

CERTIFICATE OF ANALYSIS



Instrumentation
Laboratory
A Werfen Company

PRODUCT NAME:	CoaTest SP4 FVIII Kit	EXPIRATION DATE:	2024-02
PRODUCT NUMBER:	82409463		
LOT NUMBER:	N0320651		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
Coatest SP4 Factor VIII Kit (82409463)					
High Range					
Slope	0.0077	0.0112	--	0.0107	PASS
Intercept	--	0.250	--	0.199	PASS
Standard Curve (r)	0.99	--	--	0.995	PASS
Low Range					
Slope	0.020	0.060	--	0.048	PASS
Intercept	--	0.406	--	0.257	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS

KIT COMPONENTS:

DESCRIPTION	LOT NUMBER	VOLUME
COATEST SP FVIII CACL2	N0220227	6 mL
COATEST SP FVIII FACTOR IXa + FACTOR X	N0320647	3 mL
COATEST SP FVIII S-2765 + I-2581	N0320638	12 mL
COATEST SP FVIII BUFFER	N0320641	20 mL
COATEST SP FVIII PHOSPHOLIPID	N0220445	2 mL

PREPARED BY: Girle Reinoso G. Reinoso
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DATE: 5/24/2022 5/24/22

TITLE: QC Analyst III

APPROVAL SIGNATURE: Nehal Patel N-m-Patel
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DATE: 5/24/2022 5-24-22

TITLE: Senior QC Analyst