

CERTIFICATE OF ANALYSIS

CHROMOGENIX

**Instrumentation
Laboratory**
A Werfen Company

PRODUCT NAME:	COATEST Heparin	EXPIRATION DATE:	2023-02
PRODUCT NUMBER:	25553963		
LOT NUMBER:	N0907427		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa					
ACTIVITY	61	81	nkat/vial	73	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.0	73.0	nkat/vial	69.0	PASS
RESIDUAL MOISTURE (KF)	0	5	%	1.0	PASS
RESIDUAL MOISTURE (FMS)	0	12.0	Torr	NA	

B. S-2222, FOR COATEST HEPARIN					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	14.97	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.2	PASS
RESIDUAL MOISTURE	0	5	%	0.9	PASS

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

D. NORMAL CONTROL PLASMA					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0.05	PASS
STANDARD CURVE:					
regression coefficient (r ²)	0.99	1.00	--	0.998	PASS
slope	-0.800	-0.500	--	-0.569	PASS
intercept	0.650	1.030	--	0.791	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.316	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	--	8.5	PASS

F. COATEST HEPARIN KIT					
SLOPE	-0.800	-0.500	--	-0.658	PASS
INTERCEPT	0.650	1.030	--	0.836	PASS
REGRESSION COEFFICIENT (r ²)	0.99	1.00		0.997	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST HEPARIN FACTOR Xa	N0806560	2 mL
COATEST HEPARIN S-2222	N0907235	4 mL
COATEST ANTITHROMBIN	N0806557	1 mL
COATEST HEPARIN NORMAL PLASMA	N0907240	1 mL
COATEST HEPARIN BUFFER	N0907426	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: Maria Oettinger
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Maria Oettinger
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DATE: 10-7-2020

TITLE: QC Analyst III

APPROVAL SIGNATURE: Donna Tencza
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DATE: 10/7/20

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