

PLASMA CONTROL LEVEL 1 (LYOPHILISED)

DESCRIPTION	QCCPCL1
PLASMA CONTROL LEVEL 1	5x1mL

Intended Use:

Plasma Controls are intended to be used as a quality control material for determining accuracy and precision of coagulation assays listed in this insert.

Preparation and Stability:

Unopened vials are stable up to the expiry date on the vial label when stored tightly capped at 2 - 8°C.

Open the vial carefully without the loss of any lyophilised material and add 1ml (One ml) of distilled water. Swirl gently and ensure that all the material has gone into solution. Set aside for 10 - 15 minutes, mix gently and use.

Once reconstituted, Fibrinogen, aPTT, Thrombin time, Antithrombin III and D-Dimer are stable for a period of 48 hours when stored tightly capped at 2 - 25°C. PT is stable for 24 hours when stored tightly capped at 2 - 25°C.

Assayed values:

Value assignment is performed in a number of European reference laboratories and is a mean of the results thus obtained. It is suggested that individual laboratories, perform replicate analysis to work out their own mean values and assay ranges before proceeding with the usage of these controls.

Summary of Values:

LOT NO. A3481 EXP: 2021/07

Analyte	Units	Plasma Control Level 1 A3481 (2021-07)
Prothrombin Time (PT)		
HemosIL RecombiPlasTin 2G	INR	1.04 (0.94 – 1.14)
HemosIL RecombiPlasTin	INR	1.06 (0.95 – 1.17)
HemosIL PT-Fib HS Plus	INR	1.08 (0.98 – 1.18)
Stago/Roche STA Neoplastin plus	INR	1.05 (0.95 – 1.15)
Siemens PT Innovin	INR	1.15 (1.06 – 1.24)
Siemens PT Thromborel S	INR	1.08 (0.97 – 1.19)
Prothrombin Time (PT)		
HemosIL RecombiPlasTin 2G	Seconds	11.7 (9.6 – 13.7)
HemosIL RecombiPlasTin	Seconds	11.8 (8.9 – 14.7)
HemosIL PT-Fib HS Plus	Seconds	16.1 (14.9 – 17.3)
Stago/Roche STA Neoplastin plus	Seconds	14.5 (13.6 – 15.4)
Siemens PT Innovin	Seconds	N/A
Siemens PT Thromborel S	Seconds	13.5 (12.0 – 14.9)
Activated Partial Thromboplastin Time (aPTT)		
HemosIL SynthASil APTT-SP	Seconds	28 (25 – 31)
HemosIL SynthASil APTT	Seconds	32 (27 – 36)
Siemens APTT Pathrombin SL	Seconds	37 (35 – 39)
Siemens Actin FS	Seconds	33 (26 – 39)
Stago/Roche STA Cephascreen APTT	Seconds	33 (31 – 34)
Thrombin Time (TT)		
HemosIL Thrombin Time	Seconds	15.0 (N/A)
Fibrinogen		
HemosIL QFA Thrombin	mg/dl	266 (235 – 296)
HemosIL Fib-C	mg/dl	258 (182 – 333)
Siemens Thrombin	mg/dl	252 (219 – 285)
Siemens Multifibren U	mg/dl	273 (205 – 342)
Stago/Roche STA Fibrinogen	mg/dl	277 (251 – 304)
Antithrombin III		
HemosIL Liquid Antithrombin	%	92 (84 – 100)
IL Antithrombin III Chromogenic	%	93 (83 – 102)
Siemens Innovance Antithrombin	%	94 (76 – 113)
Siemens Berichrom Antithrombin III	%	92 (86 – 97)
D-Dimer		
HemosIL D-Dimer HS	ng/ml (DDU)	362 (N/A)
HemosIL D-Dimer	ng/ml (DDU)	454 (324 – 584)
Siemens Innovance D-Dimer	ng/ml (FEU)	1308 (1204 – 1412)
Stago/Roche D-Dimer LIA	ug/ml (FEU)	0.74 (0.56 – 0.91)

Note:

All individual donor units used in the manufacture of this lot of controls have been tested and found to be non-reactive for HBsAg and negative for antibodies to HIV and HCV. As with all blood products, this product should be handled as potentially infectious biological material.