

CERTIFICATE OF ANALYSIS

CHROMOGENIX

 **Instrumentation
Laboratory**
A Werfen Company

PRODUCT NAME: <u>CoaTest SP Factor FVIII Kit</u>	EXPIRATION DATE: <u>2022-12</u>
PRODUCT NUMBER: <u>82408663</u>	
LOT NUMBER: <u>N0119684</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
High Range					
Slope	0.0077	0.0112	--	0.0083	PASS
Intercept	--	0.250	--	0.128	PASS
Standard Curve (r)	0.99	--	--	0.994	PASS
Low Range					
Slope	0.020	0.060	--	0.047	PASS
Intercept	--	0.406	--	0.160	PASS
Standard Curve (r)	0.99	--	--	1.000	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl ₂	N1209244	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0119679	10 mL
COATEST SP FVIII S-2765 + I-2581	N1209536	12 mL
COATEST SP FVIII Buffer, stock solution	N1209242	20 mL
COATEST SP FVIII Phospholipid	N1209398	2 mL

PREPARED BY: Nehal Patel *N.M. Patel* DATE: 1-21-21
PRINT SIGNATURE

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 1/21/2021
PRINT SIGNATURE

TITLE: Technical Supervisor