

# CERTIFICATE OF ANALYSIS

## CHROMOGENIX

## werfen

PRODUCT NAME: <u>COATEST SP FVIII</u>	EXPIRATION DATE: <u>2026-12-31</u>
PRODUCT NUMBER: <u>00082408663</u>	
LOT NUMBER: <u>N0158860</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>High Range</b>					
Slope	0.0077	0.0112	--	0.0105	PASS
Intercept	--	0.250	--	0.138	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS
<b>Low Range</b>					
Slope	0.020	0.060	--	0.054	PASS
Intercept	--	0.406	--	0.252	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl <sub>2</sub>	N1248427	6 mL
COATEST SP FVIII Factor IXa + Factor X	N1248554	10 mL
COATEST SP FVIII S-2765 + I-2581	N0158859	12 mL
COATEST SP FVIII Buffer, stock solution	N1248426	20 mL
COATEST SP FVIII Phospholipid	N1248396	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: Monika Skowronska 1-24-25  
PRINT SIGNATURE DATE: 01/24/25

TITLE QC Analyst II

APPROVAL SIGNATURE: Nehal Patel 1-24-25  
PRINT SIGNATURE DATE: 01/24/25

TITLE Senior Group Leader