

# CERTIFICATE OF ANALYSIS



**Instrumentation Laboratory**  
 A Werfen Company

PRODUCT NAME : <u>COAMATIC FACTOR VIII</u>	EXPIRATION DATE: <u>2023-08</u>
PRODUCT NUMBER : <u>82258563</u>	
LOT NUMBER: <u>N0815323</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.57	--	0.39	PASS
Intercept	---	0.12	--	0.10	PASS
r	0.990	---	--	0.998	PASS
LOW RANGE					
Slope	2.8	6.9	--	4.5	PASS
Intercept	---	0.21	--	0.17	PASS
r	0.990	---	--	1.000	PASS

**KIT COMPONENTS**

NAME	LOT NUMBER	VOLUME
COAMATIC FVIII FACTOR REAGENT	N0815321	3 mL
COAMATIC FVIII S-2765 + I-2581	N0815322	6 mL
COAMATIC FVIII BUFFER	N0815158	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*  
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DATE: 9-9-21  
9/9/2021

TITLE: Senior QC Analyst  
 APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz*  
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DATE: 9/9/21  
9/9/2021

TITLE: Technical Supervisor