

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC FACTOR VIII	PRODUCT #: 82258563
EXP. DATE: 2019-11	LOT #: N1174046
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	--	0.33	PASS
Intercept	--	0.12	--	0.05	PASS
r	0.990	--	--	0.997	PASS
LOW RANGE					
Slope	2.8	6.9	--	3.8	PASS
Intercept	--	0.21	--	0.07	PASS
r	0.990	--	--	0.999	PASS

Kit Components:

Name	Lot Number	Exp. date
S-2765/ I-2581	N1174041	2019-11
Factor Reagent	N1173751	2019-11
Buffer	N1174045	2019-11

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: 12-20-17
12/20/2017

APPROVAL SIGNATURE: DTENCZA D. Encza

DATE: 12/20/17
12/20/2017