

CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation
Laboratory
A Werfen Company

PRODUCT NAME:	<u>CoaTest SP Factor FVIII Kit</u>	EXPIRATION DATE:	<u>2023-06</u>
PRODUCT NUMBER:	<u>82408663</u>		
LOT NUMBER :	<u>N0613881</u>		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
High Range					
Slope	0.0077	0.0112	--	0.0093	PASS
Intercept	--	0.250	--	0.170	PASS
Standard Curve (r)	0.99	--	--	0.996	PASS
Low Range					
Slope	0.020	0.060	--	0.045	PASS
Intercept	--	0.406	--	0.297	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl2	N0613858	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0613879	10 mL
COATEST SP FVIII S-2765 + I-2581	N0613857	12 mL
COATEST SP FVIII Buffer, stock solution	N0613875	20 mL
COATEST SP FVIII Phospholipid	N0613873	2 mL

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7-21-21

DATE: 07/21/21

TITLE Senior QC Analyst

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