

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	<u>COAMATIC FACTOR VIII</u>	PRODUCT # :	<u>82258563</u>
EXP. DATE:	<u>2017-10</u>	LOT # :	<u>N1059203</u>
VENDOR:	<u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM:	<u>822585/49730503</u>

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.51	--	0.48	PASS
Intercept	--	0.12	--	0.05	PASS
r	0.990	--	--	0.996	PASS
LOW RANGE					
Slope	2.8	5.8	--	5.8	PASS
Intercept	--	0.18	--	0.09	PASS
r	0.990	--	--	0.994	PASS

Kit Components:

Name	Lot Number	Exp. date
S-2765/ I-2581	N1059201	2017-10
Factor Reagent	N1059195	2017-10
Buffer	N1059197	2017-10

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* DATE: 11/24/2015

APPROVAL SIGNATURE: *D. Harz* DATE: 11/24/2015