

CERTIFICATE OF ANALYSIS

CHROMOGENIX

**Instrumentation
Laboratory**
A Werfen Company

PRODUCT NAME: <u>CoaTest SP Factor FVIII Kit</u>	EXPIRATION DATE: <u>2024-01</u>
PRODUCT NUMBER: <u>82408663</u>	
LOT NUMBER: <u>N0129752</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
High Range					
Slope	0.0077	0.0112	--	0.0109	PASS
Intercept	--	0.250	--	0.179	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS
Low Range					
Slope	0.020	0.060	--	0.052	PASS
Intercept	--	0.406	--	0.289	PASS
Standard Curve (r)	0.99	--	--	1.000	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl2	N0129509	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0129751	10 mL
COATEST SP FVIII S-2765 + I-2581	N0129531	12 mL
COATEST SP FVIII Buffer, stock solution	N0129750	20 mL
COATEST SP FVIII Phospholipid	N0129519	2 mL

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DATE: 3-28-22
03/28/22

TITLE Senior QC Analyst

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