

CERTIFICATE OF ANALYSIS



PRODUCT NAME:	HEMOSIL SPECIAL TEST CONTROL LEVEL 2	EXPIRATION DATE :	2024 - 02
PRODUCT NUMBER :	0020012000		
LOT NUMBER :	N0229773		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
HEMOSIL SPECIAL TEST CONTROL LEVEL 2 (LYOPHILIZED)					
pH @ 37 C LEVEL 2	7.3	7.6	pH	7.4	PASS
PLG ACTIVITY LEVEL 2 (TOP)	15	30	%	28	PASS
HOMOGENEITY LEVEL 2 (CV)	-	5	%	2	PASS
AT ACTIVITY LEVEL 2 (TOP)	20	30	%	28	PASS
PI ACTIVITY LEVEL 2 (TOP)	20	40	%	39	PASS
ELECTRACHROME FACTOR VIII (ACL9/10000/Elite/Pro)	20	47	%	35	PASS
PROTEIN C LEVEL 2 (TOP)	10	40	%	30	PASS
FREE PROTEIN S LEVEL 2 (TOP)	10	40	%	28	PASS
VON WILLEBRAND FACTOR ANTIGEN (TOP)	20	45	%	30	PASS
FACTOR II ACTIVITY (TOP)	19	39	%	30	PASS
FACTOR V ACTIVITY (TOP)	18	38	%	31	PASS
FACTOR VII ACTIVITY (TOP)	14	34	%	28	PASS
FACTOR X ACTIVITY (TOP)	18	38	%	30	PASS
FACTOR FVIII ACTIVITY (TOP)	15	35	%	28	PASS
FACTOR IX ACTIVITY (TOP)	22	42	%	32	PASS
FACTOR XI ACTIVITY (TOP)	16	36	%	28	PASS
FACTOR XII ACTIVITY (TOP)	16	36	%	31	PASS

The human plasma used to manufacture this product has been tested at the source and has been found negative for HIV-1 antigen, HIV, and HCV Antibody, and non-reactive for HbsAg by FDA required tests.

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: Orest Pavliv *Orest Pavliv* DATE: 3/3/2022
Print Signature

TITLE : QC Analyst

APPROVED BY: Thomas Mathew *Thomas Mathew* DATE: 03/03/2022
Print Signature

TITLE : Senior QC Analyst