

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

CAT NO. CG5022

LOT NO. 275CG

SIZE: 12 x 1 ml

EXPIRY: 2020-10-28

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 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. 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. CG5022 Lot No. 275CG Size: 12 x 1 ml Expiry: 2020-10-28

Range					
Analyte	unit	Target	low	high	methods
Activated Partial Thromboplastin Time (APTT)	seconds	57.7	46.2	69.2	Tcoag TriniCLOT aPTT S
	seconds	49.9	39.9	59.9	Tcoag TriniCLOT aPTT HS
	seconds	53.0	42.4	63.6	Siemens/Dade Actin
	seconds	46.7	37.4	56.0	Siemens/Dade Actin FS
	seconds	43.4	34.7	52.1	Siemens/Dade Actin FSL
	seconds	85.7	68.6	103	Siemens/Dade Actin SL
	seconds	81.5	65.2	97.8	Siemens/Dade Pathromtin SL
	seconds	56.5	45.2	67.8	Helena aPTT
	seconds	44.1	35.3	52.9	HemosIL APTT-SP Liquid
	seconds	59.1	47.3	70.9	HemosIL Synthasil
	seconds	59.1	47.3	70.9	Pacific Hemostasis APTT-XL
	seconds	54.3	43.4	65.2	Stago aPTT
	seconds	49.9	39.9	59.9	Stago Cephascreen
	seconds	58.0	46.4	69.6	Stago CK-Prest
	seconds	58.1	46.5	69.7	Stago PTT Automate
	seconds	54.2	43.4	65.0	Teco TEClot APTT
	seconds	51.3	41.0	61.6	Human Hemostat APTT
	seconds	48.3	38.6	58.0	Bio-Ksel System APTTs
	seconds	59.7	47.8	71.6	Diagon Dia-PTT
	seconds	51.3	41.0	61.6	Weiner Lab APTT
	seconds	54.0	43.2	64.8	Biolabo Bio-CK APTT
	seconds	55.4	44.3	66.5	Spinreact APTT
	seconds	54.0	43.2	64.8	Tcoag TriniCLOT Automated aPTT
	seconds	42.0	33.6	50.4	Biodevice aPTT
	seconds	48.1	38.5	57.7	Biomedica QuikCoag aPTT
	seconds	57.9	46.3	69.5	Siemens Dade Actin Cephaloplastin
	seconds	47.6	38.1	57.1	Labitec aPTT
	seconds	51.5	41.2	61.8	Sclavo APTT-S
	seconds	54.4	43.5	65.3	HemoDiagnostica aPTT
	seconds	53.5	42.8	64.2	Cypress Diagnostics aPTT
seconds	57.3	45.8	68.8	Tokra Medikal APTT	
seconds	44.4	35.5	53.3	Coagpia APTT-N	
seconds	79.3	63.4	95.2	Cobas aPTT MedS	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.64	1.31	1.97	Siemens/Dade Actin FSL
	ratio	2.61	2.09	3.13	Siemens/Dade Actin SL
	ratio	1.66	1.33	1.99	Stago Cephascreen
	ratio	1.75	1.40	2.10	Stago PTT Automate
	ratio	1.73	1.38	2.08	Stago aPTT
	ratio	2.54	2.03	3.05	Siemens/Dade Pathromtin SL
	ratio	1.42	1.14	1.70	HemosIL APTT-SP Liquid
	ratio	2.03	1.62	2.44	HemosIL Synthasil
	ratio	1.75	1.40	2.10	Pacific Hemostasis APTT-XL

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Analyte	unit	Target	Range		methods
			low	high	
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	1.56	1.25	1.87	Helena aPTT
	ratio	1.88	1.50	2.26	Stago CK-Prest
	ratio	1.98	1.58	2.38	Human Hemostat APTT
	ratio	1.42	1.14	1.70	Bio-Ksel System APTTs
	ratio	1.79	1.43	2.15	Siemens/Dade Actin FS
	ratio	1.83	1.46	2.20	Diagon Dia-PTT
	ratio	1.69	1.35	2.03	Biolabo Bio-CK APTT
	ratio	1.65	1.32	1.98	Biodevice aPTT
	ratio	1.51	1.21	1.81	Labitec aPTT
	ratio	1.71	1.37	2.05	Sclavo APTT-S
Antithrombin III activity	ratio	1.41	1.13	1.69	Coagpia APTT-N
	%	70.5	56.4	84.6	Siemens/Dade Berichrom ATIII
	%	67.3	53.8	80.8	HemosIL Liquid Antithrombin
	%	71.0	56.8	85.2	Roche Chronogenic Thrombin
	%	66.3	53.0	79.6	Hemosil Lyophilised Antithrombin III
	%	72.2	57.8	86.6	STACHrom ATIII
	%	75.2	60.2	90.2	Siemens/Dade Antithrombin III
	%	71.1	56.9	85.3	Diagon ATIII
	%	72.6	58.1	87.1	Siemens Innovance Antithrombin III
Factor II activity	%	66.6	53.3	79.9	Sclavo ATIII
	%	71.2	57.0	85.4	Dade Innovin
	%	73.9	59.1	88.7	Siemens/Dade Thromborel S
	%	72.7	58.2	87.2	Stago Neoplastine CI Plus
	%	69.2	55.4	83.0	HemosIL PT-Fibrinogen HS Plus
Factor IX activity	%	65.2	52.2	78.2	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	67.2	53.8	80.6	Siemens/Dade Actin FS
	%	64.1	51.3	76.9	Siemens/Dade Pathromtin SL
	%	58.8	47.0	70.6	HemosIL Synthasil
	%	68.0	54.4	81.6	Stago CK-Prest
	%	62.6	50.1	75.1	Siemens/Dade Actin FSL
	%	59.7	47.8	71.6	HemosIL APTT-SP Liquid
	%	72.5	58.0	87.0	Stago Deficient / ImmunoDef IX
Factor V activity	%	57.5	46.0	69.0	HemosIL Factor IX deficient plasma
	%	54.3	43.4	65.2	Stago Neoplastine CI Plus
	%	57.0	45.6	68.4	Siemens/Dade Thromborel S
	%	42.7	34.2	51.2	Dade Innovin
	%	50.3	40.2	60.4	HemosIL PT-Fibrinogen HS Plus
	%	52.5	42.0	63.0	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VII activity	%	53.0	42.4	63.6	HemosIL Factor V deficient plasma
	%	87.5	70.0	105	Stago Neoplastine CI Plus
	%	87.0	69.6	104	Siemens/Dade Thromborel S
	%	89.4	71.5	107	Dade Innovin
	%	89.7	71.8	108	HemosIL PT-Fibrinogen HS Plus
	%	96.3	77.0	116	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor VIII activity	%	98.3	78.6	118	HemosIL Factor VII deficient plasma
	%	41.9	33.5	50.3	Siemens/Dade Actin FS

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Range					
Analyte	unit	Target	low	high	methods
Factor VIII activity	%	39.5	31.6	47.4	Siemens/Dade Pathromtin SL
	%	36.6	29.3	43.9	Siemens/Dade Actin FSL
	%	36.5	29.2	43.8	HemosIL Synthasil
	%	37.6	30.1	45.1	HemosIL APTT-SP Liquid
	%	40.3	32.2	48.4	Stago STA Factor VIII
	%	40.3	32.2	48.4	Stago Deficient / ImmunoDef VIII
	%	33.9	27.1	40.7	HemosIL Factor VIII deficient plasma
Factor X activity	%	75.4	60.3	90.5	Siemens/Dade Thromborel S
	%	72.8	58.2	87.4	Dade Innovin
	%	74.1	59.3	88.9	HemosIL PT-Fibrinogen HS Plus
	%	70.0	56.0	84.0	Stago Neoplastine CI Plus
	%	66.8	53.4	80.2	HemosIL PT-Fibrinogen Recombiplastin 2G
Factor XI activity	%	39.2	31.4	47.0	Siemens/Dade Actin FS
	%	41.2	33.0	49.4	Siemens/Dade Pathromtin SL
	%	34.0	27.2	40.8	HemosIL Synthasil
	%	22.4	17.9	26.9	Siemens/Dade Actin FSL
	%	35.4	28.3	42.5	HemosIL APTT-SP Liquid
	%	37.8	30.2	45.4	HemosIL Factor XI Deficient Plasma
Factor XII activity	%	70.9	56.7	85.1	Siemens/Dade Actin FS
	%	64.6	51.7	77.5	Siemens/Dade Pathromtin SL
	%	60.8	48.6	73.0	HemosIL Synthasil
	%	57.2	45.8	68.6	Siemens/Dade Actin FSL
Fibrinogen	g/L	1.85	1.48	2.22	HemosIL PT-Fibrinogen HS Plus
	mg/dL	185	148	222	
	g/L	2.01	1.61	2.41	Helena Fibrinogen
	mg/dL	201	161	241	
	g/L	2.03	1.62	2.44	Stago Fibrinogen / Liquid-Fib
	mg/dL	203	162	244	
	g/L	1.77	1.42	2.12	Siemens/Dade Multifibren U
	mg/dL	177	142	212	
	g/L	1.95	1.56	2.34	HemosIL Fibrinogen C
	mg/dL	195	156	234	
	g/L	1.70	1.36	2.04	Dade Thrombin
	mg/dL	170	136	204	
	g/L	2.37	1.90	2.84	Technoclone Fibrinogen
	mg/dL	237	190	284	
	g/L	1.94	1.55	2.33	Tcoag TriniCLOT Fibrinogen
	mg/dL	194	155	233	
	g/L	1.93	1.54	2.32	Biolabo Bio-Fibri
	mg/dL	193	154	232	
g/L	1.84	1.47	2.21	HemosIL QFA (bovine thrombin)	
mg/dL	184	147	221		
g/L	2.01	1.61	2.41	Stago STA Fibri-Prest Automate	
mg/dL	201	161	241		
g/L	1.80	1.44	2.16	Bio-Ksel Fibrinogen	
mg/dL	180	144	216		

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Analyte	unit	Target	Range		methods
			low	high	
Fibrinogen	g/L	1.89	1.51	2.27	Diagon Dia-F
	mg/dL	189	151	227	
	g/L	1.50	1.20	1.80	Dade Innovin Derived Fibrinogen
	mg/dL	150	120	180	
	g/L	1.38	1.10	1.66	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	138	110	166	
	g/L	1.83	1.46	2.20	Sclavo Fibrinogen
	mg/dL	183	146	220	
	g/L	1.77	1.42	2.12	Labitec Fibrinogen
	mg/dL	177	142	212	
	g/L	1.92	1.54	2.30	HemoDiagnostica Fibrinogen
	mg/dL	192	154	230	
	g/L	2.03	1.62	2.44	Helena Clauss Fibrinogen 100
	mg/dL	203	162	244	
Plasminogen activity	g/L	1.68	1.34	2.02	Coagpia Fibrinogen
	mg/dL	168	134	202	
Plasminogen activity	g/L	1.97	1.58	2.36	Diagon PT
	mg/dL	197	158	236	
Plasminogen activity	g/L	2.02	1.62	2.42	Cobas Fibrinogen
	mg/dL	202	162	242	
Plasminogen activity	%	70.0	56.0	84.0	Stago Stachrom Plasminogen
	%	78.4	62.7	94.1	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	67.6	54.1	81.1	Siemens/Dade Berichrom Protein C
	%	61.5	49.2	73.8	IL HemosIL Protein C
	%	73.4	58.7	88.1	Siemens
	%	71.8	57.4	86.2	STACHrom Protein C
Protein S activity	%	64.9	45.4	84.4	STA Liatest
	%	65.8	46.1	85.5	Stago StaClot
	%	68.6	48.0	89.2	IL HemosIL Free Protein S
	%	50.0	35.0	65.0	Dade Protein S Ac
	%	67.6	47.3	87.9	Siemens Innovance Free PS Ag
	%	59.3	41.5	77.1	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	16.0	12.8	19.2	Tcoag TriniCLOT PT Excel
	Seconds	17.5	14.0	21.0	Dade Innovin
	Seconds	15.7	12.6	18.8	Siemens/Dade Thromborel IS
	Seconds	15.6	12.5	18.7	Siemens/Dade Thromborel S
	Seconds	20.4	16.3	24.5	HemosIL PT-Fibrinogen HS Plus
	Seconds	24.3	19.4	29.2	Pacific Thromboplastin DS
	Seconds	16.7	13.4	20.0	Stago Neoplastine CI
	Seconds	18.8	15.0	22.6	Stago Neoplastine CI Plus
	Seconds	22.2	17.8	26.6	R2 Phosphoplastin RL
	Seconds	18.9	15.1	22.7	Teco TEClot PT-S
	Seconds	19.9	15.9	23.9	Biolabo Bio-TP
	Seconds	16.9	13.5	20.3	Stago Neoplastin R
	Seconds	12.9	10.3	15.5	Bio-Ksel System PT
	Seconds	18.1	14.5	21.7	Human Thromboplastin

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Analyte	unit	Target	Range		methods
			low	high	
Prothrombin Time (PT)	Seconds	18.9	15.1	22.7	Diagon PT
	Seconds	21.0	16.8	25.2	Spinreact PT
	Seconds	25.2	20.2	30.2	TCoag TriniCLOT PT Excel S
	Seconds	18.2	14.6	21.8	Media IVD PT
	Seconds	15.9	12.7	19.1	Biodevice PT
	Seconds	21.3	17.0	25.6	Biomedica QuikCoag PT-HS
	Seconds	13.8	11.0	16.6	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	19.7	15.8	23.6	Helena Thromboplastin
	Seconds	17.7	14.2	21.2	Labitec PT
	Seconds	19.4	15.5	23.3	Cypress Diagnostics PT
	Seconds	18.9	15.1	22.7	Tokra Medikal PT
	Seconds	20.9	16.7	25.1	Coagpia PT-N
	Seconds	12.4	9.92	14.9	Bio-Ksel PT Plus
	Seconds	14.3	11.4	17.2	Diagon PT R
	Seconds	16.0	12.8	19.2	Cobas PT Screen
Prothrombin Time (PT) activity	%	39.6	31.7	47.5	Tcoag TriniCLOT PT Excel
	%	39.4	31.5	47.3	Dade Innovin
	%	58.7	47.0	70.4	Siemens/Dade Thromborel S
	%	53.7	43.0	64.4	Stago Neoplastine CI
	%	54.4	43.5	65.3	Stago Neoplastine CI Plus
	%	54.5	43.6	65.4	HemosIL PT-Fibrinogen HS Plus
	%	35.2	28.2	42.2	Pacific Thromboplastin DS
	%	52.5	42.0	63.0	Teco TEClot PT-S
	%	51.3	41.0	61.6	Biolabo Bio-TP
	%	68.8	55.0	82.6	Stago Neoplastin R
	%	52.2	41.8	62.6	Human Thromboplastin
	%	55.2	44.2	66.2	Diagon PT
	%	33.2	26.6	39.8	TCoag TriniCLOT PT Excel S
	%	44.3	35.4	53.2	Media IVD PT
	%	72.5	58.0	87.0	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	51.2	41.0	61.4	Helena Thromboplastin
	%	51.0	40.8	61.2	Labitec PT
	%	36.6	29.3	43.9	Coagpia PT-N
	%	90.0	72.0	108	Bio-Ksel PT Plus
	%	57.0	45.6	68.4	Diagon PT R
%	52.8	42.2	63.4	Cobas PT Screen	
Prothrombin Time (PT) INR	INR	1.88	1.50	2.26	Tcoag TriniCLOT PT Excel
	INR	1.73	1.38	2.08	Dade Innovin
	INR	1.33	1.06	1.60	Siemens/Dade Thromborel IS
	INR	1.34	1.07	1.61	Siemens/Dade Thromborel S
	INR	1.52	1.22	1.82	HemosIL PT-Fibrinogen HS Plus
	INR	1.79	1.43	2.15	Pacific Thromboplastin DS
	INR	1.60	1.28	1.92	Stago Neoplastine CI
	INR	1.56	1.25	1.87	Stago Neoplastine CI Plus
	INR	1.51	1.21	1.81	Human Thromboplastin
	INR	1.46	1.17	1.75	Teco TEClot PT-S

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Analyte	unit	Target	Range		methods
			low	high	
Prothrombin Time (PT) INR	INR	1.66	1.33	1.99	Biolabo Bio-TP
	INR	1.22	0.976	1.46	Stago Neoplastin R
	INR	1.17	0.936	1.40	Bio-Ksel System PT
	INR	1.48	1.18	1.78	Diagon PT
	INR	1.82	1.46	2.18	Weiner Lab Soluplastin
	INR	1.73	1.38	2.08	Spinreact PT
	INR	2.25	1.80	2.70	TCoag TriniCLOT PT Excel S
	INR	1.45	1.16	1.74	Media IVD PT
	INR	1.30	1.04	1.56	Biodevice PT
	INR	1.60	1.28	1.92	Biomedica QuikCoag PT-HS
	INR	1.21	0.968	1.45	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	1.34	1.07	1.61	Technoclone Technoplastin HIS
	INR	1.57	1.26	1.88	Helena Thromboplastin
	INR	1.54	1.23	1.85	Labitec PT
	INR	1.54	1.23	1.85	Cypress Diagnostics PT
	INR	1.47	1.18	1.76	Tokra Medikal PT
	INR	1.73	1.38	2.08	Coagpia PT-N
	INR	1.14	0.912	1.37	Bio-Ksel PT Plus
INR	1.35	1.08	1.62	Diagon PT R	
INR	1.51	1.21	1.81	Cobas PT Screen	
Prothrombin Time (PT) ratio	ratio	1.80	1.44	2.16	Dade Innovin
	ratio	1.35	1.08	1.62	Siemens/Dade Thromborel S
	ratio	1.53	1.22	1.84	Stago Neoplastine CI Plus
	ratio	1.20	0.960	1.44	Stago Neoplastin R
	ratio	1.54	1.23	1.85	Diagon PT
	ratio	1.38	1.10	1.66	HemosIL PT-Fibrinogen HS Plus
	ratio	1.22	0.976	1.46	HemosIL PT-Fibrinogen Recombiplastin 2G
Thrombin Time (TT)	Seconds	29.9	23.9	35.9	Dade Thrombin
	Seconds	21.1	16.9	25.3	Siemens/Dade Thromboclotin
	Seconds	27.6	22.1	33.1	Stago Thrombin
	Seconds	29.6	23.7	35.5	Sysmex Thrombin Time
	Seconds	27.3	21.8	32.8	Diagon, Dia-TT
	Seconds	23.5	18.8	28.2	HemosIL Thrombin Time 5ml
	Seconds	33.6	26.9	40.3	HemosIL Thrombin Time 8ml