

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME: <u>CoaTest SP Factor FVIII Kit</u>	EXPIRATION DATE: <u>2023-03</u>
PRODUCT NUMBER: <u>82408663</u>	
LOT NUMBER: <u>N0311449</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
High Range					
Slope	0.0077	0.0112	--	0.0090	PASS
Intercept	--	0.250	--	0.132	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS
Low Range					
Slope	0.020	0.060	--	0.037	PASS
Intercept	--	0.406	--	0.243	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl ₂	N0311305	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0311448	10 mL
COATEST SP FVIII S-2765 + I-2581	N0311446	12 mL
COATEST SP FVIII Buffer, stock solution	N0311442	20 mL
COATEST SP FVIII Phospholipid	N0311443	2 mL

PREPARED BY: D.Tencza *D.Tencza* DATE: 4/12/21
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