

# CERTIFICATE OF ANALYSIS

## CHROMOGENIX

## werfen

PRODUCT NAME: <u>COATEST SP FVIII</u>	EXPIRATION DATE: <u>2026-08-31</u>
PRODUCT NUMBER: <u>00082408663</u>	
LOT NUMBER: <u>N0845166</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>High Range</b>					
Slope	0.0077	0.0112	--	0.0094	PASS
Intercept	--	0.250	--	0.135	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS
<b>Low Range</b>					
Slope	0.020	0.060	--	0.040	PASS
Intercept	--	0.406	--	0.212	PASS
Standard Curve (r)	0.99	--	--	0.995	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl <sub>2</sub>	N0845164	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0845157	10 mL
COATEST SP FVIII S-2765 + I-2581	N0844982	12 mL
COATEST SP FVIII Buffer, stock solution	N0845150	20 mL
COATEST SP FVIII Phospholipid	N0845165	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 9-16-24  
 PRINT Monika Skowronska SIGNATURE DATE: 09/16/24

TITLE QC Analyst II

APPROVAL SIGNATURE: Nehal Patel 9-16-24  
 PRINT N.M. Patel SIGNATURE DATE: 09/16/24

TITLE Senior Group Leader