CERTIFICATE OF ANALYSIS

CHROMOGENIX Instrumentation Laboratory
A Werfen Company

PRODUCT NAME:	CoaTest SP4 FVIII Kit	EXPIRATION DATE:	2023-02
PRODUCT NUMBER:	82409463		
LOT NUMBER:	N0210910		

TEST DESCRIPTION		SPECIFICATIONS			RESULTS	DISPOSITION
		MIN	MAX	UNITS		PASS/FAIL
Coatest SP4 Factor VIII Kit (82409463)						
High Range						
	Slope	0.0077	0.0112	--	0.0091	PASS
	Intercept	--	0.250	--	0.120	PASS
	Standard Curve (r)	0.99	--	--	0.999	PASS
Low Range						
	Slope	0.020	0.060	--	0.039	PASS
	Intercept	--	0.406	--	0.164	PASS
	Standard Curve (r)	0.99	--	--	0.999	PASS

KIT COMPONENTS:

DESCRIPTION	LOT NUMBER	VOLUME
COATEST SP FVIII CACL2	N0210686	6 mL
COATEST SP FVIII FACTOR IXa + FACTOR X	N0210906	3 mL
COATEST SP FVIII S-2765 + I-2581	N0210903	12 mL
COATEST SP FVIII BUFFER	N0210687	20 mL
COATEST SP FVIII PHOSPHOLIPID	N0210904	2 mL

PREPARED BY: Maria Oettinger (PRINT) Maria Oettinger (SIGNATURE) DATE: 3/30/2021 3-30-21

TITLE: QC Analyst III

APPROVAL SIGNATURE: Donna Tencza (PRINT) Donna Tencza (SIGNATURE) DATE: 3/30/2021 3/30/21

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