

**CERTIFICATE OF ANALYSIS**



PRODUCT NAME :	<u>COAMATIC FACTOR VIII</u>	EXPIRATION DATE: <u>2027-10-31</u>
PRODUCT NUMBER :	<u>82258563</u>	
LOT NUMBER:	<u>N1158414</u>	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.57	--	0.47	PASS
Intercept	---	0.12	--	0.09	PASS
r	0.990	---	--	0.998	PASS
LOW RANGE					
Slope	2.8	6.9	--	5.1	PASS
Intercept	---	0.21	--	0.11	PASS
r	0.990	---	--	0.996	PASS

**KIT COMPONENTS**

NAME	LOT NUMBER	VOLUME
COAMATIC FVIII FACTOR REAGENT	N1057798	3 mL
COAMATIC FVIII S-2765 + I-2581	N1158160	6 mL
COAMATIC FVIII BUFFER	N1157998	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: Monika Skowronska *Monika Skowronska* DATE: 12-9-25  
 PRINT SIGNATURE 12/9/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N. M. Patel* DATE: 12-9-25  
 PRINT SIGNATURE 12/9/2025

TITLE: Senior Group Leader

2

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX** **werfen**

PRODUCT NAME:	COATEST APC Resistance V-S	EXPIRATION DATE:	2027-06-30
PRODUCT NUMBER:	00082313863		
LOT:	N0160244		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	Pass/Fail
	MIN	MAX	UNITS		
APT-time on ACL					
Diluted Control Plasma Level 1	27	43	seconds	35	PASS
Diluted Control Plasma Level 2	28	48	seconds	36	PASS

APC-V ratio on ACL					
Control Plasma Level 1	2.8	3.2	--	3.0	PASS
Control Plasma Level 2	1.4	1.9	--	1.8	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N1258726	2 mL
COATEST APC Resistance APTT reagent	N1258728	4 mL
COATEST APC Resistance APC/CaCl2	N0169890	2 mL
COATEST APC Resistance Control Plasma Level 1	N0169897	1 mL
COATEST APC Resistance Control Plasma Level 2	N0169611	1 mL
COATEST APC Resistance V-DEF Plasma	N1259082	4 mL

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY:

*Monica Skowronka* *Monika Skowronka*  
 PRINT SIGNATURE

DATE: 2-9-26  
 2/9/2026

TITLE: QC Analyst II

APPROVAL SIGNATURE:

*Nehal Patel* *N.M. Patel*  
 PRINT SIGNATURE

DATE: 2-9-26  
 2/9/2026

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

# CHROMOGENIX werfen

PRODUCT NAME:	CoaTest SP4 FVIII Kit	EXPIRATION DATE:	2026-11-30
PRODUCT NUMBER:	00082409463		
LOT NUMBER:	N1147744		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
Coatest SP4 Factor VIII Kit (00082409463)					
<b>High Range</b>					
Slope	0.0077	0.0112	--	0.0105	PASS
Intercept	--	0.250	--	0.134	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS
<b>Low Range</b>					
Slope	0.020	0.060	--	0.052	PASS
Intercept	--	0.406	--	0.229	PASS
Standard Curve (r)	0.99	--	--	0.998	PASS

**KIT COMPONENTS:**

DESCRIPTION	LOT NUMBER	VOLUME
COATEST SP FVIII CACL2	N1147742	6 mL
COATEST SP FVIII FACTOR IXa + FACTOR X	N1147735	3 mL
COATEST SP FVIII S-2765 + I-2581	N0250405	12 mL
COATEST SP FVIII BUFFER	N1147743	20 mL
COATEST SP FVIII PHOSPHOLIPID	N1147724	2 mL

PREPARED BY: Monika Skowronska *Monika Skowronska*  
 PRINT SIGNATURE

DATE: 3/20/2025 *3-20-25*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.m. Patel*  
 PRINT SIGNATURE

DATE: 3/20/2025 *3.20.25*

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX** werfen

PRODUCT NAME:	COAMATIC HEPARIN	EXP DATE:	2027-03-31
PRODUCT NUMBER:	00082339363		
LOT NUMBER:	N0351183		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. FACTOR Xa</b>					
ACTIVITY	31.5	38.5	nkat/vial	37.6	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.7	73.7	nkat/vial	70.3	PASS

<b>B. S-2732, FOR COAMATIC HEPARIN</b>					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.4	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS

<b>C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP</b>					
SLOPE	-0.351	-0.103	--	-0.191	PASS
r <sup>2</sup>	0.985	--	--	0.997	PASS

<b>D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP</b>					
SLOPE	-0.336	-0.114	--	-0.193	PASS
r <sup>2</sup>	0.985	--	--	0.998	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COAMATIC HEPARIN FACTOR Xa	N0351180	1 mL
COAMATIC HEPARIN S-2732	N0351181	2 mL

We hereby certify that the above product(s):  
 · have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;

PREPARED BY: Brianna Randazzo *Brianna Randazzo* DATE: 5/7/2025  
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 5-7-25  
 PRINT SIGNATURE

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX** werfen

PRODUCT NAME:	FXa, 10 x 71 nkat	EXPIRATION DATE:	2028-05-31
PRODUCT NUMBER:	00082098539		
LOT NUMBER:	N1158150		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
FACTOR Xa, 71 nkat (650515)					
ACTIVITY	61	81	nkat/vial	78	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.7	73.7	nkat/vial	72.7	PASS

We hereby certify that the above product(s):  
 · have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;

PREPARED BY: Maria Somoza  
 PRINT

Maria Somoza  
 SIGNATURE

DATE: 12/2/2025 12/2/25

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel  
 PRINT

N.m. Patel  
 SIGNATURE

DATE: 12/2/2025 12.2.25

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX** **werfen**

PRODUCT NAME:	<u>Antithrombin 10 x 10 IU</u>	EXPIRATION DATE:	<u>2028-07-31</u>
PRODUCT NUMBER:	<u>00082072039</u>		
LOT NUMBER:	<u>N0169364</u>		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
<b>ANTITHROMBIN, 10 IU (654023)</b>					
ANTITHROMBIN ACTIVITY	9	11	IU/vial	10	PASS

All human source material used to manufacture this product have been tested according to FDA guidelines and found to be non-reactive for: HBsAg, antibodies to HIV1 and 2, and antibodies to HCV.

PREPARED BY: Fabiha Bushra *Fabiha Bushra* DATE: 1/20/2026 1/20/26  
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N. M. Patel* DATE: 1/20/2026 1-20-26  
 PRINT SIGNATURE

TITLE: Senior Group Leader

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX** **werfen**

PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2027-04-30
PRODUCT NUMBER:	00082312063		
LOT NUMBER:	N1158524		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
<b>APT-time on ACL</b>					
Diluted Control Plasma Level 1	27	43	seconds	35	PASS
Diluted Control Plasma Level 2	28	48	seconds	36	PASS

APC-V ratio on ACL	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
<b>APC-V ratio on ACL</b>					
Control Plasma Level 1	2.8	3.2	--	3.1	PASS
Control Plasma Level 2	1.4	1.9	--	1.9	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N1057318	8 mL
COATEST APC Resistance APTT reagent	N1057330	16 mL
COATEST APC Resistance APC/CaCl2	N1158522	2 mL
COATEST APC Resistance Control Plasma Level 1	N1158523	1 mL
COATEST APC Resistance Control Plasma Level 2	N1057583	1 mL
COATEST APC Resistance V-DEF Plasma	N1057140	4 mL

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY: Monika Skowronska *Monika Skowronska* DATE: 12-17-25  
 PRINT SIGNATURE 12/17/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *p.m. Patel* DATE: 12-17-25  
 PRINT SIGNATURE 12/17/2025

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX** werfen

PRODUCT NAME:	<u>Antithrombin 1 x 25 IU</u>	EXPIRATION DATE:	<u>2027-10-31</u>
PRODUCT NUMBER:	<u>00081079639</u>		
LOT NUMBER:	<u>N1057317</u>		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
Antithrombin Activity	25	30	IU/vial	28	PASS
Assay Slope @ 37°C	-0.0024	-0.0034		-0.0028	PASS
Intercept @ 37°C	0.40	0.60		0.49	PASS
r <sup>2</sup>	0.990	--		0.999	PASS

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;

PREPARED BY: Fabiha Bushra Fabiha Bushra DATE: 11/4/2025 11/4/25  
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel N. M. Patel DATE: 11/4/2025 11-4-25  
 PRINT SIGNATURE

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

**werfen**

PRODUCT NAME:	S-2288, 25 mg Substrate	EXPIRATION DATE:	2028-12-31
PRODUCT NUMBER:	00082085239		
LOT NUMBER:	N1258732		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	24.8	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.5	PASS

We hereby certify that the above product(s) have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY: Fabiha Bushra *Fabiha Bushra*  
 PRINT SIGNATURE

DATE: 1/20/2026 *1/20/26*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N. M. Patel*  
 PRINT SIGNATURE

DATE: 1/20/2026 *1-20-26*

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

**werfen**

PRODUCT NAME:	S-2765, 25 mg Substrate	EXPIRATION DATE:	2028-07-31
PRODUCT NUMBER:	00082141339		
LOT:	N0755163		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	26.0	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.3	PASS

We hereby certify that the above product(s) have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY: Monika Skowronska *Monika Skowronska*  
 PRINT SIGNATURE

DATE: 9-17-25  
 9/17/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel*  
 PRINT SIGNATURE

DATE: 9-17-25  
 9/17/2025

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX** werfen

PRODUCT NAME:	S-2302, 25 mg Substrate	EXPIRATION DATE:	2029-01-31
PRODUCT NUMBER:	00082034039		
LOT NUMBER:	N0956780		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	24.6	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

We hereby certify that the above product(s) have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY: Maria Somoza  
PRINT

Maria Somoza  
SIGNATURE

DATE: 10/20/25

TITLE: QC Analyst II

APPROVAL SIGNATURE: John Olszewski  
PRINT

John Olszewski  
SIGNATURE

DATE: 10/20/2025

TITLE: QC Lab Manager

**CERTIFICATE OF ANALYSIS**



PRODUCT NAME:	COATEST APC Resistance V-S	EXPIRATION DATE:	2027-06-30
PRODUCT NUMBER:	00082313863		
LOT:	N0160244		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
<b>APT-time on ACL</b>					
Diluted Control Plasma Level 1	27	43	seconds	35	PASS
Diluted Control Plasma Level 2	28	48	seconds	36	PASS

<b>APC-V ratio on ACL</b>					
Control Plasma Level 1	2.8	3.2	--	3.0	PASS
Control Plasma Level 2	1.4	1.9	--	1.8	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N1258726	2 mL
COATEST APC Resistance APTT reagent	N1258728	4 mL
COATEST APC Resistance APC/CaCl2	N0169890	2 mL
COATEST APC Resistance Control Plasma Level 1	N0169897	1 mL
COATEST APC Resistance Control Plasma Level 2	N0169611	1 mL
COATEST APC Resistance V-DEF Plasma	N1259082	4 mL

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY: Monica Skopronska *Monika Skopronska* DATE: 2-9-26  
 PRINT SIGNATURE 2/9/2026

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 2/9/2026  
 PRINT SIGNATURE 2-9-26

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

**werfen**

PRODUCT NAME:	S-2238, 25 mg Substrate	EXPIRATION DATE:	2028-09-30
PRODUCT NUMBER:	00082032439		
LOT NUMBER:	N0956138		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	25.7	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

We hereby certify that the above product(s) have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY: Maria Somoza  
PRINT

Maria Somoza  
SIGNATURE

DATE: 9/23/2025 09/23/25

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel  
PRINT

N. M. Patel  
SIGNATURE

DATE: 9/23/2025 9-23-25

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

**CHROMOGENIX** werfen

PRODUCT NAME:	COATEST APC Resistance Control Plasma Level 1	EXPIRATION DATE:	2027-04-30
PRODUCT NUMBER:	00082265063		
LOT	N0351418		

Analysis with COATEST APC R V:						
APT Time	CaCl <sub>2</sub>	--	39	seconds	34	PASS
	APC/CaCl <sub>2</sub>	75	--	seconds	101	PASS
APC Ratio		2.7	3.2	--	2.9	PASS

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.

PREPARED BY: Monika Skowronska *Monika Skowronska* DATE: 4/29/2025 *4-29-25*  
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 4/29/2025 *4-29-25*  
 PRINT SIGNATURE

TITLE: Senior Group Leader



**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX werfen**

PRODUCT NAME:	COATEST APC Resistance Control Plasma Level 2	EXPIRATION DATE:	2027-02-28
PRODUCT NUMBER:	00082266863		
LOT NUMBER:	N0250218		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
Analysis with COATEST APC R V:					PASS/FAIL
APT Time <u>CaCl<sub>2</sub></u>	28	41	seconds	37	PASS
APC Ratio	1.4	1.9	--	1.9	PASS

We hereby certify that the above product(s):  
 - have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;

PREPARED BY: Monika Skowronska *Monika Skowronska* DATE: 3/25/2025 *3-25-25*  
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.m. Patel* DATE: 3/25/2025 *3-25-25*  
 PRINT SIGNATURE

TITLE: Senior Group Leader

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	S-2366, 25 mg Substrate	EXPIRATION DATE:	2029-06-30
PRODUCT NUMBER:	82109039		
LOT NUMBER:	N0845152		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	25.9	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

PREPARED BY: Monika Skowronska *Monika Skowronska*  
 PRINT SIGNATURE

DATE: 9/19/2024 *9-19-24*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.m. Patel*  
 PRINT SIGNATURE

DATE: 9/19/2024 *9-19-24*

TITLE: Senior Group Leader