

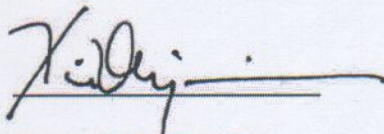
STATEMENT

We, ACON Laboratories Inc. having a registered office at 5850 Oberlin Drive #340 San Diego CA 92130 assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: 3/5/20

Signature:



Qiyi Xie, MD, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com



ACON
ACON Laboratories, Inc.

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November 11th 2016

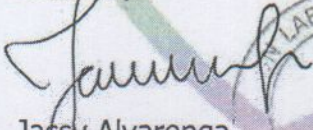
CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely



Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc. S.A.
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+1 858 875 8085



ACON BIOTECH (HANGZHOU) CO.,LTD
CERTIFICATE OF ANALYSIS

PRODUCT NAME: Mission Liquid Urine Control for combo pack

PURCHASE NO.: 37740068A

BATCH NO.: UCL0090001

EXPIRATION DATE: 2022-06-22

QUANTITY: 70kits

ANALYSIS		SPECIFICATIONS	TEST RESULT
Specific gravity	Level 1	1.015~1.030	Complies
	Level 2	1.005~1.020	Complies
pH	Level 1	5.0~7.0	Complies
	Level 2	6.5~9.0	Complies
Glucose	Level 1	Negative	Complies
	Level 2	≥+/- (100mg/dl)	Complies
Protein	Level 1	Negative	Complies
	Level 2	≥1+ (30mg/dl)	Complies
Leukocyte	Level 1	Negative	Complies
	Level 2	≥1+ (70 Leu/μl)	Complies
Nitrite	Level 1	Negative	Complies
	Level 2	Positive	Complies
Urobilinogen	Level 1	0.2(3.5) mg/dL(μmol/L)	Complies
	Level 2	≥+/- (1.0mg/dl)	Complies
Blood	Level 1	Negative	Complies
	Level 2	≥2+	Complies
Ketone	Level 1	Negative	Complies
	Level 2	≥1+ (15mg/dl)	Complies
Bilirubin	Level 1	Negative	Complies
	Level 2	≥1+ (1mg/dl)	Complies
Ascorbic acid	Level 1	Negative	Complies
	Level 2	Negative	Complies
Albumin	Level 1	10~30mg/L	Complies
	Level 2	80~150mg/L	Complies
Creatinine	Level 1	10~100mg/dL	Complies
	Level 2	100~300mg/dL	Complies
Urine Calcium	Level 1	4~10mg/dL	Complies
	Level 2	20~40mg/dL	Complies



Quality Department: Hedy Zhang

Date: Sep. 24, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HBsAg EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2004721

EXPIRATION DATE: 2021/11/12

QUANTITY: 50kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No visible deposit or floccules in solution.	Complies
Blank well		OD < 0.100 (450nm) OD < 0.050 (450/630)	Complies
Sensitivity	Ad0.2 ng/ml	OD ≥ 0.100	Complies
	Ad0.5 ng/ml	OD ≥ 0.150	Complies
	Ad1.0 ng/ml	OD ≥ 0.250	Complies
	Ay0.2 ng/ml	OD ≥ 0.100	Complies
	Ay0.5 ng/ml	OD ≥ 0.150	Complies
Coincidence of Specificity Standard		100/100	Complies
High Positive Standard		OD ≥ 3.000	Complies
Negative Control		OD < 0.100	Complies
Positive Control		OD > 1.000	Complies
Precision		CV < 15%	Complies



Quality Department: Hedy zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HCV Antibody EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2004722

EXPIRATION DATE: 2022/02/11

QUANTITY: 50kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No visible deposit or floccules in solution.	Complies
Blank Well		OD < 0.100 (450nm) OD < 0.050 (450/630 nm)	Complies
Sensitivity	H (n=2)	OD ≥ 2.500	Complies
	M (n=2)	OD ≥ 1.500	Complies
	L1 (n=2)	OD ≥ 0.150	Complies
	L2 (n=2)	OD ≥ 0.150	Complies
	L3 (n=2)	OD ≥ 0.150	Complies
Negative Control		OD < 0.100	Complies
Positive Control		OD > 1.000	Complies
Coincidence of specificity standard		≥ 99/100	Complies
Precision		CV < 15%	Complies

Quality Department: Hedy Zhang

Date: Sep 23, 2020



