

CERTIFICATE OF ANALYSIS

CHROMOGENIX

werfen

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

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

5-8-25
 DATE: 05/08/25

TITLE QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel*
 PRINT SIGNATURE

5-8-25
 DATE: 05/08/25

TITLE Senior Group Leader