

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: <u>COAMATIC FACTOR VIII</u>	PRODUCT #: <u>82258563</u>
EXP. DATE: <u>2018-08</u>	LOT #: <u>N0965025</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM: <u>822585/49730503</u>
	DATE OF MANUFACTURE <u>8/24/2016</u>

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	PASS/FAIL
	MIN	MAX			
HIGH RANGE					
Slope	0.33	0.57	--	0.53	PASS
Intercept	--	0.12	--	0.11	PASS
r	0.990	--	--	0.995	PASS
LOW RANGE					
Slope	2.8	6.9	--	6.0	PASS
Intercept	--	0.21	--	0.13	PASS
r	0.990	--	--	0.992	PASS

Kit Components:

Name	Lot Number	Exp. date
S-2765/ I-2581	N0965021	2018-09
Factor Reagent	N0965024	2018-09
Buffer	N0864683	2018-08

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: 9-26-16
9/26/2016

APPROVAL SIGNATURE: DTENCZA D. Tenca

DATE: 9/26/16
9/26/2016