

CERTIFICATE OF ANALYSIS

CHROMOGENIX



**Instrumentation
Laboratory**

A Werfen Company

PRODUCT NAME: <u>CoaTest SP Factor FVIII Kit</u>	EXPIRATION DATE: <u>2022-10</u>
PRODUCT NUMBER: <u>82408663</u>	
LOT NUMBER: <u>N1108451</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
High Range					
Slope	0.0077	0.0112	--	0.0085	PASS
Intercept	--	0.250	--	0.116	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS
Low Range					
Slope	0.020	0.060	--	0.045	PASS
Intercept	--	0.406	--	0.146	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST SP FVIII CaCl2	N1008270	6 mL
COATEST SP FVIII Factor IXa + Factor X	N1008271	10 mL
COATEST SP FVIII S-2765 + I-2581	N1108449	12 mL
COATEST SP FVIII Buffer, stock solution	N1008101	20 mL
COATEST SP FVIII Phospholipid	N1108450	2 mL

PREPARED BY: Nehal Patel *N. M. Patel* DATE: 11/23/20 *11-23-20*
 PRINT SIGNATURE

TITLE Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 11/23/20 *11-23-20*
 PRINT SIGNATURE

TITLE Technical Supervisor