

CERTIFICATE OF ANALYSIS

CHROMOGENIX

werfen

PRODUCT NAME:	COATEST SP FVIII	EXPIRATION DATE:	2027-03-31
PRODUCT NUMBER:	00082408663		
LOT NUMBER :	N0451801		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
High Range					
	Slope	0.0077	0.0112	--	0.0112
	Intercept	--	0.250	--	0.150
Low Range	Standard Curve (r)	0.99	--	--	0.994
	Slope	0.020	0.060	--	0.057
	Intercept	--	0.406	--	0.273
	Standard Curve (r)	0.99	--	--	0.999
					PASS
					PASS
					PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl2	N0351152	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0451800	10 mL
COATEST SP FVIII S-2765 + I-2581	N0451794	12 mL
COATEST SP FVIII Buffer, stock solution	N0351159	20 mL
COATEST SP FVIII Phospholipid	N0451796	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 *Monika Skowronska* DATE: 05/08/25

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SIGNATURE

TITLE QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N. Patel* DATE: 05/08/25

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TITLE Senior Group Leader