

CERTIFICATE OF ANALYSIS



PRODUCT NAME :	COAMATIC FACTOR VIII	EXPIRATION DATE: 2021-03
PRODUCT NUMBER :	82258563	
LOT NUMBER:	N0394315	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.57	--	0.43	PASS
Intercept	---	0.12	--	0.05	PASS
r	0.990	---	--	0.999	PASS
LOW RANGE					
Slope	2.8	6.9	--	4.7	PASS
Intercept	---	0.21	--	0.11	PASS
r	0.990	---	--	0.998	PASS

KIT COMPONENTS

NAME	LOT NUMBER	VOLUME
COAMATIC FVIII FACTOR REAGENT	N0394311	3 mL
COAMATIC FVIII S-2765 + I-2581	N0394313	6 mL
COAMATIC FVIII BUFFER	N0394312	24 mL

· have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all

PREPARED BY: Nehal Patel *N.M. Patel*
 PRINT SIGNATURE

DATE: 4-8-19
 4/8/2019

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Donna Tencza *Donna Tencza*
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DATE: 4/8/2019
 4/8/19

TITLE: Senior QC Analyst