

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

Instrumentation  
Laboratory  
A Werfen Company

PRODUCT NAME:	COATEST Heparin	EXPIRATION DATE:	2020-12
PRODUCT NUMBER:	25553963		
LOT NUMBER:	N0789229		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. FACTOR Xa (650515)</b>					
ACTIVITY	61	81	nkat/vial	71	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	67.8	75.0	nkat/vial	68.3	PASS
RESIDUAL MOISTURE (KF)	0	5	%	NA	NA
RESIDUAL MOISTURE (FMS)	0	12.0	Torr	0.2	PASS

<b>B. S-2222, FOR COATEST HEPARIN (654009)</b>					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	14.48	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS
RESIDUAL MOISTURE	0	5	%	0	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	0.01	PASS
<b>STANDARD CURVE:</b>					
regression coefficient (r <sup>2</sup> )	0.99	1.00	--	0.996	PASS
slope	-0.800	-0.500	--	-0.643	PASS
intercept	0.650	1.030	--	0.800	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.396	PASS
APPEARANCE	yellowish-white, lyophilized powder			PASS	PASS

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

<b>F. COATEST HEPARIN KIT</b>					
SLOPE	-0.800	-0.500	--	-0.559	PASS
INTERCEPT	0.650	1.030	--	0.879	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: 8/29/2018 8-29-18

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz Debra Lee Harz  
PRINT SIGNATURE

DATE: 8/29/2018 8-29-18

TITLE: Technical Supervisor