

CERTIFICATE OF ANALYSIS

CHROMOGENIX

werfen

PRODUCT NAME:	COATEST SP FVIII	EXPIRATION DATE:	2028-02-29
PRODUCT NUMBER:	00082408663		
LOT NUMBER :	N0361946		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
					PASS/FAIL
High Range					
Slope	0.0077	0.0112	--	0.0095	PASS
Intercept	--	0.250	--	0.083	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS
Low Range					
Slope	0.020	0.060	--	0.042	PASS
Intercept	--	0.406	--	0.090	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl ₂	N0260988	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0855808	10 mL
COATEST SP FVIII S-2765 + I-2581	N0261002	12 mL
COATEST SP FVIII Buffer, stock solution	N0261066	20 mL
COATEST SP FVIII Phospholipid	N0260998	2 mL

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.

PREPARED BY:

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04/03/26

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