

CERTIFICATE OF ANALYSIS



PRODUCT NAME:	CoaTest SP4 FVIII Kit	EXPIRATION DATE:	2026-03
PRODUCT NUMBER:	82409463		
LOT NUMBER:	N0341006		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
Coatest SP4 Factor VIII Kit (82409463)					
High Range					
Slope	0.0077	0.0112	--	0.0086	PASS
Intercept	--	0.250	--	0.127	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS
Low Range					
Slope	0.020	0.060	--	0.038	PASS
Intercept	--	0.406	--	0.230	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS

KIT COMPONENTS:

DESCRIPTION	LOT NUMBER	VOLUME
COATEST SP FVIII CACL2	N0249999	6 mL
COATEST SP FVIII FACTOR IXa + FACTOR X	N0249471	3 mL
COATEST SP FVIII S-2765 + I-2581	N0341005	12 mL
COATEST SP FVIII BUFFER	N0340241	20 mL
COATEST SP FVIII PHOSPHOLIPID	N0340468	2 mL

PREPARED BY: Monika Skowronska *Monika Skowronska*
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DATE: 4/22/2024 *4-22-24*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel*
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DATE: 4/22/2024 *4-22-24*

TITLE: Senior QC Analyst