

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

Instrumentation  
Laboratory  
A Werfen Company

PRODUCT NAME	COATEST Heparin	EXPIRATION DATE	2024-09
PRODUCT NUMBER:	25553963		
LOT NUMBER	N0421784		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. FACTOR Xa</b>					
ACTIVITY	61	81	nkat/vial	80	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	65.7	72.7	nkat/vial	69.2	PASS
RESIDUAL MOISTURE (KF)	0	5	%	NA	
RESIDUAL MOISTURE (FMS)	0	12.0	Torr	0.2	PASS

<b>B. S-2222, FOR COATEST HEPARIN</b>					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	14.66	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
RESIDUAL MOISTURE	0	5	%	0.1	PASS

<b>C. ANTIHROMBIN 10 IU, FOR COATEST HEPARIN</b>					
ANTI HROMBIN ACTIVITY	9	11	IU/vial	10	PASS

<b>D. NORMAL CONTROL PLASMA</b>					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0	PASS
STANDARD CURVE					
regression coefficient (r <sup>2</sup> )	0.99	1.00	--	0.991	PASS
slope	-0.800	-0.500	--	-0.733	PASS
intercept	0.650	1.030	--	0.797	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.354	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	--	8.5	PASS

<b>F. COATEST HEPARIN KIT</b>					
SLOPE	-0.800	-0.500	--	-0.719	PASS
INTERCEPT	0.650	1.030	--	0.819	PASS
REGRESSION COEFFICIENT (r <sup>2</sup> )	0.99	1.00		0.99	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST HEPARIN FACTOR Xa	N0321009	2 ml
COATEST HEPARIN S-2222	N0320812	4 ml
COATEST ANTIHROMBIN	N0421605	1 ml
COATEST HEPARIN NORMAL PLASMA	N0421436	1 ml
COATEST HEPARIN BUFFER	N0320803	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: N. Patel *N.M. Patil*  
PRINT SIGNATURE

DATE: 5/31/2022 *5-31-22*

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: D. Tencza *D. Tencza*  
PRINT SIGNATURE

DATE: 5/31/2022 *5/31/2022*

TITLE: Senior Group Leader