

COAGULATION CONTROL - LEVEL I (COAG CONTROL I)

Cat. No.	CG 5021	Lot No.	302CG
Size:	12 x 1 ml	Expiry:	2021-11-28
GTIN:	05055273207620		

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 control 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.

- 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.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix the contents of the vial thoroughly.

MATERIALS PROVIDED

Coagulation Control - Level I 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 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 302CG Size 12 x 1 ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	41.9	33.5	50.3	Tcoag TriniCLOT aPTT S
	seconds	40.8	32.6	49.0	Tcoag TriniCLOT aPTT HS
	seconds	39.1	31.3	46.9	Siemens/Dade Actin
	seconds	36.6	29.3	43.9	Siemens/Dade Actin FS
	seconds	35.2	28.2	42.2	Siemens/Dade Actin FSL
	seconds	46.8	37.4	56.2	Siemens/Dade Actin SL
	seconds	47.2	37.8	56.6	Siemens/Dade Pathromtin SL
	seconds	34.6	27.7	41.5	HemosIL APTT-SP Liquid
	seconds	39.2	31.4	47.0	HemosIL Synthasil
	seconds	40.9	32.7	49.1	Pacific Hemostasis APTT-XL
	seconds	43.8	35.0	52.6	Stago aPTT
	seconds	41.3	33.0	49.6	Stago Cephascreen
	seconds	43.2	34.6	51.8	Stago CK-Prest
	seconds	43.9	35.1	52.7	Stago PTT Automate
	seconds	41.6	33.3	49.9	Teco TEClot APTT
	seconds	37.5	30.0	45.0	Human Hemostat APTT
	seconds	39.9	31.9	47.9	Bio-Ksel System APTTs
	seconds	46.9	37.5	56.3	Diagon Dia-PTT
	seconds	37.0	29.6	44.4	Weiner Lab APTT
	seconds	41.2	33.0	49.4	Biolabo Bio-CK APTT
	seconds	43.1	34.5	51.7	Spinreact APTT
	seconds	42.0	33.6	50.4	Tcoag TriniCLOT Automated aPTT
	seconds	36.6	29.3	43.9	Media IVD aPTT
	seconds	38.4	30.7	46.1	Biomedica QuikCoag aPTT
	seconds	42.1	33.7	50.5	Hemosil aPTT Lyophilised Silica
	seconds	38.7	31.0	46.4	Siemens/Dade Actin Cephaloplastin
	seconds	41.1	32.9	49.3	Labitec aPTT
	seconds	39.7	31.8	47.6	Sclavo APTT-S
	seconds	38.8	31.0	46.6	HemoDiagnostica aPTT
	seconds	42.0	33.6	50.4	Cypress Diagnostics aPTT
seconds	41.4	33.1	49.7	Fortress Diagnostics aPTT	
seconds	43.8	35.0	52.6	Tokra Medikal APTT	
seconds	36.7	29.4	44.0	Coagpia APTT-N	
seconds	44.6	35.7	53.5	Cobas aPTT MedS	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.31	1.05	1.57	Siemens/Dade Actin FSL
	ratio	1.52	1.22	1.82	Siemens/Dade Actin SL
	ratio	1.37	1.10	1.64	Stago Cephascreen
	ratio	1.31	1.05	1.57	Stago PTT Automate
	ratio	1.43	1.14	1.72	Stago aPTT
	ratio	1.49	1.19	1.79	Siemens/Dade Pathromtin SL
	ratio	1.14	0.912	1.37	HemosIL APTT-SP Liquid
	ratio	1.29	1.03	1.55	HemosIL Synthasil

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 302CG Size 12 x 1 ml Expiry 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.40	1.12	1.68	Stago CK-Prest
	ratio	1.29	1.03	1.55	Human Hemostat APTT
	ratio	1.14	0.912	1.37	Bio-Ksel System APTTs
	ratio	1.41	1.13	1.69	Siemens/Dade Actin FS
	ratio	1.36	1.09	1.63	Diagon Dia-PTT
	ratio	1.27	1.02	1.52	Media IVD aPTT
	ratio	1.35	1.08	1.62	Biodevice aPTT
	ratio	1.36	1.09	1.63	Labitec aPTT
	ratio	1.33	1.06	1.60	Sclavo APTT-S
	ratio	1.17	0.936	1.40	Coagpia APTT-N
Antithrombin III activity	%	79.0	63.2	94.8	Siemens/Dade Berichrom ATIII
	%	76.3	61.0	91.6	HemosIL Liquid Antithrombin
	%	77.4	61.9	92.9	Roche Chronogenic Thrombin
	%	71.8	57.4	86.2	Hemosil Lyophilised Antithrombin III
	%	78.2	62.6	93.8	STACHrom ATIII
	%	77.2	61.8	92.6	Siemens/Dade Antithrombin III
	%	79.5	63.6	95.4	Diagon ATIII
	%	77.4	61.9	92.9	Biodevice ATIII
	%	76.8	61.4	92.2	Siemens Innovance Antithrombin III
	%	74.3	59.4	89.2	Sclavo ATIII
	%	76.0	60.8	91.2	Teco TEChrom AT
Factor II activity	%	87.7	70.2	105	Siemens/Dade-Behring Innovin
	%	94.2	75.4	113	Siemens/Dade-Behring Thromborel S
	%	99.6	79.7	120	HemosIL PT-Fibrinogen HS Plus
	%	111	88.8	133	HemosIL RecombiPlasTin 2G
	%	98.3	78.6	118	HemosIL Factor II deficient plasma
Factor IX activity	%	65.7	52.6	78.8	Siemens/Dade Actin FS
	%	82.3	65.8	98.8	Siemens/Dade Pathromtin SL
	%	74.4	59.5	89.3	HemosIL Synthasil
	%	74.2	59.4	89.0	Siemens/Dade Actin FSL
	%	78.2	62.6	93.8	HemosIL APTT-SP Liquid
	%	88.7	71.0	106	Stago Deficient / ImmunoDef IX
	%	74.0	59.2	88.8	HemosIL Factor IX deficient plasma
Factor V activity	%	61.0	48.8	73.2	Stago Neoplastine CI Plus
	%	75.5	60.4	90.6	Siemens/Dade-Behring Thromborel S
	%	72.7	58.2	87.2	Siemens/Dade-Behring Innovin
	%	67.9	54.3	81.5	HemosIL PT-Fibrinogen HS Plus
	%	65.8	52.6	79.0	HemosIL RecombiPlasTin 2G
	%	68.5	54.8	82.2	HemosIL Factor V deficient plasma
Factor VII activity	%	202	162	242	Stago Neoplastine CI Plus
	%	156	125	187	Siemens/Dade-Behring Thromborel S
	%	178	142	214	Siemens/Dade-Behring Innovin
	%	264	211	317	HemosIL PT-Fibrinogen HS Plus
	%	237	190	284	HemosIL RecombiPlasTin 2G
	%	228	182	274	HemosIL Factor VII deficient plasma
Factor VIII activity	%	48.3	38.6	58.0	Stago PTT Automate

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Range					
Analyte	unit	Target	low	high	methods
Factor VIII activity	%	48.9	39.1	58.7	Siemens/Dade Actin FS
	%	48.3	38.6	58.0	Siemens/Dade Pathromtin SL
	%	47.6	38.1	57.1	Siemens/Dade Actin FSL
	%	48.4	38.7	58.1	HemosIL Synthasil
	%	49.3	39.4	59.2	HemosIL APTT-SP Liquid
	%	52.3	41.8	62.8	Stago STA Factor VIII
	%	52.7	42.2	63.2	Stago Deficient / ImmunoDef VIII
	%	47.6	38.1	57.1	HemosIL Factor VIII deficient plasma
Factor X activity	%	104	83.2	125	Siemens/Dade-Behring Thromborel S
	%	115	92.0	138	Siemens/Dade-Behring Innovin
	%	106	84.8	127	HemosIL PT-Fibrinogen HS Plus
	%	108	86.4	130	HemosIL RecombiPlasTin 2G
Factor XI activity	%	42.3	33.8	50.8	Siemens/Dade Actin FS
	%	56.7	45.4	68.0	Siemens/Dade Pathromtin SL
	%	42.6	34.1	51.1	HemosIL Synthasil
	%	42.3	33.8	50.8	Siemens/Dade Actin FSL
	%	42.9	34.3	51.5	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	65.1	52.1	78.1	Siemens/Dade Actin FS
	%	79.8	63.8	95.8	Siemens/Dade Pathromtin SL
	%	75.2	60.2	90.2	HemosIL Synthasil
	%	71.6	57.3	85.9	Siemens/Dade Actin FSL
	%	73.5	58.8	88.2	HemosIL APTT-SP Liquid
Fibrinogen	g/L	2.30	1.84	2.76	HemosIL PT-Fibrinogen HS Plus
	mg/dL	230	184	276	
	g/L	2.38	1.90	2.86	Stago Fibrinogen / Liquid-Fib
	mg/dL	238	190	286	
	g/L	2.12	1.70	2.54	Siemens/Dade Multifibren U
	mg/dL	212	170	254	
	g/L	2.23	1.78	2.68	HemosIL Fibrinogen C
	mg/dL	223	178	268	
	g/L	2.02	1.62	2.42	Dade Thrombin
	mg/dL	202	162	242	
	g/L	2.66	2.13	3.19	Technoclone Fibrinogen
	mg/dL	266	213	319	
	g/L	2.29	1.83	2.75	Tcoag TriniCLOT Fibrinogen
	mg/dL	229	183	275	
	g/L	2.14	1.71	2.57	Biolabo Bio-Fibri
	mg/dL	214	171	257	
	g/L	2.01	1.61	2.41	Teco Teclot Fibrinogen
	mg/dL	201	161	241	
	g/L	2.09	1.67	2.51	HemosIL QFA (bovine thrombin)
	mg/dL	209	167	251	
g/L	2.25	1.80	2.70	Human Fibrinogen	
mg/dL	225	180	270		
g/L	2.37	1.90	2.84	Stago STA Fibri-Prest Automate	
mg/dL	237	190	284		

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 302CG Size 12 x 1 ml Expiry 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Fibrinogen	g/L	1.92	1.54	2.30	Bio-Ksel System PT
	mg/dL	192	154	230	
	g/L	2.29	1.83	2.75	Bio-Ksel Fibrinogen
	mg/dL	229	183	275	
	g/L	1.99	1.59	2.39	Diagon Dia-F
	mg/dL	199	159	239	
	g/L	1.60	1.28	1.92	Dade Innovin Derived Fibrinogen
	mg/dL	160	128	192	
	g/L	1.80	1.44	2.16	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	180	144	216	
	g/L	2.79	2.23	3.35	Wiener Lab Fibrinogen
	mg/dL	279	223	335	
	g/L	2.11	1.69	2.53	HemosIL RecombiPlasTin 2G
	mg/dL	211	169	253	
	g/L	2.21	1.77	2.65	Sclavo Fibrinogen
	mg/dL	221	177	265	
	g/L	2.52	2.02	3.02	Labitec Fibrinogen
	mg/dL	252	202	302	
	g/L	2.29	1.83	2.75	Helena Clauss Fibrinogen 100
	mg/dL	229	183	275	
g/L	2.29	1.83	2.75	Coagpia Fibrinogen	
mg/dL	229	183	275		
g/L	2.29	1.83	2.75	HemosIL PT-Fibrinogen	
mg/dL	229	183	275		
g/L	2.30	1.84	2.76	Beijing Succeeder Fibrinogen	
mg/dL	230	184	276		
g/L	2.11	1.69	2.53	Cobas Fibrinogen	
mg/dL	211	169	253		
Plasminogen activity	%	81.3	65.0	97.6	Stago Stachrom Plasminogen
	%	78.5	62.8	94.2	HemosIL Plasminogen
	%	86.6	69.3	104	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	90.0	72.0	108	Siemens/Dade Berichrom Protein C
	%	76.5	61.2	91.8	Stago StaClot
	%	71.5	57.2	85.8	Biomerieux VIDAS Protein C
	%	84.4	67.5	101	IL HemosIL Protein C
	%	87.4	69.9	105	Siemens
	%	87.5	70.0	105	STACHrom Protein C
Protein S activity	%	75.8	53.1	98.5	STA Liatest
	%	55.9	39.1	72.7	Stago StaClot
	%	65.3	45.7	84.9	IL HemosIL ProS
	%	80.9	56.6	105	IL HemosIL Free Protein S
	%	54.2	37.9	70.5	Dade Protein S Ac
	%	78.1	54.7	102	Siemens Innovance Free PS Ag
	%	35.9	25.1	46.7	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	11.2	8.96	13.4	Siemens/Dade-Behring Innovin
	Seconds	11.6	9.28	13.9	Siemens/Dade Thromborel IS

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 302CG Size 12 x 1 ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT)	Seconds	11.4	9.12	13.7	Siemens/Dade-Behring Thromborel S
	Seconds	12.7	10.2	15.2	HemosIL PT-Fibrinogen HS Plus
	Seconds	13.2	10.6	15.8	Pacific Thromboplastin DS
	Seconds	13.3	10.6	16.0	Stago Neoplastine CI
	Seconds	13.0	10.4	15.6	Stago Neoplastine CI Plus
	Seconds	12.0	9.60	14.4	Teco TEClot PT-S
	Seconds	12.9	10.3	15.5	Biolabo Bio-TP
	Seconds	12.5	10.0	15.0	Stago Neoplastin R
	Seconds	9.46	7.57	11.4	Bio-Ksel System PT
	Seconds	11.7	9.36	14.0	Human Thromboplastin
	Seconds	12.0	9.60	14.4	Diagon PT
	Seconds	14.2	11.4	17.0	Weiner Lab Soluplastin
	Seconds	12.7	10.2	15.2	Spinreact PT
	Seconds	13.6	10.9	16.3	TCoag TriniCLOT PT Excel S
	Seconds	12.3	9.84	14.8	Media IVD PT
	Seconds	11.8	9.44	14.2	Biodevice PT
	Seconds	12.0	9.60	14.4	Biomedica QuikCoag PT-HS
	Seconds	9.98	7.98	12.0	HemosIL RecombiPlasTin 2G
	Seconds	12.3	9.84	14.8	Helena Thromboplastin
	Seconds	12.2	9.76	14.6	Labitec PT
	Seconds	12.2	9.76	14.6	Cypress Diagnostics PT
	Seconds	11.2	8.96	13.4	Fortress Diagnostics PT with Calcium
	Seconds	12.1	9.68	14.5	Tokra Medikal PT
	Seconds	10.9	8.72	13.1	Coagpia PT-N
	Seconds	9.19	7.35	11.0	Bio-Ksel PT Plus
	Seconds	12.9	10.3	15.5	Beijing Succeeder PT
	Seconds	9.17	7.34	11.0	Diagon PT R
	Seconds	11.7	9.36	14.0	Cobas PT Screen
Prothrombin Time (PT) activity	%	85.0	68.0	102	Siemens/Dade-Behring Innovin
	%	103	82.4	124	Siemens/Dade-Behring Thromborel S
	%	91.4	73.1	110	Stago Neoplastine CI
	%	98.3	78.6	118	Stago Neoplastine CI Plus
	%	125	100	150	HemosIL PT-Fibrinogen HS Plus
	%	121	96.8	145	Teco TEClot PT-S
	%	103	82.4	124	Biolabo Bio-TP
	%	116	92.8	139	Stago Neoplastin R
	%	113	90.4	136	Bio-Ksel System PT
	%	108	86.4	130	Human Thromboplastin
	%	116	92.8	139	Diagon PT
	%	79.5	63.6	95.4	Weiner Lab Soluplastin
	%	85.8	68.6	103	TCoag TriniCLOT PT Excel S
	%	95.5	76.4	115	Media IVD PT
	%	106	84.8	127	Biodevice PT
	%	124	99.0	149	HemosIL RecombiPlasTin 2G
	%	111	88.8	133	Helena Thromboplastin
	%	103	82.4	124	Labitec PT

COAGULATION CONTROL LEVEL 1 (COAG CONTROL 1)

Cat. No. CG5021 Lot. No. 302CG Size 12 x 1 ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	117	93.6	140	Tokra Medikal PT
	%	116	92.8	139	Coagpia PT-N
	%	115	92.0	138	Bio-Ksel PT Plus
	%	109	87.2	131	Beijing Succeeder PT
	%	99.2	79.4	119	Cobas PT Screen
Prothrombin Time (PT) INR	INR	1.08	0.864	1.30	Siemens/Dade-Behring Innovin
	INR	0.963	0.770	1.16	Siemens/Dade Thromborel IS
	INR	0.982	0.786	1.18	Siemens/Dade-Behring Thromborel S
	INR	0.853	0.682	1.02	HemosIL PT-Fibrinogen
	INR	0.884	0.707	1.06	HemosIL PT-Fibrinogen HS Plus
	INR	0.990	0.792	1.19	Pacific Thromboplastin DS
	INR	1.09	0.872	1.31	Stago Neoplastine CI
	INR	0.996	0.797	1.20	Stago Neoplastine CI Plus
	INR	0.933	0.746	1.12	Human Thromboplastin
	INR	0.923	0.738	1.11	Teco TEClot PT-S
	INR	0.954	0.763	1.14	Biolabo Bio-TP
	INR	0.885	0.708	1.06	Stago SPA
	INR	0.932	0.746	1.12	Stago Neoplastin R
	INR	0.887	0.710	1.06	Bio-Ksel System PT
	INR	0.923	0.738	1.11	Diagon PT
	INR	1.12	0.896	1.34	Weiner Lab Soluplastin
	INR	0.978	0.782	1.17	Spinreact PT
	INR	1.08	0.864	1.30	TCoag TriniCLOT PT Excel S
	INR	1.04	0.832	1.25	Media IVD PT
	INR	1.02	0.816	1.22	Biodevice PT
	INR	0.949	0.759	1.14	Biomedica QuikCoag PT-HS
	INR	0.879	0.703	1.05	HemosIL RecombiPlasTin 2G
	INR	0.998	0.798	1.20	Technoclone Technoplastin HIS
	INR	0.935	0.748	1.12	Helena Thromboplastin
	INR	0.947	0.758	1.14	Labitec PT
	INR	1.01	0.808	1.21	Fortress Diagnostics PT with Calcium
	INR	0.882	0.706	1.06	Tokra Medikal PT
	INR	0.941	0.753	1.13	Coagpia PT-N
	INR	0.871	0.697	1.05	Bio-Ksel PT Plus
	INR	0.989	0.791	1.19	Beijing Succeeder PT
	INR	0.933	0.746	1.12	Diagon PT R
	INR	1.08	0.864	1.30	Cobas PT Screen
Prothrombin Time (PT) ratio	ratio	1.09	0.872	1.31	Siemens/Dade-Behring Innovin
	ratio	0.990	0.792	1.19	Siemens/Dade-Behring Thromborel S
	ratio	1.04	0.832	1.25	Stago Neoplastine CI Plus
	ratio	0.929	0.743	1.11	Diagon PT
	ratio	0.853	0.682	1.02	HemosIL PT-Fibrinogen HS Plus
	ratio	0.875	0.700	1.05	HemosIL RecombiPlasTin 2G
Thrombin Time (TT)	Seconds	25.2	20.2	30.2	Dade Thrombin
	Seconds	22.4	17.9	26.9	Siemens/Dade Thromboclotin
	Seconds	22.9	18.3	27.5	Stago Thrombin

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Cat. No. CG5021 Lot. No. 302CG Size 12 x 1 ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Thrombin Time (TT)	Seconds	21.6	17.3	25.9	Sysmex Thrombin Time
	Seconds	28.0	22.4	33.6	Diagon, Dia-TT
	Seconds	23.8	19.0	28.6	HemosIL Thrombin Time 5ml
	Seconds	30.6	24.5	36.7	HemosIL Thrombin Time 8ml