

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

CAT. NO. CG5023

LOT NO. 350CG

SIZE: 12 x 1 ml

EXPIRY: 2022-09-28

GTIN: 05055273207644

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.

LIMITATION

The Randox Level 3 Coagulation Control may not be suitable for the control of aPTT on some analysers due to a slow clotting time.

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 3 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.



Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

09 Apr '21 ne

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 350CG

Size: 12 x 1 ml Expiry: 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	67.6	54.1	81.1	Tcoag TriniCLOT aPTT S
	seconds	63.5	50.8	76.2	Tcoag TriniCLOT aPTT HS
	seconds	57.0	45.6	68.4	Siemens/Dade Actin
	seconds	53.3	42.6	64.0	Siemens/Dade Actin FS
	seconds	50.9	40.7	61.1	Siemens/Dade Actin FSL
	seconds	99.0	79.2	119	Siemens/Dade Pathromtin SL
	seconds	49.6	39.7	59.5	HemosIL APTT-SP Liquid
	seconds	72.1	57.7	86.5	HemosIL Synthasil
	seconds	68.6	54.9	82.3	Pacific Hemostasis APTT-XL
	seconds	65.6	52.5	78.7	Stago aPTT
	seconds	55.5	44.4	66.6	Stago Cephascreen
	seconds	71.3	57.0	85.6	Stago CK-Prest
	seconds	64.8	51.8	77.8	Stago PTT Automate
	seconds	64.6	51.7	77.5	Teco TEClot APTT
	seconds	59.2	47.4	71.0	Human Hemostat APTT
	seconds	53.1	42.5	63.7	Bio-Ksel System APTTs
	seconds	75.4	60.3	90.5	Diagon Dia-PTT
	seconds	50.1	40.1	60.1	Weiner Lab APTT
	seconds	77.1	61.7	92.5	Futura System APTT
	seconds	60.8	48.6	73.0	Biolabo Bio-CK APTT
	seconds	67.9	54.3	81.5	Spinreact APTT
	seconds	50.1	40.1	60.1	Media IVD aPTT
	seconds	52.9	42.3	63.5	Biodevice aPTT
	seconds	56.6	45.3	67.9	Biomedica QuikCoag aPTT
	seconds	68.9	55.1	82.7	Hemosil aPTT Lyophilised Silica
	seconds	57.7	46.2	69.2	Siemens/Dade Actin Cephaloplastin
	seconds	60.1	48.1	72.1	Labitec aPTT
	seconds	56.3	45.0	67.6	Dutch Diagnostics aPTT
	seconds	71.9	57.5	86.3	Sclavo APTT-S
	seconds	56.4	45.1	67.7	Fortress Diagnostics aPTT
seconds	76.0	60.8	91.2	Tokra Medikal APTT	
seconds	49.0	39.2	58.8	Coagpia APTT-N	
seconds	92.8	74.2	111	Cobas aPTT MedS	
seconds	56.7	45.4	68.0	Biolabo Bio-Sil (APTT)	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.19	1.75	2.63	Tcoag TriniCLOT aPTT S
	ratio	1.93	1.54	2.32	Siemens/Dade Actin FSL
	ratio	1.86	1.49	2.23	Stago Cephascreen
	ratio	2.03	1.62	2.44	Stago PTT Automate
	ratio	2.25	1.80	2.70	Stago aPTT
	ratio	3.05	2.44	3.66	Siemens/Dade Pathromtin SL
	ratio	1.67	1.34	2.00	HemosIL APTT-SP Liquid
	ratio	2.43	1.94	2.92	HemosIL Synthasil

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 350CG Size: 12 x 1 ml Expiry: 2022-09-28

Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.38	1.90	2.86	Stago CK-Prest
	ratio	2.21	1.77	2.65	Human Hemostat APTT
	ratio	1.52	1.22	1.82	Bio-Ksel System APTTs
	ratio	2.11	1.69	2.53	Siemens/Dade Actin FS
	ratio	2.55	2.04	3.06	Spinreact APTT
	ratio	1.70	1.36	2.04	Media IVD aPTT
	ratio	1.94	1.55	2.33	Biodevice aPTT
	ratio	2.10	1.68	2.52	Labitec aPTT
	ratio	2.71	2.17	3.25	Sclavo APTT-S
	ratio	1.52	1.22	1.82	Coagpia APTT-N
Antithrombin III activity	%	55.2	44.2	66.2	Siemens/Dade Berichrom ATIII
	%	57.9	46.3	69.5	Helena Chrom-Z
	%	54.2	43.4	65.0	HemosIL Liquid Antithrombin
	%	57.9	46.3	69.5	Roche Chronogenic Thrombin
	%	58.8	47.0	70.6	STACHrom ATIII
	%	54.5	43.6	65.4	Siemens/Dade Antithrombin III
	%	55.3	44.2	66.4	Siemens Innovance Antithrombin III
	%	53.5	42.8	64.2	Sclavo ATIII
	%	51.8	41.4	62.2	HemoDiagnostica Antithrombin III (Fxa)
Factor II activity	%	58.2	46.6	69.8	Siemens/Dade-Behring Innovin
	%	59.5	47.6	71.4	Siemens/Dade-Behring Thromborel S
	%	54.8	43.8	65.8	HemosIL RecombiPlasTin 2G
	%	56.4	45.1	67.7	HemosIL Factor II deficient plasma
	%	60.3	48.2	72.4	Stago STA-NeoPTimal
Factor IX activity	%	53.4	42.7	64.1	Siemens/Dade Actin FS
	%	58.7	47.0	70.4	Siemens/Dade Pathromtin SL
	%	56.8	45.4	68.2	HemosIL Synthasil
	%	53.8	43.0	64.6	Stago CK-Prest
	%	52.4	41.9	62.9	Siemens/Dade Actin FSL
	%	46.9	37.5	56.3	HemosIL APTT-SP Liquid
	%	57.5	46.0	69.0	Stago Deficient / ImmunoDef IX
	%	53.3	42.6	64.0	HemosIL Factor IX deficient plasma
Factor V activity	%	49.3	39.4	59.2	Siemens/Dade-Behring Thromborel S
	%	39.7	31.8	47.6	Siemens/Dade-Behring Innovin
	%	37.9	30.3	45.5	HemosIL PT-Fibrinogen HS Plus
	%	45.1	36.1	54.1	HemosIL RecombiPlasTin 2G
	%	38.5	30.8	46.2	Stago Neoplastin R
	%	39.7	31.8	47.6	HemosIL Factor V deficient plasma
	%	35.8	28.6	43.0	Stago STA-NeoPTimal
Factor VII activity	%	74.3	59.4	89.2	Siemens/Dade-Behring Thromborel S
	%	75.4	60.3	90.5	Siemens/Dade-Behring Innovin
	%	81.1	64.9	97.3	HemosIL RecombiPlasTin 2G
	%	81.0	64.8	97.2	HemosIL Factor VII deficient plasma
	%	70.8	56.6	85.0	Stago STA-NeoPTimal
Factor VIII activity	%	36.3	29.0	43.6	Siemens/Dade Actin FS
	%	35.3	28.2	42.4	Siemens/Dade Pathromtin SL

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 350CG Size: 12 x 1 ml Expiry: 2022-09-28

Analyte	unit	Target	Range		methods
			low	high	
Factor VIII activity	%	33.0	26.4	39.6	Siemens/Dade Actin FSL
	%	34.9	27.9	41.9	HemosIL Synthasil
	%	32.5	26.0	39.0	HemosIL APTT-SP Liquid
	%	32.7	26.2	39.2	Stago Deficient / ImmunoDef VIII
	%	32.1	25.7	38.5	HemosIL Factor VIII deficient plasma
Factor X activity	%	69.8	55.8	83.8	Siemens/Dade-Behring Thromborel S
	%	65.5	52.4	78.6	Siemens/Dade-Behring Innovin
	%	67.7	54.2	81.2	Stago Neoplastine CI Plus
	%	57.6	46.1	69.1	HemosIL RecombiPlasTin 2G
	%	62.8	50.2	75.4	HemosIL Factor X deficient plasma
	%	51.3	41.0	61.6	Stago STA-NeoPTimal
Factor XI activity	%	24.7	19.8	29.6	Siemens/Dade Actin FS
	%	33.9	27.1	40.7	HemosIL Synthasil
	%	29.3	23.4	35.2	Stago CK-Prest
Factor XII activity	%	58.6	46.9	70.3	Siemens/Dade Actin FS
	%	53.3	42.6	64.0	Siemens/Dade Pathromtin SL
	%	55.0	44.0	66.0	HemosIL Synthasil
	%	54.0	43.2	64.8	Siemens/Dade Actin FSL
	%	45.9	36.7	55.1	HemosIL APTT-SP Liquid
	%	52.8	42.2	63.4	HemosIL Factor XII deficient plasma
Fibrinogen	g/L	1.72	1.38	2.06	HemosIL PT-Fibrinogen HS Plus
	mg/dL	172	138	206	
	g/L	1.66	1.33	1.99	Stago Fibrinogen / Liquid-Fib
	mg/dL	166	133	199	
	g/L	1.15	0.920	1.38	Siemens/Dade Multifibren U
	mg/dL	115	92.0	138	
	g/L	1.53	1.22	1.84	HemosIL Fibrinogen C
	mg/dL	153	122	184	
	g/L	1.41	1.13	1.69	Dade Thrombin
	mg/dL	141	113	169	
	g/L	1.87	1.50	2.24	Technoclone Fibrinogen
	mg/dL	187	150	224	
	g/L	1.60	1.28	1.92	Tcoag TriniCLOT Fibrinogen
	mg/dL	160	128	192	
	g/L	1.64	1.31	1.97	Biolabo Bio-Fibri
	mg/dL	164	131	197	
	g/L	1.38	1.10	1.66	Teco Teclot Fibrinogen
	mg/dL	138	110	166	
	g/L	1.52	1.22	1.82	HemosIL QFA (bovine thrombin)
	mg/dL	152	122	182	
g/L	1.69	1.35	2.03	Human Fibrinogen	
mg/dL	169	135	203		
g/L	1.65	1.32	1.98	Stago STA Fibri-Prest Automate	
mg/dL	165	132	198		
g/L	1.02	0.816	1.22	Bio-Ksel System PT	
mg/dL	102	81.6	122		

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 350CG Size: 12 x 1 ml Expiry: 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
Fibrinogen	g/L	1.70	1.36	2.04	Bio-Ksel Fibrinogen
	mg/dL	170	136	204	
	g/L	1.35	1.08	1.62	Diagon Dia-F
	mg/dL	135	108	162	
	g/L	1.27	1.02	1.52	Dade Innovin Derived Fibrinogen
	mg/dL	127	102	152	
	g/L	1.31	1.05	1.57	Siemens/Dade Thromboplastin Derived Fibrinogen
	mg/dL	131	105	157	
	g/L	1.50	1.20	1.80	Sclavo Fibrinogen
	mg/dL	150	120	180	
	g/L	1.60	1.28	1.92	HemoDiagnostica Fibrinogen
	mg/dL	160	128	192	
	g/L	1.72	1.38	2.06	Helena Clauss Fibrinogen 100
	mg/dL	172	138	206	
	g/L	1.27	1.02	1.52	Coagpia Fibrinogen
	mg/dL	127	102	152	
g/L	1.70	1.36	2.04	HemosIL PT-Fibrinogen	
mg/dL	170	136	204		
g/L	1.26	1.01	1.51	Beijing Succeeder Fibrinogen	
mg/dL	126	101	151		
g/L	1.59	1.27	1.91	Cobas Fibrinogen	
mg/dL	159	127	191		
Plasminogen activity	%	58.8	47.0	70.6	Stago Stachrom Plasminogen
	%	58.5	46.8	70.2	HemosIL Plasminogen
	%	64.6	51.7	77.5	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	58.6	46.9	70.3	Siemens/Dade Berichrom Protein C
	%	60.1	48.1	72.1	Stago StaClot
	%	54.7	43.8	65.6	Biomerieux VIDAS Protein C
	%	56.4	45.1	67.7	IL HemosIL Protein C
	%	59.2	47.4	71.0	Siemens
	%	61.7	49.4	74.0	STACHrom Protein C
Protein S activity	%	58.6	41.0	76.2	STA Liatest
	%	53.5	37.5	69.6	Stago StaClot
	%	57.9	40.5	75.3	IL HemosIL ProS
	%	56.7	39.7	73.7	IL HemosIL Free Protein S
	%	47.1	33.0	61.2	Dade Protein S Ac
	%	55.6	38.9	72.3	Siemens Innovance Free PS Ag
	%	47.7	33.4	62.0	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	30.1	24.1	36.1	Siemens/Dade-Behring Innovin
	Seconds	18.0	14.4	21.6	Siemens/Dade Thromborel IS
	Seconds	18.3	14.6	22.0	Siemens/Dade-Behring Thromborel S
	Seconds	28.6	22.9	34.3	HemosIL PT-Fibrinogen HS Plus
	Seconds	32.2	25.8	38.6	Pacific Thromboplastin DS
	Seconds	24.1	19.3	28.9	Stago Neoplastine CI Plus
	Seconds	24.1	19.3	28.9	Teco TEClot PT-S
	Seconds	31.9	25.5	38.3	Biolabo Bio-TP

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 350CG Size: 12 x 1 ml Expiry: 2022-09-28

Analyte	unit	Target	Range		methods
			low	high	
Prothrombin Time (PT)	Seconds	19.1	15.3	22.9	Stago Neoplastin R
	Seconds	16.8	13.4	20.2	Bio-Ksel System PT
	Seconds	22.6	18.1	27.1	Human Thromboplastin
	Seconds	25.8	20.6	31.0	Diagon PT
	Seconds	22.7	18.2	27.2	Shanghai Changdao Biotech PT
	Seconds	42.6	34.1	51.1	TCoag TriniCLOT PT Excel S
	Seconds	21.3	17.0	25.6	Media IVD PT
	Seconds	20.9	16.7	25.1	Biodevice PT
	Seconds	24.8	19.8	29.8	Biomedica QuikCoag PT-HS
	Seconds	16.7	13.4	20.0	HemosIL RecombiPlasTin 2G
	Seconds	24.0	19.2	28.8	Helena Thromboplastin LI
	Seconds	28.5	22.8	34.2	Helena Thromboplastin
	Seconds	29.4	23.5	35.3	Fortress Diagnostics PT with Calcium
	Seconds	29.1	23.3	34.9	Technoclone Technoclot PT Plus
	Seconds	24.7	19.8	29.6	Tokra Medikal PT
	Seconds	35.2	28.2	42.2	Coagpia PT-N
	Seconds	16.4	13.1	19.7	Bio-Ksel PT Plus
	Seconds	19.8	15.8	23.8	Beijing Succeeder PT
	Seconds	19.1	15.3	22.9	Cobas PT Screen
	Seconds	33.4	26.7	40.1	Stago STA-NeoPTimal
Prothrombin Time (PT) activity	%	19.9	15.9	23.9	Siemens/Dade-Behring Innovin
	%	47.1	37.7	56.5	Siemens/Dade-Behring Thromborel S
	%	38.0	30.4	45.6	Stago Neoplastine CI
	%	38.1	30.5	45.7	Stago Neoplastine CI Plus
	%	35.0	28.0	42.0	HemosIL PT-Fibrinogen HS Plus
	%	57.8	46.2	69.4	Stago Neoplastin R
	%	38.1	30.5	45.7	Human Thromboplastin
	%	16.7	13.4	20.0	TCoag TriniCLOT PT Excel S
	%	40.8	32.6	49.0	Media IVD PT
	%	39.0	31.2	46.8	Biodevice PT
	%	55.4	44.3	66.5	HemosIL RecombiPlasTin 2G
	%	18.6	14.9	22.3	Coagpia PT-N
	%	69.7	55.8	83.6	Bio-Ksel PT Plus
	%	21.7	17.4	26.0	Diagon PT R
	%	46.0	36.8	55.2	Cobas PT Screen
	%	28.4	22.7	34.1	Stago STA-NeoPTimal
Prothrombin Time (PT) INR	INR	3.06	2.45	3.67	Siemens/Dade-Behring Innovin
	INR	1.53	1.22	1.84	Siemens/Dade Thromborel IS
	INR	1.62	1.30	1.94	Siemens/Dade-Behring Thromborel S
	INR	2.17	1.74	2.60	HemosIL PT-Fibrinogen HS Plus
	INR	2.58	2.06	3.10	Pacific Thromboplastin DS
	INR	2.04	1.63	2.45	Stago Neoplastine CI Plus
	INR	2.02	1.62	2.42	Human Thromboplastin
	INR	1.88	1.50	2.26	Teco TEClot PT-S
	INR	1.26	1.01	1.51	Stago SPA
	INR	1.41	1.13	1.69	Stago Neoplastin R

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 350CG Size: 12 x 1 ml Expiry: 2022-09-28

Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) INR	INR	1.55	1.24	1.86	Bio-Ksel System PT
	INR	2.19	1.75	2.63	Diagon PT
	INR	4.84	3.87	5.81	Weiner Lab Soluplastin
	INR	1.90	1.52	2.28	Futura System Thromboplastin S
	INR	4.30	3.44	5.16	TCoag TriniCLOT PT Excel S
	INR	1.55	1.24	1.86	Media IVD PT
	INR	1.91	1.53	2.29	Biodevice PT
	INR	1.94	1.55	2.33	Biomedica QuikCoag PT-HS
	INR	1.48	1.18	1.78	HemosIL RecombiPlasTin 2G
	INR	2.46	1.97	2.95	Helena Thromboplastin
	INR	1.81	1.45	2.17	Technoclone Technoclot PT Plus
	INR	2.02	1.62	2.42	Tokra Medikal PT
	INR	3.04	2.43	3.65	Coagpia PT-N
	INR	1.50	1.20	1.80	Bio-Ksel PT Plus
	INR	1.56	1.25	1.87	Beijing Succeeder PT
	INR	1.97	1.58	2.36	Diagon PT R
	INR	1.84	1.47	2.21	Cobas PT Screen
	INR	2.64	2.11	3.17	Stago STA-NeoPTimal
Prothrombin Time (PT) ratio	ratio	2.93	2.34	3.52	Siemens/Dade-Behring Innovin
	ratio	1.62	1.30	1.94	Siemens/Dade-Behring Thromborel S
	ratio	2.00	1.60	2.40	Diagon PT
	ratio	1.84	1.47	2.21	HemosIL PT-Fibrinogen HS Plus
	ratio	3.85	3.08	4.62	TCoag TriniCLOT PT Excel S
	ratio	1.46	1.17	1.75	HemosIL RecombiPlasTin 2G
	ratio	2.52	2.02	3.02	Stago STA-NeoPTimal
Thrombin Time (TT)	Seconds	32.1	25.7	38.5	Dade Thrombin
	Seconds	29.7	23.8	35.6	Siemens/Dade Thromboclotin
	Seconds	36.7	29.4	44.0	Stago Thrombin
	Seconds	31.2	25.0	37.4	Sysmex Thrombin Time
	Seconds	34.6	27.7	41.5	Diagon, Dia-TT
	Seconds	28.7	23.0	34.4	HemosIL Thrombin Time 5ml
	Seconds	35.3	28.2	42.4	HemosIL Thrombin Time 8ml