

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC FACTOR VIII	PRODUCT #: 82258563
EXP. DATE: 2019-06	LOT #: N0771265
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 822585/49730503
	DATE OF MANUFACTURE 07-2017

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.57	--	0.44	PASS
Intercept	--	0.12	--	0.06	PASS
r	0.990	--	--	0.994	PASS
LOW RANGE					
Slope	2.8	6.9	--	5.6	PASS
Intercept	--	0.21	--	0.08	PASS
r	0.990	--	--	1.000	PASS

Kit Components:

Name	Lot Number	Exp. date
S-2765/ I-2581	N0670773	2019-06
Factor Reagent	N0771262	2019-07
Buffer	N0771264	2019-07

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: 8-16-17
8/16/2017

APPROVAL SIGNATURE: DTENCZA D. Encza

DATE: 8/16/17
8/16/2017