

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		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
ANTITHROMBIN, 10 IU (654023)					PASS/FAIL
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

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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

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

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
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 Maria Somoza DATE: 10/20/25
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: John Olszewski John Olszewski DATE: 10/20/2025
 PRINT SIGNATURE

TITLE: QC Lab Manager

CERTIFICATE OF ANALYSIS

CHROMOGENIX

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PRODUCT NAME:	S-2222, 25 mg Substrate	EXPIRATION DATE:	2029-06-30
PRODUCT NUMBER:	00082031639		
LOT:	N0260992		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	25.0	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	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: Brianna Randazzo *Brianna Randazzo* DATE: 03/23/2026
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 3-23-26
 PRINT SIGNATURE

TITLE: Senior Group Leader

QCM00820316-2 Rev. 01

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PRODUCT NAME:	S-2765, 25 mg Substrate	EXPIRATION DATE:	2029-02-28
PRODUCT NUMBER:	00082141339		
LOT:	N0260986		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	25.2	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: Brianna Randazzo *Brianna Randazzo* DATE: 03/16/2026
 PRINT SIGNATURE 3/16/2026

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 3-16-26
 PRINT SIGNATURE 3/16/2026

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

CHROMOGENIX

werfen

PRODUCT NAME:	S-2238, 25 mg Substrate	EXPIRATION DATE:	2029-02-28
PRODUCT NUMBER:	00082032439		
LOT NUMBER:	N0260987		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
SUBSTRATE CONCENTRATION	23.7	26.3	mg/vial	25.7	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	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: Brianna Randazzo *Brianna Randazzo* DATE: 03/18/2026
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N. M. Patel* DATE: 3-18-26
 PRINT SIGNATURE

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS

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A Werfen Company

PRODUCT NAME:	COATEST Heparin	EXPIRATION DATE:	2027-11-30
PRODUCT NUMBER:	25553963		
LOT NUMBER:	N0553172		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa					
ACTIVITY	61	81	nka/vial	72	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.7	73.7	nka/vial	70.2	PASS
RESIDUAL MOISTURE (KF)	0	5	%	NA	
RESIDUAL MOISTURE (FMS)	0	12.0	Torr	0.3	PASS

B. S-2222, FOR COATEST HEPARIN					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	15.91	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
RESIDUAL MOISTURE	0	5	%	0.1	PASS

C. ANTITHROMBIN 10 IU, FOR COATEST HEPARIN					
ANTITHROMBIN ACTIVITY	9	11	IU/vial	11	PASS

D. NORMAL CONTROL PLASMA					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0	PASS
STANDARD CURVE:					
regression coefficient (r ²)	0.99	1.00	--	0.99	PASS
slope	-0.800	-0.500	--	-0.701	PASS
intercept	0.650	1.030	--	0.795	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.173	PASS
APPEARANCE	yellowish-white, lyophilized powder			PASS	PASS

E. BUFFER pH 8.4 CONC., FOR COATEST HEPARIN					
APPEARANCE	clear, colorless solution			PASS	PASS
pH @ 20 - 25°C	8.3	8.5	--	8.4	PASS

F. COATEST HEPARIN KIT					
SLOPE	-0.800	-0.500	--	-0.728	PASS
INTERCEPT	0.650	1.030	--	0.820	PASS
REGRESSION COEFFICIENT (r ²)	0.99	1.00		1.00	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST HEPARIN FACTOR Xa	N0552882	2 mL
COATEST HEPARIN S-2222	N0553150	4 mL
COATEST ANTITHROMBIN	N0553157	1 mL
COATEST HEPARIN NORMAL PLASMA	N0553167	1 mL
COATEST HEPARIN BUFFER	N0552883	12 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;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: Monika Skowronska *Monika SKOWRONSKA* DATE: 6/18/2025 *6-18-25*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 6/18/2025 *6-18-25*

TITLE: Senior QC Analyst

CERTIFICATE OF ANALYSIS

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

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
FACTOR Xa, 71 nkat (650515)					PASS/FAIL
ACTIVITY	61	81	nkat/vial	78	PASS
STANDARD CURVE (r ²)	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 Maria Somoza
 PRINT SIGNATURE

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

TITLE: QC Analyst II

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

DATE: 12/2/2025 12.2.25

TITLE: Senior Group Leader

CERTIFICATE OF ANALYSIS



PRODUCT NAME :	COAMATIC FACTOR VIII	EXPIRATION DATE: 2027-12-31
PRODUCT NUMBER :	82258563	
LOT NUMBER:	N0169896	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.57	..	0.53	PASS
Intercept	---	0.12	..	0.10	PASS
r	0.990	---	..	0.998	PASS
LOW RANGE					
Slope	2.8	6.9	..	6.5	PASS
Intercept	---	0.21	..	0.12	PASS
r	0.990	---	..	0.998	PASS

KIT COMPONENTS

NAME	LOT NUMBER	VOLUME
COAMATIC FVIII FACTOR REAGENT	N1258735	3 mL
COAMATIC FVIII S-2765 + I-2581	N0169613	6 mL
COAMATIC FVIII BUFFER	N1258734	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: 2/5/2026 *2-5-26*
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 2/5/2026 *2-5-26*
 PRINT SIGNATURE

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			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
Coatest SP4 Factor VIII Kit (00082409463)					PASS/FAIL
High Range					
Slope	0.0077	0.0112	--	0.0105	PASS
Intercept	--	0.250	--	0.134	PASS
Standard Curve (r)	0.99	--	--	0.999	PASS
Low Range					
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			
A. FACTOR Xa					
ACTIVITY	31.5	38.5	nkat/vial	37.6	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.7	73.7	nkat/vial	70.3	PASS

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

C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.191	PASS
r ²	0.985	--	--	0.997	PASS

D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.193	PASS
r ²	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:	COATEST APC Resistance V	EXPIRATION DATE:	2027-04-30
PRODUCT NUMBER:	00082312063		
LOT NUMBER:	N1158524		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
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					
	MIN	MAX	UNITS	RESULTS	Pass/Fail
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

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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	<u>CaCl₂</u>	--	39	seconds	34	PASS
	<u>APC/CaCl₂</u>	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>CaCl₂</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