122	94.3	150	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	111	88.8	133	Technoclone Technoclot PT Plus
Prothrombin Time (PT) INR	INR	0.960	0.768	1.15	Trinity/Biomerieux Simplastin/PT HTF
	INR	0.970	0.776	1.16	Dade Innovin
	INR	0.950	0.760	1.14	Siemens/Dade Thromborel S
	INR	0.870	0.696	1.04	HemosIL PT-Fibrinogen
	INR	0.830	0.664	0.996	HemosIL PT-Fibrinogen HS Plus
	INR	0.860	0.688	1.03	HemosIL PT-Fibrinogen Recombinant
	INR	0.870	0.696	1.04	HemosIL RecombiPlasTin
	INR	1.02	0.816	1.22	Pacific Thromboplastin DS
	INR	0.990	0.792	1.19	Stago Neoplastine CI
	INR	0.930	0.744	1.12	Stago Neoplastine CI Plus
	INR	0.970	0.776	1.16	Human Thromboplastin
	INR	0.870	0.696	1.04	Teco TEClot PT-S
	INR	0.920	0.736	1.10	Biolabo Bio-TP
	INR	0.870	0.696	1.04	Stago SPA
	INR	0.960	0.768	1.15	Stago Neoplastin R
	INR	0.820	0.656	0.984	Bio-Ksel System PT
	INR	0.900	0.720	1.08	Diagon, Dia-PT
	INR	0.990	0.792	1.19	Weiner Lab Soluplastin
	INR	0.958	0.708	1.21	Futura System Thromboplastin S
	INR	1.09	0.872	1.31	Spinreact PT
	INR	0.900	0.720	1.08	Gernon Hemoplastin PT
	INR	1.00	0.800	1.20	SGM Italia Thromboplastin
	INR	0.920	0.736	1.10	Trinity/Biomerieux Simplastin/PT Excel S
	INR	0.940	0.752	1.13	Pokler Italia Thromboplastin
	INR	0.960	0.768	1.15	Biodevice PT
	INR	0.880	0.704	1.06	Biomedica QuikCoag PT-HS
	INR	0.910	0.728	1.09	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	0.810	0.648	0.972	Technoclone Technoplastin HIS
	INR	0.890	0.712	1.07	Technoclone Technoclot PT Plus
	INR	0.950	0.760	1.14	Tokra Medikal PT
Prothrombin Time (PT) ratio	ratio	0.960	0.768	1.15	Dade Innovin
	ratio	0.970	0.776	1.16	Siemens/Dade Thromborel S
	ratio	0.970	0.776	1.16	Stago Neoplastine CI
	ratio	0.960	0.768	1.15	Stago Neoplastine CI Plus
	ratio	0.870	0.696	1.04	HemosIL RecombiPlasTin
	ratio	0.860	0.688	1.03	Stago Neoplastin R
	ratio	0.980	0.784	1.18	Diagon, Dia-PT
	ratio	0.900	0.720	1.08	HemosIL PT-Fibrinogen HS Plus
	ratio	0.870	0.696	1.04	Siemens/Dade Thromboplastin CL
	ratio	0.920	0.736	1.10	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	1.00	0.800	1.20	Biodevice PT
Thrombin Time (TT)	Seconds	17.6	14.1	21.1	Siemens/Dade Thromboclotin
	Seconds	17.1	13.7	20.5	HemosIL Thrombin Time

COAGULATION CONTROL - LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot No. 156CG Size: 12 x 1ml Expiry: 2016-03

Range					
Analyte	unit	target	low	high	methods
Thrombin Time (TT)	Seconds	17.0	13.6	20.4	Stago Thrombin
	Seconds	16.9	13.5	20.3	Technology-Standard Thrombin