

CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation
Laboratory
A Werfen Company

PRODUCT NAME :	<u>COAMATIC FACTOR VIII</u>	EXPIRATION DATE: <u>2023-05</u>
PRODUCT NUMBER :	<u>82258563</u>	
LOT NUMBER:	<u>N0512814</u>	

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	PASS/FAIL
	MIN	MAX	UNITS		
HIGH RANGE					
Slope	0.33	0.57	--	0.41	PASS
Intercept	---	0.12	--	0.06	PASS
r	0.990	---	--	0.999	PASS
LOW RANGE					
Slope	2.8	6.9	--	4.3	PASS
Intercept	---	0.21	--	0.12	PASS
r	0.990	---	--	0.996	PASS

KIT COMPONENTS

NAME	LOT NUMBER	VOLUME
COAMATIC FVIII FACTOR REAGENT	N0512805	3 mL
COAMATIC FVIII S-2765 + I-2581	N0512813	6 mL
COAMATIC FVIII BUFFER	N0512812	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
PRINT SIGNATURE

DATE: 6-2-21
6/2/2021

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz
PRINT SIGNATURE

DATE: 6/2/21
6/2/2021

TITLE: Technical Supervisor