

CERTIFICATE OF ANALYSIS

CHROMOGENIX

 **Instrumentation
Laboratory**
A Werfen Company

PRODUCT NAME:	<u>CoaTest SP Factor FVIII Kit</u>	EXPIRATION DATE:	<u>2025-06</u>
PRODUCT NUMBER:	<u>82408663</u>		
LOT NUMBER :	<u>N0633082</u>		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
High Range					
Slope	0.0077	0.0112	--	0.0088	PASS
Intercept	--	0.250	--	0.173	PASS
Standard Curve (r)	0.99	--	--	0.993	PASS
Low Range					
Slope	0.020	0.060	--	0.038	PASS
Intercept	--	0.406	--	0.277	PASS
Standard Curve (r)	0.99	--	--	0.995	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl ₂	N0632923	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0632925	10 mL
COATEST SP FVIII S-2765 + I-2581	N0632922	12 mL
COATEST SP FVIII Buffer, stock solution	N0633081	20 mL
COATEST SP FVIII Phospholipid	N0633077	2 mL

PREPARED BY: Girlie Reinoso G. Reinoso DATE: 7/25/23
 PRINT SIGNATURE

TITLE QC Analyst III

APPROVAL SIGNATURE: Nehal Patel N.m. Patel DATE: 7-25-23
 PRINT SIGNATURE

TITLE Senior QC Analyst