

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME:	CoaTest SP Factor FVIII Kit	EXPIRATION DATE:	2021-06
PRODUCT NUMBER:	82408663		
LOT NUMBER :	N0696554		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
High Range					
Slope	0.0077	0.0112	--	0.0085	PASS
Intercept	--	0.250	--	0.144	PASS
Standard Curve (r)	0.99	--	--	0.997	PASS
Low Range					
Slope	0.020	0.060	--	0.045	PASS
Intercept	--	0.406	--	0.171	PASS
Standard Curve (r)	0.99	--	--	1.000	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl2	N0696553	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0696453	10 mL
COATEST SP FVIII S-2765 + I-2581	N0696551	12 mL
COATEST SP FVIII Buffer, stock solution	N0696552	20 mL
COATEST SP FVIII Phospholipid	N0696454	2 mL

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