

CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation
Laboratory
A Werfen Company

PRODUCT NAME:	COATEST Heparin	EXPIRATION DATE:	2026-08-31
PRODUCT NUMBER:	25553963		
LOT NUMBER:	N0441744		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa					
ACTIVITY	61	81	nkat/vial	72	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	69.4	76.8	nkat/vial	75.1	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	15.15	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
RESIDUAL MOISTURE	0	5	%	0.2	PASS

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

D. NORMAL CONTROL PLASMA					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0.01	PASS
STANDARD CURVE:					
regression coefficient (r ²)	0.99	1.00	--	0.99	PASS
slope	-0.800	-0.500	--	-0.666	PASS
intercept	0.650	1.030	--	0.825	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.360	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	--	8.3	PASS

F. COATEST HEPARIN KIT					
SLOPE	-0.800	-0.500	--	-0.612	PASS
INTERCEPT	0.650	1.030	--	0.774	PASS
REGRESSION COEFFICIENT (r ²)	0.99	1.00	--	0.99	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS

KIT COMPONENTS:		
NAME	LOT NUMBER	VOLUME
COATEST HEPARIN FACTOR Xa	N0249469	2 mL
COATEST HEPARIN S-2222	N0441733	4 mL
COATEST ANTITHROMBIN	N0249477	1 mL
COATEST HEPARIN NORMAL PLASMA	N0441731	1 mL
COATEST HEPARIN BUFFER	N0441736	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*
 PRINT SIGNATURE

DATE: 5/8/2024 *5-8-24*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel*
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DATE: 5/8/2024 *5-8-24*

TITLE: Senior QC Analyst