

CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

PRODUCT NAME:	CoaTest SP4 FVIII Kit	EXPIRATION DATE:	2026-11-30
PRODUCT NUMBER:	00082409463		
LOT NUMBER:	N1147744		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION	
	MIN	MAX				PASS/FAIL
Coatest SP4 Factor VIII Kit (00082409463)						
High Range	Slope	0.0077	0.0112	--	0.0105	PASS
	Intercept	--	0.250	--	0.134	PASS
	Standard Curve (r)	0.99	--	--	0.999	PASS
Low Range	Slope	0.020	0.060	--	0.052	PASS
	Intercept	--	0.406	--	0.229	PASS
	Standard Curve (r)	0.99	--	--	0.998	PASS

KIT COMPONENTS:

DESCRIPTION	LOT NUMBER	VOLUME
COATEST SP FVIII CACL2	N1147742	6 mL
COATEST SP FVIII FACTOR IXa + FACTOR X	N1147735	3 mL
COATEST SP FVIII S-2765 + I-2581	N0250405	12 mL
COATEST SP FVIII BUFFER	N1147743	20 mL
COATEST SP FVIII PHOSPHOLIPID	N1147724	2 mL

PREPARED BY: Monika Skowronska *Monika Skowronska*
 PRINT SIGNATURE

DATE: 3/20/2025 *3-20-25*

TITLE: QC Analyst II

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

DATE: 3/20/2025 *3.20.25*

TITLE: Senior Group Leader