

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COAMATIC FACTOR VIII	PRODUCT # :	82258563
EXP. DATE:	2019-12	LOT # :	N1274365
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	822585/49730503
		DATE OF MANUFACTURE	2017-12

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.57	--	0.45	PASS
Intercept	--	0.12	--	0.06	PASS
r	0.990	--	--	0.995	PASS
LOW RANGE					
Slope	2.8	6.9	--	4.8	PASS
Intercept	--	0.21	--	0.11	PASS
r	0.990	--	--	1.000	PASS

Kit Components:

Name	Lot Number	Exp. date
S-2765/ I-2581	N1274206	2019-12
Factor Reagent	N1274208	2019-12
Buffer	N1274363	2019-12

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: NPATEL N.M. Patel DATE: 1-22-18
 APPROVAL SIGNATURE: D TENOZA P. Tenocza DATE: 1/22/18