

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

CAT NO. CG5022

LOT NO. 303CG

SIZE: 12 x 1 ml

EXPIRY: 2021-11-28

GTIN: 05055273207637

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.

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. 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.

14 Feb '20 ne

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 303CG Size: 12 x 1 ml Expiry: 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	57.9	46.3	69.5	Tcoag TriniCLOT aPTT S
	seconds	52.9	42.3	63.5	Tcoag TriniCLOT aPTT HS
	seconds	49.8	39.8	59.8	Siemens/Dade Actin
	seconds	45.6	36.5	54.7	Siemens/Dade Actin FS
	seconds	45.6	36.5	54.7	Siemens/Dade Actin FSL
	seconds	70.5	56.4	84.6	Siemens/Dade Actin SL
	seconds	70.3	56.2	84.4	Siemens/Dade Pathromtin SL
	seconds	43.7	35.0	52.4	HemosIL APTT-SP Liquid
	seconds	54.1	43.3	64.9	HemosIL Synthasil
	seconds	54.8	43.8	65.8	Stago aPTT
	seconds	49.6	39.7	59.5	Stago Cephascreen
	seconds	56.0	44.8	67.2	Stago CK-Prest
	seconds	56.6	45.3	67.9	Stago PTT Automate
	seconds	55.5	44.4	66.6	Teco TEClot APTT
	seconds	48.9	39.1	58.7	Human Hemostat APTT
	seconds	49.5	39.6	59.4	Bio-Ksel System APTTs
	seconds	62.3	49.8	74.8	Diagon Dia-PTT
	seconds	49.0	39.2	58.8	Weiner Lab APTT
	seconds	52.3	41.8	62.8	Biolabo Bio-CK APTT
	seconds	55.0	44.0	66.0	Spinreact APTT
	seconds	56.3	45.0	67.6	Tcoag TriniCLOT Automated aPTT
	seconds	51.9	41.5	62.3	Biomedica QuikCoag aPTT
	seconds	55.0	44.0	66.0	Hemosil aPTT Lyophilised Silica
	seconds	50.5	40.4	60.6	Siemens Dade Actin Cephaloplastin
	seconds	50.1	40.1	60.1	Labitec aPTT
	seconds	56.1	44.9	67.3	Sclavo APTT-S
seconds	49.6	39.7	59.5	HemoDiagnostica aPTT	
seconds	47.2	37.8	56.6	Fortress Diagnostics aPTT	
seconds	59.9	47.9	71.9	Tokra Medikal APTT	
seconds	46.4	37.1	55.7	Coagpia APTT-N	
seconds	67.1	53.7	80.5	Cobas aPTT MedS	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.67	1.34	2.00	Siemens/Dade Actin FSL
	ratio	2.18	1.74	2.62	Siemens/Dade Actin SL
	ratio	1.64	1.31	1.97	Stago Cephascreen
	ratio	1.66	1.33	1.99	Stago PTT Automate
	ratio	1.76	1.41	2.11	Stago aPTT
	ratio	2.26	1.81	2.71	Siemens/Dade Pathromtin SL
	ratio	1.46	1.17	1.75	HemosIL APTT-SP Liquid
	ratio	1.80	1.44	2.16	HemosIL Synthasil
	ratio	1.84	1.47	2.21	Stago CK-Prest
	ratio	1.69	1.35	2.03	Human Hemostat APTT
	ratio	1.47	1.18	1.76	Bio-Ksel System APTTs

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 303CG Size: 12 x 1 ml Expiry: 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.79	1.43	2.15	Siemens/Dade Actin FS
	ratio	1.82	1.46	2.18	Diagon Dia-PTT
	ratio	1.73	1.38	2.08	Siemens/Dade Actin
	ratio	2.00	1.60	2.40	Media IVD aPTT
	ratio	1.71	1.37	2.05	Biodevice aPTT
	ratio	1.67	1.34	2.00	Labitec aPTT
	ratio	1.88	1.50	2.26	Sclavo APTT-S
	ratio	1.46	1.17	1.75	Coagpia APTT-N
Antithrombin III activity	%	67.0	53.6	80.4	Siemens/Dade Berichrom ATIII
	%	60.3	48.2	72.4	HemosIL Liquid Antithrombin
	%	66.1	52.9	79.3	Roche Chronogenic Thrombin
	%	60.6	48.5	72.7	Hemosil Lyophilised Antithrombin III
	%	65.7	52.6	78.8	STACHrom ATIII
	%	65.0	52.0	78.0	Siemens/Dade Antithrombin III
	%	63.2	50.6	75.8	Diagon ATIII
	%	66.1	52.9	79.3	Siemens Innovance Antithrombin III
	%	62.5	50.0	75.0	Sclavo ATIII
	%	63.0	50.4	75.6	Teco TEChrom AT
Factor II activity	%	72.5	58.0	87.0	Dade Innovin
	%	83.0	66.4	100	Siemens/Dade Thromborel S
	%	80.7	64.6	96.8	HemosIL PT-Fibrinogen HS Plus
	%	83.8	67.0	101	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor IX activity	%	55.9	44.7	67.1	Siemens/Dade Actin FS
	%	68.9	55.1	82.7	Siemens/Dade Pathromtin SL
	%	59.2	47.4	71.0	HemosIL Synthasil
	%	60.1	48.1	72.1	Siemens/Dade Actin FSL
	%	59.9	47.9	71.9	HemosIL APTT-SP Liquid
	%	70.2	56.2	84.2	Stago Deficient / ImmunoDef IX
Factor V activity	%	60.8	48.6	73.0	HemosIL Factor IX deficient plasma
	%	63.9	51.1	76.7	Siemens/Dade Thromborel S
	%	52.6	42.1	63.1	Dade Innovin
	%	59.1	47.3	70.9	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VII activity	%	56.6	45.3	67.9	HemosIL Factor V deficient plasma
	%	129	103	155	Siemens/Dade Thromborel S
	%	144	115	173	Dade Innovin
	%	189	151	227	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VIII activity	%	190	152	228	HemosIL Factor VII deficient plasma
	%	34.3	27.4	41.2	Stago CK-Prest
	%	32.6	26.1	39.1	Siemens/Dade Actin FS
	%	33.5	26.8	40.2	Siemens/Dade Pathromtin SL
	%	31.0	24.8	37.2	Siemens/Dade Actin FSL
	%	32.9	26.3	39.5	HemosIL Synthasil
	%	36.7	29.4	44.0	HemosIL APTT-SP Liquid
	%	33.9	27.1	40.7	Stago Deficient / ImmunoDef VIII
Factor X activity	%	34.1	27.3	40.9	HemosIL Factor VIII deficient plasma
	%	91.0	72.8	109	Siemens/Dade Thromborel S

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 303CG Size: 12 x 1 ml Expiry: 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Factor X activity	%	88.0	70.4	106	Dade Innovin
	%	76.6	61.3	91.9	Stago Neoplastine CI Plus
	%	81.3	65.0	97.6	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	50.2	40.2	60.2	Siemens/Dade Pathromtin SL
	%	39.2	31.4	47.0	HemosIL Synthasil
	%	28.7	23.0	34.4	Siemens/Dade Actin FSL
	%	38.0	30.4	45.6	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	58.5	46.8	70.2	Siemens/Dade Actin FS
	%	67.3	53.8	80.8	Siemens/Dade Pathromtin SL
	%	65.1	52.1	78.1	HemosIL Synthasil
	%	60.3	48.2	72.4	Siemens/Dade Actin FSL
	%	72.7	58.2	87.2	HemosIL APTT-SP Liquid
Fibrinogen	g/L	1.54	1.23	1.85	HemosIL PT-Fibrinogen HS Plus
	mg/dL	154	123	185	
	g/L	1.73	1.38	2.08	Stago Fibrinogen / Liquid-Fib
	mg/dL	173	138	208	
	g/L	1.44	1.15	1.73	Siemens/Dade Multifibren U
	mg/dL	144	115	173	
	g/L	1.56	1.25	1.87	HemosIL Fibrinogen C
	mg/dL	156	125	187	
	g/L	1.43	1.14	1.72	Dade Thrombin
	mg/dL	143	114	172	
	g/L	2.08	1.66	2.50	Technoclone Fibrinogen
	mg/dL	208	166	250	
	g/L	1.67	1.34	2.00	Tcoag TriniCLOT Fibrinogen
	mg/dL	167	134	200	
	g/L	1.60	1.28	1.92	Biolabo Bio-Fibri
	mg/dL	160	128	192	
	g/L	1.56	1.25	1.87	Teco Teclot Fibrinogen
	mg/dL	156	125	187	
	g/L	1.55	1.24	1.86	HemosIL QFA (bovine thrombin)
	mg/dL	155	124	186	
	g/L	1.63	1.30	1.96	Human Fibrinogen
	mg/dL	163	130	196	
	g/L	1.75	1.40	2.10	Stago STA Fibri-Prest Automate
	mg/dL	175	140	210	
g/L	1.10	0.880	1.32	Bio-Ksel System PT	
mg/dL	110	88.0	132		
g/L	1.66	1.33	1.99	Bio-Ksel Fibrinogen	
mg/dL	166	133	199		
g/L	1.42	1.14	1.70	Grifols DG-FIB	
mg/dL	142	114	170		
g/L	1.46	1.17	1.75	Diagon Dia-F	
mg/dL	146	117	175		
g/L	1.13	0.904	1.36	Dade Innovin Derived Fibrinogen	
mg/dL	113	90.4	136		

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 303CG Size: 12 x 1 ml Expiry: 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Fibrinogen	g/L	1.30	1.04	1.56	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	130	104	156	
	g/L	2.13	1.70	2.56	Wiener Lab Fibrinogen
	mg/dL	213	170	256	
	g/L	1.24	0.992	1.49	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	124	99.2	149	
	g/L	1.68	1.34	2.02	Sclavo Fibrinogen
	mg/dL	168	134	202	
	g/L	1.76	1.41	2.11	Labitec Fibrinogen
	mg/dL	176	141	211	
	g/L	1.94	1.55	2.33	HemoDiagnostica Fibrinogen
	mg/dL	194	155	233	
	g/L	1.73	1.38	2.08	Helena Clauss Fibrinogen 100
	mg/dL	173	138	208	
Plasminogen activity	g/L	1.51	1.21	1.81	Coagpia Fibrinogen
	mg/dL	151	121	181	
	g/L	1.81	1.45	2.17	Beijing Succeeder Fibrinogen
Protein C activity	mg/dL	181	145	217	
	g/L	1.64	1.31	1.97	Cobas Fibrinogen
Protein S activity	mg/dL	164	131	197	
	%	68.3	54.6	82.0	Stago Stachrom Plasminogen
	%	65.3	52.2	78.4	HemosIL Plasminogen
	%	71.9	57.5	86.3	Siemens/Dade Berichrom Plasminogen
	%	70.6	56.5	84.7	Siemens/Dade Berichrom Protein C
Prothrombin Time (PT)	%	69.5	55.6	83.4	Stago StaClot
	%	64.2	51.4	77.0	IL HemosIL Protein C
	%	73.2	58.6	87.8	Siemens
	%	72.4	57.9	86.9	STACHrom Protein C
	%	64.0	44.8	83.2	STA Liatest
Prothrombin Time (PT)	%	51.0	35.7	66.3	Stago StaClot
	%	64.1	44.9	83.3	IL HemosIL Free Protein S
	%	46.7	32.7	60.7	Dade Protein S Ac
	%	63.4	44.4	82.4	Siemens Innovance Free PS Ag
	Seconds	15.4	12.3	18.5	Dade Innovin
	Seconds	14.0	11.2	16.8	Siemens/Dade Thromborel IS
	Seconds	13.6	10.9	16.3	Siemens/Dade Thromborel S
	Seconds	17.2	13.8	20.6	HemosIL PT-Fibrinogen HS Plus
	Seconds	20.6	16.5	24.7	Pacific Thromboplastin DS
	Seconds	16.6	13.3	19.9	Stago Neoplastine CI
	Seconds	16.3	13.0	19.6	Stago Neoplastine CI Plus
	Seconds	21.3	17.0	25.6	R2 Phosphoplastin RL
	Seconds	15.7	12.6	18.8	Teco TEClot PT-S
	Seconds	17.9	14.3	21.5	Biolabo Bio-TP
Seconds	14.4	11.5	17.3	Stago Neoplastin R	
Seconds	11.3	9.04	13.6	Bio-Ksel System PT	
Seconds	14.7	11.8	17.6	Human Thromboplastin	

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 303CG Size: 12 x 1 ml Expiry: 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Prothrombin Time (PT)	Seconds	14.7	11.8	17.6	Diagon PT
	Seconds	20.3	16.2	24.4	Weiner Lab Soluplastin
	Seconds	16.6	13.3	19.9	Spinreact PT
	Seconds	21.4	17.1	25.7	TCoag TriniCLOT PT Excel S
	Seconds	18.1	14.5	21.7	Media IVD PT
	Seconds	15.0	12.0	18.0	Biodevice PT
	Seconds	16.0	12.8	19.2	Biomedica QuikCoag PT-HS
	Seconds	11.5	9.20	13.8	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	16.7	13.4	20.0	Helena Thromboplastin
	Seconds	15.4	12.3	18.5	Labitec PT
	Seconds	17.9	14.3	21.5	Fortress Diagnostics PT with Calcium
	Seconds	15.1	12.1	18.1	Tokra Medikal PT
	Seconds	17.1	13.7	20.5	Coagpia PT-N
	Seconds	10.6	8.48	12.7	Bio-Ksel PT Plus
	Seconds	17.0	13.6	20.4	Beijing Succeeder PT
	Seconds	13.2	10.6	15.8	Diagon PT R
	Seconds	13.9	11.1	16.7	Cobas PT Screen
Prothrombin Time (PT) activity	%	44.8	35.8	53.8	Dade Innovin
	%	73.5	58.8	88.2	Siemens/Dade Thromborel S
	%	59.9	47.9	71.9	Stago Neoplastine CI
	%	65.2	52.2	78.2	Stago Neoplastine CI Plus
	%	74.7	59.8	89.6	HemosIL PT-Fibrinogen
	%	73.4	58.7	88.1	HemosIL PT-Fibrinogen HS Plus
	%	88.7	71.0	106	Teco TEClot PT-S
	%	63.8	51.0	76.6	Biolabo Bio-TP
	%	102	81.6	122	Stago SPA
	%	91.8	73.4	110	Stago Neoplastin R
	%	92.0	73.6	110	Bio-Ksel System PT
	%	73.8	59.0	88.6	Human Thromboplastin
	%	76.2	61.0	91.4	Diagon PT
	%	44.3	35.4	53.2	Weiner Lab Soluplastin
	%	42.2	33.8	50.6	TCoag TriniCLOT PT Excel S
	%	58.9	47.1	70.7	Media IVD PT
	%	68.5	54.8	82.2	Biodevice PT
	%	98.1	78.5	118	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	67.6	54.1	81.1	Helena Thromboplastin
	%	70.0	56.0	84.0	Labitec PT
	%	74.6	59.7	89.5	Tokra Medikal PT
	%	52.9	42.3	63.5	Coagpia PT-N
	%	101	80.8	121	Bio-Ksel PT Plus
%	72.8	58.2	87.4	Beijing Succeeder PT	
%	49.9	39.9	59.9	Diagon PT R	
%	68.8	55.0	82.6	Cobas PT Screen	
Prothrombin Time (PT) INR	INR	1.52	1.22	1.82	Dade Innovin
	INR	1.12	0.896	1.34	Siemens/Dade Thromborel IS
	INR	1.19	0.952	1.43	Siemens/Dade Thromborel S

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

Cat. No. CG5022 Lot No. 303CG

Size: 12 x 1 ml Expiry: 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
Prothrombin Time (PT) INR	INR	1.18	0.944	1.42	HemosIL PT-Fibrinogen
	INR	1.23	0.984	1.48	HemosIL PT-Fibrinogen HS Plus
	INR	1.55	1.24	1.86	Pacific Thromboplastin DS
	INR	1.42	1.14	1.70	Stago Neoplastine CI
	INR	1.32	1.06	1.58	Stago Neoplastine CI Plus
	INR	1.17	0.936	1.40	Human Thromboplastin
	INR	1.19	0.952	1.43	Teco TEClot PT-S
	INR	1.40	1.12	1.68	Biolabo Bio-TP
	INR	1.00	0.800	1.20	Stago SPA
	INR	1.04	0.832	1.25	Stago Neoplastin R
	INR	1.08	0.864	1.30	Bio-Ksel System PT
	INR	1.18	0.944	1.42	Diagon PT
	INR	1.78	1.42	2.14	Weiner Lab Soluplastin
	INR	1.36	1.09	1.63	Spinreact PT
	INR	1.89	1.51	2.27	TCoag TriniCLOT PT Excel S
	INR	1.45	1.16	1.74	Media IVD PT
	INR	1.35	1.08	1.62	Biodevice PT
	INR	1.30	1.04	1.56	Biomedica QuikCoag PT-HS
	INR	1.01	0.808	1.21	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.16	0.928	1.39	Technoclon Technoplastin HIS
	INR	1.32	1.06	1.58	Helena Thromboplastin
	INR	1.21	0.968	1.45	Labitec PT
	INR	1.71	1.37	2.05	Fortress Diagnostics PT with Calcium
	INR	1.15	0.920	1.38	Tokra Medikal PT
	INR	1.47	1.18	1.76	Coagpia PT-N
	INR	1.00	0.800	1.20	Bio-Ksel PT Plus
INR	1.31	1.05	1.57	Beijing Succeeder PT	
INR	1.29	1.03	1.55	Diagon PT R	
INR	1.33	1.06	1.60	Cobas PT Screen	
Prothrombin Time (PT) ratio	ratio	1.51	1.21	1.81	Dade Innovin
	ratio	1.19	0.952	1.43	Siemens/Dade Thromborel S
	ratio	1.32	1.06	1.58	Stago Neoplastine CI Plus
	ratio	1.38	1.10	1.66	Diagon PT
	ratio	1.11	0.888	1.33	HemosIL PT-Fibrinogen HS Plus
	ratio	1.02	0.816	1.22	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	30.3	24.2	36.4	Dade Thrombin
	Seconds	21.6	17.3	25.9	Siemens/Dade Thromboclotin
	Seconds	26.5	21.2	31.8	Stago Thrombin
	Seconds	27.4	21.9	32.9	Diagon, Dia-TT
	Seconds	23.1	18.5	27.7	HemosIL Thrombin Time 5ml
	Seconds	26.2	21.0	31.4	HemosIL Thrombin Time 8ml