

CERTIFICATE OF ANALYSIS

CHROMOGENIX



**Instrumentation
Laboratory**

A Werfen Company

PRODUCT NAME: <u>CoaTest SP Factor FVIII Kit</u>	EXPIRATION DATE: <u>2021-04</u>
PRODUCT NUMBER: <u>82408663</u>	
LOT NUMBER: <u>N0495233</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
					PASS/FAIL
High Range					
Slope	0.0077	0.0112	--	0.0088	PASS
Intercept	--	0.250	--	0.143	PASS
Standard Curve (r)	0.99	--	--	0.997	PASS
Low Range					
Slope	0.020	0.060	--	0.045	PASS
Intercept	--	0.406	--	0.174	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl2	N0494987	6 mL
COATEST SP FVIII Factor IXa + Factor X	N0495120	10 mL
COATEST SP FVIII S-2765 + I-2581	N0495106	12 mL
COATEST SP FVIII Buffer, stock solution	N0495115	20 mL
COATEST SP FVIII Phospholipid	N0495222	2 mL

5-17-19

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DATE: 05/17/19

TITLE Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz*
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DATE: 05/17/19 *5-17-19*

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