COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat No. CG5023 **Lot No.** 181CG
Size: 12 x 1 ml **Expiry:** 2018-02

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 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.

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Cat. No. CG5023 Lot No. 181CG Size: 12 x 1 ml Expiry: 2018-02

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT)	seconds	109	83.2	135	Tcoag TriniCLOT aPTT S
	seconds	114	91.2	137	Tcoag TriniCLOT aPTT HS
	seconds	122	88.7	155	Siemens/Dade Actin
	seconds	105	76.0	134	Siemens/Dade Actin FS
	seconds	77.2	58.6	95.8	Siemens/Dade Actin FSL
	seconds	182	130	234	Siemens/Dade Pathromtin SL
	seconds	89.7	71.8	108	HemosIL APTT-SP Liquid
	seconds	90.9	72.7	109	HemosIL Synthasil
	seconds	89.9	67.6	112	HemosIL Synthafax
	seconds	82.4	62.9	102	Pacific Hemostasis APTT-XL
	seconds	106	84.8	127	Stago aPTT
	seconds	101	80.8	121	Stago Cephascreen
	seconds	104	82.0	126	Stago CK-Prest
	seconds	110	88.0	132	Stago PTT Automate
	seconds	97.5	72.0	123	Teco TEClot APTT
	seconds	85.4	60.0	111	Bio-Ksel System APTTs
	seconds	117	91.5	143	Diagon Dia-PTT
	seconds	101	74.1	128	Weiner Lab APTT
	seconds	82.3	64.9	99.7	Futura System APTT
	seconds	103	82.3	124	Biolabo Bio-CK APTT
	seconds	72.9	58.3	87.5	Vital Diagnostics ElectaLab APTT
	seconds	66.0	52.8	79.2	Technology-Standard aPTT
	seconds	115	92.0	138	Tcoag TriniCLOT Automated aPTT
	seconds	74.1	59.3	88.9	Biomedica QuikCoag aPTT
	seconds	122	88.8	155	Siemens Dade Actin Cephaloplastin
	seconds	95.4	76.3	114	Renam APTT
	seconds	97.8	78.2	117	Technoclone Siron aPTT
	seconds	105	84.0	126	Sclavo APTT-S
	seconds	112	89.6	134	HemoDiagnostica aPTT
	seconds	105	84.0	126	LTA APTT Ellagic Acid
	seconds	70.8	54.8	86.8	Coagpia APTT-N
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	2.79	2.23	3.35	Siemens/Dade Actin FSL
	ratio	6.33	4.96	7.70	Siemens/Dade Actin SL
	ratio	3.34	2.67	4.01	Stago Cephascreen
	ratio	3.13	2.50	3.76	Stago PTT Automate
	ratio	3.27	2.62	3.92	Stago aPTT
	ratio	5.66	4.53	6.79	Siemens/Dade Pathromtin SL
	ratio	2.93	2.34	3.52	HemosIL APTT-SP Liquid
	ratio	3.00	2.40	3.60	HemosIL Synthasil
	ratio	2.54	2.03	3.05	Pacific Hemostasis APTT-XL
	ratio	3.29	2.52	4.06	Stago CK-Prest
	ratio	2.73	2.04	3.42	Bio-Ksel System APTTs

%

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 181CG Size: 12 x 1 ml Expiry: 2018-02

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Activated Partial Thromboplastin Time (APTT) Ratio	ratio	3.90	2.96	4.84	Siemens/Dade Actin FS
	ratio	3.56	2.85	4.27	Diagon Dia-PTT
	ratio	3.54	2.83	4.25	Biolabo Bio-CK APTT
	ratio	3.85	3.08	4.62	Tcoag TriniCLOT Automated aPTT
	ratio	5.20	4.16	6.24	Biodevice aPTT
	ratio	3.57	2.86	4.28	Sclavo APTT-S
	ratio	2.28	1.79	2.77	Coagpia APTT-N
Antithrombin III activity	%	44.0	35.2	52.8	Tcoag TriniCHROM Antithrombin
	%	40.1	30.9	49.3	Siemens/Dade Berichrom ATIII
	%	36.0	28.8	43.2	HemosIL Liquid Antithrombin
	%	40.5	32.4	48.6	Chromogenix Coamatic LR
	%	42.8	34.2	51.4	Roche Chronogenic Thrombin
	%	40.1	32.1	48.1	STAChrom ATIII
	%	38.9	28.6	49.2	Siemens/Dade Antithrombin III
	%	45.8	36.6	55.0	Biodevice ATIII
	%	41.0	32.8	49.2	Siemens Innovance Antithrombin III
	%	42.8	33.3	52.3	Sclavo ATIII
Factor II activity	%	10.7	8.45	13.0	Dade Innovin
	%	9.27	7.42	11.1	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	10.2	8.16	12.2	Stago Neoplastin R
Factor IX activity	%	11.5	9.20	13.8	Stago PTT Automate
	%	9.74	7.79	11.7	Siemens/Dade Actin FS
	%	9.25	6.95	11.6	HemosIL Synthasil
	%	11.3	9.04	13.6	Stago CK-Prest
	%	12.2	9.76	14.6	Siemens/Dade Actin FSL
Factor V activity	%	22.0	17.6	26.4	Stago Neoplastine CI Plus
	%	22.0	17.4	26.6	Siemens/Dade Thromborel S
	%	20.3	16.2	24.4	Dade Innovin
	%	19.9	14.4	25.4	HemosIL PT-Fibrinogen HS Plus
	%	20.0	15.7	24.3	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	19.8	15.8	23.8	Stago Neoplastin R
	%	20.5	15.6	25.4	HemosIL Factor V deficient plasma
Factor VII activity	%	14.0	11.2	16.8	Stago Neoplastine CI Plus
	%	11.5	8.47	14.5	Siemens/Dade Thromborel S
	%	13.9	11.1	16.7	Dade Innovin
	%	13.2	9.40	17.0	HemosIL PT-Fibrinogen HS Plus
	%	14.5	11.6	17.4	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	12.8	10.2	15.4	Stago Neoplastin R
Factor VIII activity	%	16.7	12.5	20.9	Stago CK-Prest
	%	20.0	16.0	24.0	Stago PTT Automate
	%	18.5	14.8	22.2	Siemens/Dade Actin FS
	%	20.2	16.2	24.2	Siemens/Dade Pathromtin SL
	%	19.0	15.0	23.0	Siemens/Dade Actin FSL
	%	18.3	12.9	23.7	HemosIL Synthasil
Factor X activity	%	10.6	7.95	13.3	Siemens/Dade Thromborel S
	%	10.9	8.44	13.4	Dade Innovin

%

COAGULATION CONTROL - LEVEL 3 (COAG CONTROL 3)

Cat. No. CG5023 Lot No. 181CG Size: 12 x 1 ml Expiry: 2018-02

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Factor X activity	%	8.60	6.81	10.4	Stago Neoplastine CI Plus
	%	9.28	7.42	11.1	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	10.0	8.00	12.0	Stago Neoplastin R
Factor XI activity	%	14.2	11.4	17.0	Siemens/Dade Actin FS
	%	13.8	10.5	17.1	HemosIL Synthasil
	%	14.3	11.4	17.2	Stago aPTT
Factor XII activity	%	37.8	30.2	45.4	Siemens/Dade Pathromtin SL
	%	35.7	28.6	42.8	HemosIL Synthasil
	%	48.3	38.6	58.0	Siemens/Dade Actin FSL
	%	41.4	33.1	49.7	HemosIL APTT-SP Liquid
	%	45.3	36.2	54.4	Stago CK-Prest
Fibrinogen	g/L	1.03	0.762	1.30	HemosIL PT-Fibrinogen HS Plus
	mg/dL	103	76.2	130	
	g/L	1.09	0.872	1.31	Stago Fibrinogen
	mg/dL	109	87.2	131	
	g/L	1.07	0.856	1.28	Tcoag TriniCLOT Thrombin Time
	mg/dL	107	85.6	128	
	g/L	1.10	0.880	1.32	Dade Multifibrin
	mg/dL	110	88.0	132	
	g/L	1.10	0.880	1.32	HemosIL Fibrinogen C
	mg/dL	110	88.0	132	
	g/L	1.05	0.840	1.26	Dade Thrombin
	mg/dL	105	84.0	126	
	g/L	0.980	0.784	1.18	Technoclone Fibrinogen
	mg/dL	98.0	78.4	118	
	g/L	1.11	0.877	1.34	Tcoag TriniCLOT Fibrinogen
	mg/dL	111	87.7	134	
	g/L	1.12	0.896	1.34	Biolabo Bio-Fibri
	mg/dL	112	89.6	134	
	g/L	1.28	1.02	1.54	Teco Teclot Fibrinogen
	mg/dL	128	102	154	
	g/L	1.07	0.856	1.28	HemosIL QFA (bovine thrombin)
	mg/dL	107	85.6	128	
	g/L	1.18	0.944	1.42	Human Fibrinogen
	mg/dL	118	94.4	142	
	g/L	1.09	0.872	1.31	Stago STA Fibri-Prest Automate
	mg/dL	109	87.2	131	
	g/L	1.06	0.848	1.27	Bio-Ksel System PT
	mg/dL	106	84.8	127	
	g/L	1.05	0.840	1.26	Bio-Ksel Fibrinogen
	mg/dL	105	84.0	126	
	g/L	1.13	0.904	1.36	Diagon Dia-FIB
	mg/dL	113	90.4	136	
	g/L	0.980	0.784	1.18	Dade Innovin Derived Fibrinogen
	mg/dL	98.0	78.4	118	
	g/L	1.38	0.993	1.77	Liofilchem Fibrinogen
	mg/dL	138	99.3	177	

%

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Fibrinogen	g/L	1.19	0.952	1.43	Helena Thrombin
	mg/dL	119	95.2	143	
	g/L	1.02	0.734	1.31	HemosIL PT-Fibrinogen Recombiplastin 2G
	mg/dL	102	73.4	131	
	g/L	1.14	0.884	1.40	Sclavo Fibrinogen
	mg/dL	114	88.4	140	
	g/L	1.17	0.936	1.40	HemoDiagnostica Fibrinogen
	mg/dL	117	93.6	140	
	g/L	1.15	0.805	1.50	Beijing Steelex Fibrinogen
	mg/dL	115	80.5	150	
	g/L	1.19	0.952	1.43	Coagpia Fibrinogen
	mg/dL	119	95.2	143	
Plasminogen activity	%	51.0	40.8	61.2	Stago Stachrom Plasminogen
	%	42.4	33.9	50.9	HemosIL Plasminogen
	%	50.0	40.0	60.0	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	15.5	12.4	18.6	Siemens/Dade Berichrom Protein C
	%	10.3	8.24	12.4	IL HemosIL Protein C
	%	14.8	10.7	18.9	Siemens
	%	15.7	12.6	18.8	STAChrom Protein C
	%	14.5	11.6	17.4	Hyphen Biophen Protein C
	%	14.6	11.7	17.5	Chromogenix Coatest APC
Protein S activity	%	16.0	11.2	20.8	STA Liatest
	%	12.0	8.40	15.6	IL HemosIL Free Protein S
	%	9.44	6.61	12.3	Dade Protein S Ac
	%	14.8	10.4	19.2	Siemens Innovance Free PS Ag
Prothrombin Time (PT)	Seconds	33.1	26.5	39.7	Tcoag TriniCLOT PT Excel
	Seconds	43.2	34.6	51.8	Tcoag TriniCLOT PT HTF
	Seconds	35.2	28.2	42.2	Dade Innovin
	Seconds	46.6	37.3	55.9	Siemens/Dade Thromborel IS
	Seconds	47.9	38.3	57.5	Siemens/Dade Thromborel S
	Seconds	59.0	47.2	70.8	HemosIL PT-Fibrinogen HS Plus
	Seconds	54.0	43.2	64.8	STA Hepato Quick
	Seconds	50.3	40.2	60.4	Stago Neoplastine CI
	Seconds	53.5	42.8	64.2	Stago Neoplastine CI Plus
	Seconds	54.0	38.8	69.2	Teco TEClot PT-S
	Seconds	52.6	37.8	67.4	Biolabo Bio-TP
	Seconds	51.5	41.2	61.8	Stago SPA
	Seconds	60.0	48.0	72.0	Stago Neoplastin R
	Seconds	41.6	33.3	49.9	Bio-Ksel System PT
	Seconds	54.1	43.3	64.9	Human Thromboplastin
	Seconds	52.2	37.8	66.6	Diagon, Dia-PT
	Seconds	54.0	43.2	64.8	Weiner Lab Soluplastin
	Seconds	54.1	43.3	64.9	Spinreact PT
	Seconds	51.7	41.4	62.0	Vital Diagnostics ElectaLab PT
	Seconds	62.9	46.5	79.3	TCoag TriniCLOT PT Excel S

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT)	Seconds	51.4	41.1	61.7	Biodevice PT
	Seconds	49.9	39.8	60.0	Biomedica QuikCoag PT-HS
	Seconds	44.8	35.8	53.8	HemosIL PT-Fibrinogen Recombiplastin 2G
	Seconds	54.4	43.5	65.3	Helena Thromboplastin LI
	Seconds	55.0	44.0	66.0	Technoclone Technoplastin HIS
	Seconds	56.3	45.0	67.6	Labitec PT
	Seconds	41.4	33.1	49.7	Technoclone Technoclot PT Plus
	Seconds	41.6	33.3	49.9	Tokra Medikal PT
	Seconds	54.6	43.7	65.5	Coagpia PT-N
	Seconds	41.0	32.8	49.2	Bio-Ksel PT Plus
Prothrombin Time (PT) activity	%	14.5	11.6	17.4	Tcoag TriniCLOT PT Excel
	%	17.7	14.2	21.2	Dade Innovin
	%	16.0	12.5	19.5	Siemens/Dade Thromborel S
	%	16.1	12.9	19.3	Stago Neoplastine CI
	%	13.6	10.9	16.3	Stago Neoplastine CI Plus
	%	13.3	10.6	16.0	HemosIL PT-Fibrinogen HS Plus
	%	13.5	10.8	16.2	Biolabo Bio-TP
	%	11.7	9.36	14.0	Stago SPA
	%	14.7	11.8	17.6	Stago Neoplastin R
	%	25.8	20.6	31.0	Bio-Ksel System PT
	%	14.2	11.4	17.0	Human Thromboplastin
	%	16.5	12.6	20.4	Diagon, Dia-PT
	%	20.2	16.2	24.2	Futura System Thromboplastin S
	%	16.1	12.7	19.5	HemosIL PT-Fibrinogen Recombiplastin 2G
	%	12.7	10.2	15.2	Technoclone Technoclot PT Plus
	%	11.2	8.96	13.4	Coagpia PT-N
Prothrombin Time (PT) INR	INR	7.78	6.22	9.34	Tcoag TriniCLOT PT Excel
	INR	4.39	3.38	5.40	Tcoag TriniCLOT PT HTF
	INR	3.21	2.57	3.85	Dade Innovin
	INR	3.98	3.18	4.78	Siemens/Dade Thromborel IS
	INR	4.15	3.32	4.98	Siemens/Dade Thromborel S
	INR	5.33	4.26	6.40	HemosIL PT-Fibrinogen HS Plus
	INR	6.81	5.12	8.50	STA Hepato Quick
	INR	6.33	5.06	7.60	Stago Neoplastine CI
	INR	5.99	4.79	7.19	Stago Neoplastine CI Plus
	INR	4.36	3.07	5.65	Human Thromboplastin
	INR	4.39	3.51	5.27	Teco TEClot PT-S
	INR	5.93	4.73	7.13	Biolabo Bio-TP
	INR	4.29	3.43	5.15	Stago SPA
	INR	4.06	3.25	4.87	Stago Neoplastin R
	INR	3.87	3.10	4.64	Bio-Ksel System PT
	INR	4.46	3.57	5.35	Grifols DG-PT
	INR	4.72	3.78	5.66	Diagon, Dia-PT
	INR	5.29	3.77	6.81	Weiner Lab Soluplastin
	INR	4.54	3.63	5.45	Vital Diagnostics ElectaLab PT
	INR	3.99	3.19	4.79	Gernon Hemoplastin PT

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prothrombin Time (PT) INR	INR	4.88	3.90	5.86	Biodevice PT
	INR	3.99	3.19	4.79	HemosIL PT-Fibrinogen Recombiplastin 2G
	INR	4.07	3.26	4.88	Helena Thromboplastin LI
	INR	3.23	2.58	3.88	Technoclone Technoclot PT Plus
	INR	4.20	3.36	5.04	Tokra Medikal PT
	INR	4.53	3.44	5.62	Coagpia PT-N
	INR	3.88	3.10	4.66	Bio-Ksel PT Plus
Prothrombin Time (PT) ratio	ratio	3.47	2.78	4.16	Dade Innovin
	ratio	4.17	3.34	5.00	Siemens/Dade Thromborel S
	ratio	4.06	3.25	4.87	Stago Neoplastine CI Plus
	ratio	4.59	3.67	5.51	Stago Neoplastin R
	ratio	3.85	3.08	4.62	Diagon, Dia-PT
	ratio	4.19	3.35	5.03	HemosIL PT-Fibrinogen HS Plus
	ratio	3.93	3.14	4.72	HemosIL PT-Fibrinogen Recombiplastin 2G
	ratio	4.15	3.32	4.98	Technoclone Technoplastin HIS
Thrombin Time (TT)	Seconds	23.9	19.1	28.7	Siemens/Dade Thromboclotin
	Seconds	26.0	20.8	31.2	Stago Thrombin
	Seconds	34.2	27.4	41.0	Sysmex Thrombin Time
	Seconds	26.7	21.4	32.0	Human - Hemostat
	Seconds	24.5	19.6	29.4	Teco TEClot APTT
	Seconds	21.6	17.3	25.9	Technoclone Thrombin Reagent
	Seconds	30.5	23.7	37.3	HemosIL Thrombin Time 5ml
	Seconds	41.1	32.9	49.3	HemosIL Thrombin Time 8ml