

CERTIFICATE OF ANALYSIS

CHROMOGENIX

**Instrumentation
Laboratory**
A Werfen Company

PRODUCT NAME:	COATEST Heparin	EXPIRATION DATE:	2022-04
PRODUCT NUMBER:	25553963		
LOT NUMBER:	N1099447		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa					
ACTIVITY	61	81	nkat/vial	69	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.0	73.0	nkat/vial	69.3	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	15.00	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	10	PASS

D. NORMAL CONTROL PLASMA					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0.04	PASS
STANDARD CURVE:					
regression coefficient (r ²)	0.99	1.00	--	1.00	PASS
slope	-0.800	-0.500	--	-0.591	PASS
intercept	0.650	1.030	--	0.796	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.388	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	--	-0.631	PASS
INTERCEPT	0.650	1.030	--	0.803	PASS
REGRESSION COEFFICIENT (r ²)	0.99	1.00	--	1.00	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST HEPARIN FACTOR Xa	N1099290	2 mL
COATEST HEPARIN S-2222	N1099442	4 mL
COATEST ANTITHROMBIN	N1099446	1 mL
COATEST HEPARIN NORMAL PLASMA	N1099101	1 mL
COATEST HEPARIN BUFFER	N1098987	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: Nehal Patel *N. Patel*
PRINT SIGNATURE

DATE: 11/11/2019 *11-11-19*

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz*
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DATE: 11/11/2019 *11/11/19*

TITLE: Technical Supervisor