

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	COATEST Heparin	EXPIRATION DATE:	2021-08
PRODUCT NUMBER:	25553963		
LOT NUMBER:	N0293834		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. FACTOR Xa (650515)</b>					
ACTIVITY	61	81	nkat/vial	66	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	0.999	PASS
CONTROL RECOVERY	66.0	73.0	nkat/vial	71.4	PASS
RESIDUAL MOISTURE (KF)	0	5	%	NA	NA
RESIDUAL MOISTURE (FMS)	0	12.0	Torr	0.3	PASS

<b>B. S-2222, FOR COATEST HEPARIN (654009)</b>					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	15.2	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
RESIDUAL MOISTURE	0	5	%	0.2	PASS

<b>C. ANTITHROMBIN 10 IU, FOR COATEST HEPARIN (654023)</b>					
ANTITHROMBIN ACTIVITY	9	11	IU/vial	11	PASS

<b>D. NORMAL CONTROL PLASMA (650292)</b>					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0.07	PASS
<u>STANDARD CURVE:</u>					
regression coefficient (r <sup>2</sup> )	0.99	1.00	--	1.000	PASS
slope	-0.800	-0.500	--	-0.560	PASS
intercept	0.650	1.030	--	0.863	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.366	PASS
APPEARANCE	yellowish-white, lyophilized powder			PASS	PASS

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

<b>F. COATEST HEPARIN KIT</b>					
SLOPE	-0.800	-0.500	--	-0.552	PASS
INTERCEPT	0.650	1.030	--	0.793	PASS
REGRESSION COEFFICIENT (r <sup>2</sup> )	0.99	1.00		0.998	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	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;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: Nehal Patel *N.M. Patel*  
 PRINT SIGNATURE

DATE: 3/7/2019 *3-7-19*

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *DebraLeeHarz*  
 PRINT SIGNATURE

DATE: 3/7/2019 *3-7-19*

TITLE: Technical Supervisor