

CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

PRODUCT NAME:	CoaTest SP4 FVIII Kit	EXPIRATION DATE:	2028-01-31
PRODUCT NUMBER:	00082409463		
LOT NUMBER:	N0160096		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION	
	MIN	MAX				PASS/FAIL
Coatest SP4 Factor VIII Kit (00082409463)						
High Range						
	Slope	0.0077	0.0112	--	0.0087	PASS
	Intercept	--	0.250	--	0.071	PASS
	Standard Curve (r)	0.99	--	--	1.000	PASS
Low Range						
	Slope	0.020	0.060	--	0.041	PASS
	Intercept	--	0.406	--	0.092	PASS
	Standard Curve (r)	0.99	--	--	0.997	PASS

KIT COMPONENTS:

DESCRIPTION	LOT NUMBER	VOLUME
COATEST SP FVIII CACL2	N0169384	6 mL
COATEST SP FVIII FACTOR IXa + FACTOR X	N0160082	3 mL
COATEST SP FVIII S-2765 + I-2581	N0160064	12 mL
COATEST SP FVIII BUFFER	N0160079	20 mL
COATEST SP FVIII PHOSPHOLIPID	N0261115	2 mL

PREPARED BY: Monika Skowronska *Monika Skowronska*
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DATE: 3/24/2026 *3-24-26*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.m. Patel*
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DATE: 3/24/2026 *3.24.26*

TITLE: Senior Group Leader