

COAGULATION CONTROL - LEVEL 2 (COAG CONTROL 2)

CAT. NO. CG5022 **LOT NO.** 385CG
SIZE: 12 x 1 ml **EXPIRY:** 2024-04-28
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

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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.

EC	REP
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Analyte	unit	Target	Range		methods
			low	high	
Fibrinogen	g/L	1.98	1.58	2.38	Human Fibrinogen
	mg/dL	198	158	238	
	g/L	1.86	1.49	2.23	Stago STA Fibri-Prest Automate
	mg/dL	186	149	223	
	g/L	1.20	0.960	1.44	Bio-Ksel System PT
	mg/dL	120	96.0	144	
	g/L	1.96	1.57	2.35	Bio-Ksel Fibrinogen
	mg/dL	196	157	235	
	g/L	1.57	1.26	1.88	Diagon Dia-F
	mg/dL	157	126	188	
	g/L	1.28	1.02	1.54	Dade Innovin Derived Fibrinogen
	mg/dL	128	102	154	
	g/L	1.64	1.31	1.97	Technology-Standard Fibrinogen
	mg/dL	164	131	197	
	g/L	2.09	1.67	2.51	Wiener Lab Fibrinogen
	mg/dL	209	167	251	
	g/L	1.40	1.12	1.68	HemosIL RecombiPlasTin 2G
	mg/dL	140	112	168	
	g/L	1.90	1.52	2.28	Sclavo Fibrinogen
	mg/dL	190	152	228	
g/L	1.94	1.55	2.33	HemoDiagnostica Fibrinogen	
mg/dL	194	155	233		
g/L	1.51	1.21	1.81	Cypress Diagnostics Fibrinogen	
mg/dL	151	121	181		
g/L	1.98	1.58	2.38	Helena Clauss Fibrinogen 100	
mg/dL	198	158	238		
g/L	1.86	1.49	2.23	Cobas Fibrinogen	
mg/dL	186	149	223		
g/L	1.77	1.42	2.12	Yumizen G Fibrinogen	
mg/dL	177	142	212		
g/L	1.72	1.38	2.06	Roche Cobas t511/t711 Fibrinogen	
mg/dL	172	138	206		
g/L	1.82	1.46	2.18	Roche Cobas t411 Fibrinogen	
mg/dL	182	146	218		
g/L	1.68	1.34	2.02	Mindray/LongIsland Fibrinogen	
mg/dL	168	134	202		
Plasminogen activity	%	70.6	56.5	84.7	HemosIL Plasminogen
	%	78.1	62.5	93.7	Siemens/Dade Berichrom Plasminogen
Protein C activity	%	67.5	54.0	81.0	Siemens/Dade Berichrom Protein C
	%	75.4	60.3	90.5	Stago StaClot
	%	72.8	58.2	87.4	Biomerieux VIDAS Protein C
	%	63.1	50.5	75.7	IL HemosIL Protein C
	%	74.7	59.8	89.6	Siemens
	%	70.4	56.3	84.5	STACHrom Protein C
Protein S activity	%	74.1	51.9	96.3	STA Liatest
	%	63.0	44.1	81.9	Stago StaClot

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Analyte	unit	Target	low	high	methods
Protein S activity	%	78.0	54.6	101	IL HemosIL ProS
	%	73.9	51.7	96.1	IL HemosIL Free Protein S
	%	59.9	41.9	77.9	Dade Protein S Ac
	%	69.4	48.6	90.2	Siemens Innovance Free PS Ag
	%	64.9	45.4	84.4	IL HemosIL Protein S Activity
Prothrombin Time (PT)	Seconds	17.8	14.2	21.4	Siemens/Dade-Behring Innovin
	Seconds	15.3	12.2	18.4	Siemens/Dade Thromborel IS
	Seconds	14.7	11.8	17.6	Siemens/Dade-Behring Thromborel S
	Seconds	20.1	16.1	24.1	HemosIL PT-Fibrinogen HS Plus
	Seconds	19.6	15.7	23.5	Pacific Thromboplastin DS
	Seconds	21.7	17.4	26.0	Stago Neoplastine CI
	Seconds	19.2	15.4	23.0	Stago Neoplastine CI Plus
	Seconds	17.3	13.8	20.8	Teco TEClot PT-S
	Seconds	20.3	16.2	24.4	Biolabo Bio-TP
	Seconds	16.5	13.2	19.8	Stago Neoplastin R
	Seconds	13.2	10.6	15.8	Bio-Ksel System PT
	Seconds	16.7	13.4	20.0	Human Thromboplastin
	Seconds	17.5	14.0	21.0	Diagon PT
	Seconds	17.8	14.2	21.4	Spinreact PT
	Seconds	18.2	14.6	21.8	Technology-Standard PT
	Seconds	24.0	19.2	28.8	TCoag TriniCLOT PT Excel S
	Seconds	19.4	15.5	23.3	Biomedica QuikCoag PT-HS
	Seconds	13.8	11.0	16.6	HemosIL RecombiPlasTin 2G
	Seconds	18.6	14.9	22.3	Helena Thromboplastin
	Seconds	15.0	12.0	18.0	Labitec PT
	Seconds	17.7	14.2	21.2	Sclavo PT
	Seconds	17.0	13.6	20.4	Cypress Diagnostics PT
	Seconds	13.2	10.6	15.8	Bio-Ksel PT Plus
	Seconds	18.0	14.4	21.6	Beijing Succeeder PT
	Seconds	15.9	12.7	19.1	Diagon PT R
	Seconds	15.2	12.2	18.2	Cobas PT Screen
	Seconds	23.2	18.6	27.8	Stago STA-NeoPTimal
	Seconds	18.9	15.1	22.7	Yumizen G PT
	Seconds	14.4	11.5	17.3	HemosIL ReadiPlasTin
	Seconds	18.5	14.8	22.2	Roche Cobas PT Rec
Prothrombin Time (PT) activity	%	37.9	30.3	45.5	Siemens/Dade-Behring Innovin
	%	63.9	51.1	76.7	Siemens/Dade-Behring Thromborel S
	%	48.3	38.6	58.0	Stago Neoplastine CI
	%	54.7	43.8	65.6	Stago Neoplastine CI Plus
	%	58.8	47.0	70.6	HemosIL PT-Fibrinogen HS Plus
	%	56.4	45.1	67.7	Teco TEClot PT-S
	%	81.9	65.5	98.3	Stago SPA
	%	70.9	56.7	85.1	Stago Neoplastin R
	%	44.8	35.8	53.8	Diagon PT
	%	59.4	47.5	71.3	Technology-Standard PT
	%	33.4	26.7	40.1	TCoag TriniCLOT PT Excel S

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT) activity	%	74.8	59.8	89.8	HemosIL RecombiPlasTin 2G
	%	52.0	41.6	62.4	Helena Thromboplastin
	%	63.3	50.6	76.0	Sclavo PT
	%	80.3	64.2	96.4	Bio-Ksel PT Plus
	%	62.1	49.7	74.5	Cobas PT Screen
	%	44.0	35.2	52.8	Stago STA-NeoPTimal
	%	69.2	55.4	83.0	HemosIL ReadiPlasTin
	%	31.2	25.0	37.4	Roche Cobas PT Rec
Prothrombin Time (PT) INR	INR	1.77	1.42	2.12	Siemens/Dade-Behring Innovin
	INR	1.29	1.03	1.55	Siemens/Dade-Behring Thromborel S
	INR	1.40	1.12	1.68	HemosIL PT-Fibrinogen HS Plus
	INR	1.48	1.18	1.78	Pacific Thromboplastin DS
	INR	1.66	1.33	1.99	Stago Neoplastine CI
	INR	1.53	1.22	1.84	Stago Neoplastine CI Plus
	INR	1.40	1.12	1.68	Human Thromboplastin
	INR	1.35	1.08	1.62	Teco TEClot PT-S
	INR	1.09	0.872	1.31	Stago SPA
	INR	1.21	0.968	1.45	Stago Neoplastin R
	INR	1.22	0.976	1.46	Bio-Ksel System PT
	INR	1.47	1.18	1.76	Diagon PT
	INR	1.77	1.42	2.12	Spinreact PT
	INR	1.48	1.18	1.78	Technology-Standard PT
	INR	2.05	1.64	2.46	TCoag TriniCLOT PT Excel S
	INR	1.56	1.25	1.87	Biomedica QuikCoag PT-HS
	INR	1.22	0.976	1.46	HemosIL RecombiPlasTin 2G
	INR	1.36	1.09	1.63	Technoclon Technoplastin HIS
	INR	1.66	1.33	1.99	Helena Thromboplastin
	INR	1.38	1.10	1.66	Labitec PT
	INR	1.40	1.12	1.68	Sclavo PT
	INR	1.51	1.21	1.81	Haemo Diagnostics Thromboplastin
	INR	1.24	0.992	1.49	Bio-Ksel PT Plus
	INR	1.39	1.11	1.67	Beijing Succeeder PT
	INR	1.49	1.19	1.79	Diagon PT R
	INR	1.45	1.16	1.74	Cobas PT Screen
	INR	1.78	1.42	2.14	Stago STA-NeoPTimal
	INR	1.59	1.27	1.91	Yumizen G PT Reco
	INR	1.36	1.09	1.63	Rayto Prothrombin Time Reagent
	INR	1.27	1.02	1.52	HemosIL ReadiPlasTin
	INR	2.02	1.62	2.42	Roche Cobas PT Rec
	Prothrombin Time (PT) ratio	ratio	1.75	1.40	2.10
ratio		1.29	1.03	1.55	Siemens/Dade-Behring Thromborel S
ratio		1.50	1.20	1.80	Stago Neoplastine CI Plus
ratio		1.31	1.05	1.57	HemosIL PT-Fibrinogen HS Plus
ratio		1.19	0.952	1.43	HemosIL RecombiPlasTin 2G
ratio		1.36	1.09	1.63	Sclavo PT
ratio		1.75	1.40	2.10	Stago STA-NeoPTimal

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Range					
Analyte	unit	Target	low	high	methods
Prothrombin Time (PT)	ratio	1.25	1.00	1.50	HemosIL ReadiPlasTin
Thrombin Time (TT)	Seconds	28.5	22.8	34.2	Dade Thrombin
	Seconds	23.6	18.9	28.3	Siemens/Dade Thromboclotin
	Seconds	28.8	23.0	34.6	Stago Thrombin
	Seconds	28.6	22.9	34.3	Sysmex Thrombin Time
	Seconds	21.5	17.2	25.8	Helena Thrombin Clotting Time rgt
	Seconds	23.6	18.9	28.3	HemosIL Thrombin Time 5ml
	Seconds	32.1	25.7	38.5	HemosIL Thrombin Time 8ml
	Seconds	31.7	25.4	38.0	Siemens BC Thrombin