

CERTIFICATE OF ANALYSIS



PRODUCT NAME:	CoaTest SP4 FVIII Kit	EXPIRATION DATE:	2022-01
PRODUCT NUMBER:	82409463		
LOT NUMBER:	N0201709		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
Coatest SP4 Factor VIII Kit (82409463)					
High Range					
Slope	0.0077	0.0112	--	0.0085	PASS
Intercept	--	0.250	--	0.128	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS
Low Range					
Slope	0.020	0.060	--	0.044	PASS
Intercept	--	0.406	--	0.151	PASS
Standard Curve (r)	0.99	--	--	1.000	PASS

KIT COMPONENTS:

DESCRIPTION	LOT NUMBER	VOLUME
COATEST SP FVIII CACL2	N0101181	6 mL
COATEST SP FVIII FACTOR IXa + FACTOR X	N0101560	3 mL
COATEST SP FVIII S-2765 + I-2581	N0201708	12 mL
COATEST SP FVIII BUFFER	N0101423	20 mL
COATEST SP FVIII PHOSPHOLIPID	N0201707	2 mL

PREPARED BY: Nehal Patel *N.m. Patel*
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DATE: 2/26/2020 *2-26-20*

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz*
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DATE: 2/26/2020 *2/26/20*

TITLE: Technical Supervisor