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

Digitally signed by Gangan Dumitru
Date: 2021.07.21 10:10:13 EEST
Reason: MoldSign Signature
Location: Moldova

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

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HBcAb EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2008762

EXPIRATION DATE: 2021/11/08

QUANTITY: 11kits

SPECIFICATION	STANDARD	CONCLUSION
Appearance	No visible deposit or floccules in liquid component	Complies
Negative Control	OD＞1.000	Complies
Positive Control	OD＜0.080	Complies
QCO reference	0.500≤QCO/Cutoff value≤1.500	Complies
Compliance rate of negative reference	15/15	Complies
Compliance rate of positive references	15/15	Complies
Precision criteria	CV＜20%	Complies

Quality Department: Hedy zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HBsAb Quantitative EIA Test Kit

PURCHASE NO.: 37740066B

BATCH NO.: 2003706

EXPIRATION DATE: 2021/03/04

QUANTITY: 33kits

SPECIFICATION		STANDARD	CONCLUSION
Appearance		No obvious sediments or floccules in liquid component and color meets requirement	Complies
Sensitivity Standard	10mIU/mL	0.105<OD<0.400	Complies
	100mIU/mL	0.500<OD<1.600	Complies
	200mIU/mL	OD>1.200 and OD>100.0mIU/mL OD	Complies
Compliance of Negative Standard		OD < Calibrator 2# OD	Complies
Calibrator 1#		OD < 0.105	Complies
Calibrator 2#		OD > 0.105	Complies
Calibrator 3#		OD > 0.250	Complies
Calibrator 4#		OD > 0.500	Complies
Calibrator 5#		OD > 1.000	Complies
R value		R > 0.98	Complies
Precision		CV < 15%	Complies
The above results based on evaluation on the whole kit with all components manufactured by ACON			

Quality Department: Antony. Hu

Date: Apr. 21, 2020

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Mission ® U500 Urine Analyzer (U211-101, U211-111)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Mission ® Liquid Urine Control (U021-011, U021-021, U021-031)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

5850 Oberlin Drive #340 · San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 104507 0001 Rev. 01

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development,
Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for
the Determination of Infectious Diseases,
Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker,
Fertility/Pregnancy and Blood Glucose
Monitoring System,
Lancing Devices and Lancets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1974310

Valid from: 2019-10-24
Valid until: 2022-09-06

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 104507 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Mission® U500 Urine Analyzer

Clinical Accuracy | 15 Strip Combinations | 8 Software Languages | Urine Clarity & Colorfor POCT

High Accuracy and Reliability

- Up to 500 tests/hour for medium volume labs or small hospitals
- Large color touchscreen display offers intuitive menu navigation
- Ability to input urine color and clarity for better reference
- Flags abnormal results automatically
- 15 combinations of strips available, including Microalbumin, Creatinine, Ascorbic Acid and Calcium
- Strip Lockout prevents using strips of another brand with a customized canister code
- Order of parameters can be selected for display and printout
- Urine clarity and color can be captured
- Automatic strip detection and alignment
- Reads strips with up to 14 parameters, including Microalbumin, Creatinine and Calcium
- 8 languages preloaded into the software
- Automatic calibration
- USB Port and RS232C Port for data transfer to a computer and LIS

Large Color Touchscreen | **Automatic Strip Detection** | **Easy Access to Strip Carrier**

Strip Combinations for U500 Urine Analyzer

Catalog Number	Numbers of Parameters	Type of Strip U500 Analyzer	Parameter Order (First parameter is closest to strip handle)	Parameter													
				ASC	GLU	BIL	KET	SG	BLO	PH	PRO	URO	NIT	LEU	ALB	CRE	Ca
U031-141	14	14C	Ca/Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-131	13	13CE	Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-111	11	11A	Asc/Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu	*	*	*	*	*	*	*	*	*	*	*			
U031-101	10	10U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu		*	*	*	*	*	*	*	*	*	*			
U031-091	9	9U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit		*	*	*	*	*	*	*	*	*	*			
U031-081	8	8N	Glu/Ket/SG/Blo/pH/Pro/Nit/Leu[1]		*		*	*	*	*	*		*	*			
U031-071	7	7N	Glu/Ket/Pro/pH/Blo/Nit/Leu		*		*		*	*	*						
U031-051	5	5NE	Blo/pH/Pro/Ket/Glu		*				*		*		*	*			
		5NE	Glu/Pro/Nit/Blo/Leu		*				*		*		*	*			
U031-041	4	4PE	Glu/Pro/Nit/Leu		*						*		*	*			
		4SE	Glu/SG/pH/Pro		*			*		*	*						
U031-031	3	3PE	Glu/pH/Pro		*					*	*						
		3KE	Glu/Ket/Pro		*		*				*						
U031-021	2	2GE	Glu/Pro		*						*						
		2CE	ALB/CRE												*	*	

Specifications

Feature	Specifications
Analyzer Type	Semi- Automatic
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	500 tests/ hour / (Measuring cycle: 7 seconds/ test)
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 results
Strip Incubation Time	1 Minute
Wavelength	525 and 635 nm
Default Strips*	2, 3, 4, 5, 7, 8, 9, 10, 11, 13, and 14 Parameters (108 mm x 5 mm)
Strips Available*	1- 14 Parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations per Analyzer*	15 combinations available currently; capacity for unlimited
Software Languages*	8 languages
Analyzer Ports*	RS232C Port for Barcode Reader, Data Transfer, and Software Update USB Port for Data Transfer, 25 Pin Parallel Port for External Printer
Data Entry Capabilities*	Urine Color and Clarity - Manual Entry / Operator ID/Patient ID - Manual Entry and Barcode Reader (Up to 25 characters)
Data Transfer Options*	Data for single entry, all the data in database, data from specific date
Data Search Options*	Test number, positive results, patient ID, date, STAT results, QC results
Software Updates*	Download software from ACON website and update analyzer via RS232C Cable
Connection Capabilities*	RS232C port for Software Update (included) / RS232C Barcode Reader (optional) / USB or RS232C Data Transfer Cable (optional)
Screen Type*	LCD color touchscreen
LIS Interface*	HL-7 compliant
Calibration	Automatic
Operating Conditions	0 – 40 °C (32 – 104 °F); ≤ 85% RH
Storage Conditions	- 5 – 50 °C (23 – 122 °F); ≤ 90% RH
Power Source	100 - 240 Volts AC, 50- 60 Hz
Dimensions (L x W x H)	36.6 cm x 28.3 cm x 19.5 cm (14.4” x 11.1” x 7.7”)
Display Dimensions (L x W)	11.5 cm x 9 cm (4.5” x 3.5”)
Weight	4.0 kg (8.8 lbs.) without batteries or power supply

*Enhanced Feature

Ordering Information

Product Name	Catalog Number	Components		Kit Box Dimensions (L x W x H) & Weight Carton Dimensions (L x W x H) & Weight			Number of Kits/ Carton
U500 Urine Analyzer	U211-101	1 Urine Analyzer 1 Strip Platform/ Waste Tray 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual	51.0 cm x 42.0 cm x 38.5 cm; 7 kg			1
				20.1” X 16.5” x 15.2”; 246.9 oz			
Printer Paper Rolls	U121-101	4 Printer Paper Rolls		**Thermal Paper** (0.06 m x 20 m): 200 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg	50
					4.7” x 4.7” x 2.6”; 12.7oz	24.8” x 14.6” x 11.8”; 42.8 lbs	
				Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg	
					4.7” x 4.7” x 2.6”; 14.1oz	24.8” x 14.6” x 11.8”; 47.2 lbs	

CE Marked for sale in the European Community and 510(k) Cleared

aconlabs.com

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego, CA 92121, U.S.A.
Tel: 1.858.875.8000
Fax: 1.858.200.0729
Email: info@aconlabs.com

PN 2170004201 • Date 7/17

Certificat

Certificate

N° 2007/28642.5

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:

ZAO "EKOlab"
ЗАО «ЭКОлаб»

for the following activities:
для следующих областей деятельности:

DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES FOR IN-VITRO DIAGNOSTICS.

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ IN-VITRO ДИАГНОСТИКИ.

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485:2016

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1A

This certificate is valid from (year/month/day)
Данный сертификат действителен с (год/ месяц/ день)
2019-06-28 until *до* **2022-06-27**

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ЗАО "ЭКОлаб"

ИНСТРУКЦИЯ
"Сифилис-АгКЛ-РМП"
Антиген кардиолипиновый для реакции микропреципитации[1]

Регистрационное удостоверение № ФСР 2011/09957 от 30 октября 2012 г.

Комплект № 2

Кат. № 03.07.1
Кат. № 03.07.2
Кат.№ 03.07.3

[1] Взамен инструкции, утвержденной 26.01.2011 г. № 215-Пр/11

НАЗНАЧЕНИЕ

Набор применяется при диагностике сифилиса для исследования плазмы (сыворотки) крови или спинно-мозговой жидкости (СМЖ) человека в реакции микропреципитации (РМП).

ПРИНЦИП МЕТОДА

Тест основан на взаимодействии кардиолипинового антигена (АгКЛ), аналогичного липопротеиновому антигену Treponema pallidum, с соответствующими антителами (реагинами), которые появляются в плазме (сыворотке) нелеченных больных через 2-3 недели, а в спинно-мозговой жидкости – через 4-8 недель после заражения.

Взаимодействие АгКЛ с реагинами приводит к реакции микропреципитации (выпадение хлопьев разной величины) и регистрируется визуально.

СОСТАВ НАБОРА:

Комплект № 2 (кат. № 03.07.1, кат. № 03.07.2, кат. № 03.07.3) включает:

Взвесь АгКЛ – взвесь АгКЛ в 10 % растворе холин-хлорида, содержащая кардиолипина – 0,033 %; лецитина – 0,27 %, холестерина – 0,9 %, ЭДТА (стабилизатор) в конечной концентрации 0,0125 моль/л и тимеросал (консервант) в конечной концентрации 0,1 %. Суспензия молочно-белого цвета, при отстаивании разделяющаяся на опалесцирующую бесцветную жидкость и плотный осадок белого цвета

кат. № 03.07.1	- 3 флакона (по 5,0 мл)
кат. № 03.07.2	- 6 флаконов (по 5,0 мл).
кат. № 03.07.3	- 7 флаконов (по 10 мл).

Базовый вариант комплекта № 2 рассчитан на исследование 500 образцов (кат. № 03.07.1) , 1000 образцов (кат.№ 03.07.2), 2000 образцов (.(кат.№ 03.07.3)

По желанию потребителя базовая комплектация набора (число упаковок с реагентами и их объем) может быть изменена.

Возможна дополнительная комплектация набора положительной и отрицательной контрольными сыворотками для диагностики сифилиса производства ЗАО "ЭКОлаб" (ТУ 9398-096-70423725-2008, РУ № ФСР 2009/05912 от 22.10.09) (кат. №03.07.1к - 500 определений, № 03.072к - 1000 определений, кат. № 03.07.3к - 2000 определений)– в количестве, определяемом заявкой потребителя, а также стеклянными и пластиковыми слайдами для постановки реакции.

АНАЛИЗИРУЕМЫЕ ПРОБЫ

Реакцию проводят с плазмой (сывороткой, инактивированной при температуре $56 \pm 1^{o}C$ в течение 30 мин) крови или СМЖ, получаемыми стандартными методами.

Образцы плазмы (сыворотки) крови с выраженным гемолизом, гиперлипидемией и бактериальным ростом исследованию не подлежат.

Образцы, предназначенные для исследования, могут храниться от 2 до 8 ^{o}C не более 7 сут, допустимо их длительное хранение в замороженном состоянии при температуре минус 20 ^{o}C и ниже. Повторное замораживание размороженных образцов не допускается.

МЕРЫ ПРЕДОСТОРОЖНОСТИ ПРИ РАБОТЕ С НАБОРОМ

Набор биологически безопасен, однако с исследуемыми образцами следует обращаться как с потенциально инфицированными материалами.

ОБОРУДОВАНИЕ, МАТЕРИАЛЫ И РЕАГЕНТЫ:

- центрифуга лабораторная, обеспечивающая угловую скорость 1000-2000 об/мин;
- шейкер лабораторный;
- термостат или водяная баня, обеспечивающие температуру прогревания (37±1) ^{0}C или (56±1) ^{0}C, соответственно;
- секундомер;
- пипетки Пастеровские;
- пипетки, позволяющие отбирать объемы жидкости 0,02 и 5,0 мл;

- пробирки вместимостью 10 мл;
- вода очищенная (дистиллированная или деионизированная);
- 0,9% раствор натрия хлористого;
- стекло или пластина из плексигласа;
- перчатки резиновые или пластиковые.

ПОДГОТОВКА РЕАГЕНТОВ ДЛЯ АНАЛИЗА

Комплект № 2

Перед использованием реагенты выдержать не менее 30 мин при температуре от 18 до 25 ^{o}C, взвесь АгКЛ тщательно перемешать до образования однородной суспензии.

ПРОВЕДЕНИЕ АНАЛИЗА

Качественный метод

Комплект № 2

На обычное стекло или углубление пластинки из пластика наносят 90 мкл исследуемого образца, затем добавляют 30 мкл антигенной эмульсии. Стекло или пластину поместить на платформу шейкера и вращать в горизонтальной плоскости**– 8 мин,** после чего сразу же произвести учет результатов реакции (оптимальный температурный режим реакции 23-28 ^{0}C).

Учет результатов реакции

При исследовании образца от больных сифилисом наблюдается положительная реакция в виде выпадения хлопьев разной величины, оцениваемая в крестах (крупные (++++) и средние (+++) с четким просветлением жидкости-реакция положительная, мелкие (++)- реакция слабоположительная), а с плазмой или инактивированной сывороткой от здоровых лиц наблюдается отрицательная реакция в виде опалесценции.

Результаты реакции учитываются визуально при освещении не ниже 300 люкс.

Возможен документированный учет результатов с использованием аппаратно-программного комплекса "Эксперт-Лаб".

Полуколичественный метод (определение титра реагинов)

Титр реагинов определяется только в исследованных образцах, давших положительную или слабоположительную реакцию.

1. Исследуемую пробу развести физиологическим раствором в соотношении 1:1, 1:2; 1:4, 1:8, 1:16, 1:32.
2. Каждое разведение исследовать так же, как и в качественном методе.

Титром реагинов в исследуемого образце считать максимальное разведение, с которым получена положительная или слабоположительная реакция, при условии отрицательной реакции с последующим разведением. Если положительная реакция получена с максимальным из использованных разведении, для определения титра реагинов ряд разведений необходимо продолжить.

СРОК ГОДНОСТИ. УСЛОВИЯ ХРАНЕНИЯ И ТРАНСПОРТИРОВКИ

Комплект № 2

Срок годности – 1,5 года.

Комплект должен храниться в упаковке предприятия-изготовителя при температуре от 2 до 8 ^{o}C в течение всего срока годности. Замораживание не допускается.

Транспортируют при температуре от 2 до 8 ^{o}C. Допускается транспортирование при температуре от 9 до 25 ^{o}C не более 10 сут. Замораживание не допускается.

По вопросам, касающимся качества набора "Сифилис-АгКЛ-РМП", следует обращаться по адресу 142530 Московская обл., г. Электрогорск, ул. Буденного, д. 1. ЗАО "ЭКОлаб"; тел. (49643) 3-23-11 – отдел сбыта, 3-30-93 – ОБТК, факс (49643) 3-31-43 .

май 2016 г.

SYNTESYS

ISO9001:2008
Cert. N.6574/0

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867

COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo Ruggero & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

Denominazione degli articoli prodotti/*Description of Manufacturer*	**Contenitori per urina, contenitori per feci, contenitori universali, Pipette Pasteur, Piastre di Petri, Anse Sterili per batteriologia, Aste a "L", Puntali Eppendorf gialli e blue, cuvette per spettrofotometro, tazzine per campionamento siero, bacchette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provette diam. 12 mm e 16mm, provette con granuli ed acceleratore, provette sottovuoto per prelievo, Sistema SEDIPLAST, Microprovette, Portavetrini, Vetrini precolorati, Portaprovette, supporti per microprovette, bottiglie per raccolta urine.** ***Urine container, faeces container, universal container, Pasteur pipette, Petri dishes, Sterile loops, Sterile loops open "L", Eppendorf tips yellow and blue, cuvettes for spectrophotometer, samples cups, Rod to detach clot, disposable forceps, Disposable plastic tubes, winged stoppers for tubes diam. 12mm & 16mm, Test tube with granules and clot activator, vacuum test tube, SEDIPLAST system, micro test tubes, Slides Mailer,"TESTSIMPLETS" slides rack for test tubes, rack for micro test tubes, Bottles for urine collection.***

SYNTESYS

ISO9001:2008
Cert. N.6574/0

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35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

Materiale/*Material*	**Polipropilene, Polistirolo, Polietilene e Polimetilmetacrilato** ***Polypropylene, Polystyrene, Polyethylene and Polymetilmetacrylate***

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnotic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/*declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07/01/2016
Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s.
di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis.
Manufacturing of products for laboratory analysis and sanitary products.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on:	**2019-06-05**
First issued on:	**2014-06-21**
Expires on:	**2022-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-93779

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

0774CM_03_EN

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s.
di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis.
Manufacturing of products for laboratory analysis and sanitary products.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2019-06-05**
First issued on:	**2013-06-05**
Expires on:	**2022-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-83562

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
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Polmed.de
Vertretung und Repräsentanz

Certificate

Of Marketing Authorization of Medical Product

Nr. **AR/IVMD/Xema/01/2020**

Issued on the basis of the Declaration of conformity and registration taking into account Article 10 of Directive 98/79/EC on In Vitro Diagnostic Medical Devices and Medical Devices Act (MPG) § § 5,25,29,30

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der Richtlinie 98/97/EG Artikel 10 über In-vitro-Diagnostika und Medizinproduktgesetz (MPG) §§ 5,25,29,30

Manufacturer: Hersteller	**Xema Co., Ltd.** **bld.4, 48, The 9th Parkovaya str.** **Moscow 105264, RUSSIA,** **info@xema.ru; www.xema.ru**
Product name: Produkt	**See annex to the Certificate** Siehe Anhang zum Zertifikat
Product Classification: Produktklassifizierung	**In Vitro Diagnostic Medical Devices** In-vitro-Diagnostikum (IVD) Medizinprodukte
Category: Kategorie	**Common/ Other IVD** Sonstige IVD-Produkte
Conformity Module: Konformitätsmodul	**Module A (EC Declaration of Conformity)** **(Annex III, except point6, Directive 98/79/EC)** Modul A (EG-Konformitätserklärung) (Anhang III, außer Nummer 6, Richtlinie 98/79 / EG)
Lead Competent Authority: Zuständige Behörde	**DIMDI** – German Institute of Medical Documentation and Information **DIMDI** – Deutsches Institut für Medizinische Dokumentation und Information
Product Registration Ref. No.: (Per Article 10, Directive 98/79/EC) Produkt Registrationsnummer (Gemäß Artikel 10 der Richtlinie 98/79 / EG)	**See annex to the Certificate** Siehe Anhang zum Zertifikat

Date of issue: **2020-01-01**
Das Ausstellungsdatum

Valid to : **2022-05-25**
Gültig bis

Represented in the EC by Polmed.de
Steinacker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279

Vertretung und Repräsentanz Polmed.de D-73773 Aichwald Steinacker 5

Polmed.de

Valid with the Extract from the database www.dimdi.de (German Institute for Medical Documentation)
Gilt nur mit :Auszug aus der Datenbank www.dimdi.de (Deutsche Institut Für Medizinische Dokumentation)

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/01/2020

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DIMDI Registration number Registriernummer
1.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA Cat. Nr K131	**DE/CA37/IVD/13/44**
2.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA Cat. Nr K132	**DE/CA37/IVD/13/43**
3.	MPO ANCA	K133	aMPO EIA Cat. Nr K133	**DE/CA37/IVD/13/42**
4.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	Anti-tTG IgG EIA Cat. Nr K160; Anti-tTG IgA EIA Cat. Nr K161	**DE/CA37/IVD/13/41**
5.	GLIADIN ANTIBODIES	K180 K181 K182A K182G	Gliadin IgG EIA Cat. Nr K180; Gliadin IgA EIA Cat. Nr K181 ; Deamidated Gliadin IgA EIA, Deamidated Gliadin IgG EIA	**DE/CA37/IVD/13/40**
6.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA Cat. Nr K200	**DE/CA37/IVD/13/39**
7.	THYROID STIMULATING HORMONE	K201 K201A	TSH EIA Cat. Nr K201; TSH Plus EIA Cat. Nr K201A	**DE/CA37/IVD/13/38**
8.	LUTEINISING HORMONE	K202	LH EIA Cat. Nr K202	**DE/CA37/IVD/13/37**
9.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA Cat. Nr K203	**DE/CA37/IVD/13/36**
10.	HUMAN GROWTH HORMONE	K204	GH EIA Cat. Nr K204	**DE/CA37/IVD/13/35**
11.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	HCG EIA Cat. Nr K205	**DE/CA37/IVD/13/34**
12.	PROLACTIN	K206	Prolactin EIA Cat. Nr K206	**DE/CA37/IVD/13/33**
13.	PROGESTERONE	K207 K207S	Progesterone EIA Cat. Nr K207 ; Salivary Progesterone EIA	**DE/CA37/IVD/13/32**
14.	ESTRADIOL	K208	Estradiol EIA Cat. Nr K208	**DE/CA37/IVD/13/31**
15.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209 K209S	Testosterone EIA Cat. Nr K209 ; Salivary Testosterone EIA	**DE/CA37/IVD/13/30**
16.	CORTISOL	K210 K210S	Cortisol EIA Cat. Nr K210 ; Salivary Cortisol EIA	**DE/CA37/IVD/13/29**
17.	TRIIODOTHYRONINE	K211	T3 EIA Cat. Nr K211	**DE/CA37/IVD/13/28**
18.	THYROXINE	K212	T4 EIA Cat. Nr K212	**DE/CA37/IVD/13/27**
19.	FREE TRIIODOTHYRONINE	K213	Free T3 EIA Cat. Nr K213	**DE/CA37/IVD/13/26**
20.	FREE THYROXINE	K214	Free T4 EIA Cat. Nr K214	**DE/CA37/IVD/13/25**
21.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEA-S EIA Cat. Nr K215	**DE/CA37/IVD/13/24**
22.	17 OH PROGESTERONE	K217	17-OH-Progesterone EIA Cat. Nr K217	**DE/CA37/IVD/13/22**
23.	CANCER ANTIGEN 125	K222	CA 125 EIA Cat. Nr K222	**DE/CA37/IVD/13/23**
24.	CANCER ANTIGEN 19-9	K223	CA 19.9 EIA Cat. Nr K223	**DE/CA37/IVD/13/21**
25.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA Cat. Nr K224	**DE/CA37/IVD/13/20**

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/01/2020

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DIMDI Registration number Registriernummer
26.	ALPHAFETOPROTEIN	K225	AFP EIA Cat. Nr K225	**DE/CA37/IVD/13/19**
27.	CANCER ANTIGEN 15-3	K226	M12 (CA 15.3) EIA Cat. NrK226	**DE/CA37/IVD/13/18**
28.	OTHER CANCER ANTIGENS	K227 K228	MUCI1 M22 EIA Cat. Nr K227; MUCI1 M20 EIA Cat. Nr K228	**DE/CA37/IVD/13/17**
29.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA Cat. Nr K232	**DE/CA37/IVD/13/16**
30.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	Free beta HCG EIA Cat. Nr K235	**DE/CA37/IVD/13/15**
31.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA Cat. Nr K238	**DE/CA37/IVD/13/14**
32.	OTHER OTHER PLASMA PROTEINS	K240	Alveomucin EIA Cat. Nr K240	**DE/CA37/IVD/13/13**
33.	C-REACTIVE PROTEIN	K250	CRP EIA Cat. Nr K250	**DE/CA37/IVD/13/12**
34.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA Cat. Nr K268	**DE/CA37/IVD/13/11**
35.	TROPONIN (T + I)	K291	Troponin I EIA Cat. Nr K291	**DE/CA37/IVD/13/10**
36.	IMMUNOGLOBULIN G	K271	Total IgG EIA Cat. Nr K271	**DE/CA37/IVD/13/9**
37.	IMMUNOGLOBULIN G SUBCLASS REAGENTS	K272 K274	IgG2 EIA Cat. Nr K272; IgG4 EIA Cat. Nr K274	**DE/CA37/IVD/13/8**
38.	IMMUNOGLOBULIN A	K275	Total IgA EIA Cat. Nr K275	**DE/CA37/IVD/13/7**
39.	IMMUNOGLOBULIN M	K277	Total IgM EIA Cat. Nr K277	**DE/CA37/IVD/13/6**
40.	RHEUMATOID/AUTOIMMUNE CONTROLS	KQ13 KQ14 KQ15	AutoQon AT immunoassay control set Cat. Nr KQ13; AutoQon ANA/ENA immunoassay control set Cat. Nr KQ14; AutoQon ACL immunoassay control set Cat. Nr KQ15	**DE/CA37/IVD/13/5**
41.	HORMONE CONTROLS	KQ21	HormoQon immunoassay control set Cat. Nr KQ21	**DE/CA37/IVD/13/4**
42.	TUMOUR MARKER CONTROLS	KQ22	OmaQon immunoassay control set Cat. Nr KQ22	**DE/CA37/IVD/13/3**
43.	CYFRA 21-1	K236	CYFRA 21-1 EIA	**DE/CA37/IVD/13/45**
44.	CANCER ANTIGEN 72-4	K244	CA 72-4 EIA	**DE/CA37/IVD/13/46**
45.	NEONATAL THYROID STIMULATING HORMONE	K201N	TSH-Neo EIA	**DE/CA37/IVD/13/47**
46.	ESTRIOL	K218	Free Estriol EIA	**DE/CA37/IVD/13/48**
47.	IMMUNOGLOBULIN E - MONOTEST/MONORESULT - MULTI AG	K200S	Specific IgE EIA	**DE/CA37/IVD/13/49**
48.	KAPPA AND LAMBDA CHAIN	K279K K279L	Free kappa Igg light chain EIA, Free lambda Igg light chain EIA	**DE/CA37/IVD/13/50**
49.	TRYPSIN NEONATAL	K242	Neonatal IRT EIA Cat. Nr K242	**DE/CA37/IVD/13/51**
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	**DE/CA37/IVD/13/52**

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Polmed.de
Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/01/2020

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	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DIMDI Registration number Registriernummer
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA37/IVD/13/52
51.	OTHER OTHER TUMOUR MARKERS	K239	HE – 4 EIA Cat. Nr K239	DE/CA37/IVD/13/53
52.	HSV IgG	K104	HSV ½ IgG EIA (Cat. Nr K104)	DE/CA37/IVD/13/67
53.	HSV IgM	K104M	HSV ½ IgM EIA (Cat. Nr K104M)	DE/CA37/IVD/13/66
54.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA (Cat. Nr K106)	DE/CA37/IVD/13/65
55.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	Treponema pallidum Total Ab EIA (Cat. Nr K111)	DE/CA37/IVD/13/64
56.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA (Cat. Nr K111G)	DE/CA37/IVD/13/63
57.	SYPHILIS ANTIBODY IGM	K111M	Treponema pallidum IgM EIA (Cat. Nr K111M)	DE/CA37/IVD/13/62
58.	H. PYLORI ANTIBODY ASSAYS	K119	H.pylori IgG EIA (Cat. Nr K119)	DE/CA37/IVD/13/61
59.	H. PYLORI ANTIBODY ASSAYS	K119M	H.pylori IgM EIA (Cat. Nr K119M)	DE/CA37/IVD/13/60
60.	ASPERGILLUS	K121	Aspergillus IgG EIA (Cat. Nr K121)	DE/CA37/IVD/13/59
61.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA (Cat. Nr K126)	DE/CA37/IVD/13/58
62.	GIARDIA LAMBLIA	K171 K171X	Giardia lamblia Total Ab EIA (Cat. Nr 171) Giardia lamblia IgG/IgM/IgA EIA (Cat. No. K171X)	DE/CA37/IVD/13/57Ä1
63.	OTHER TUMOUR MARKER RAPID TESTS	X22OV	XEMAtestOvaScreen (Cat. Nr X22OV)	DE/CA37/IVD/13/56
64.	OTHER TUMOUR MARKER RAPID TESTS	X222	XEMAtestCA125 (Cat. Nr X222)	DE/CA37/IVD/13/55
65.	OTHER TUMOUR MARKER RAPID TESTS	X239	XEMAtestHE4 (Cat. Nr X239)	DE/CA37/IVD/13/54
66.	IMMUNOGLOBULIN A IgA	K276	SECRETORY IgA (sIgA) EIA (Cat. No. K276)	DE/CA37/IVD/13/68
67.	ECHINOCOCCUS	K175	Cestodes IgG EIA (Cat. No. K175)	DE/CA37/IVD/13/72E
68.	DISTOMATOSIS	K176	Fasciola IgG EIA (Cat. No. K176)	DE/CA37/IVD/13/71E
69.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	Free Testosterone EIA (Cat. No. K219)	DE/CA37/IVD/13/70E
70.	HUMAN PLACENTAL LACTOGEN HPL	K246	Human Placental Lactogen EIA (Cat. No. K246)	DE/CA37/IVD/13/69E
71.	CANCER ANTIGEN 242	K243	CA 242 EIA (Cat. No. K243)	DE/CA37/IVD/13/73
72.	INSULIN	K267N	Insulin EIA (Cat. No. K267N)	DE/CA37/IVD/13/77
73.	C-PEPTIDE	K267C	C-peptide EIA(Cat. No. K267C)	DE/CA37/IVD/13/76
74.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA (Cat. No. K245)	DE/CA37/IVD/13/75
75.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC(A) EIA (Cat. No. K237)	DE/CA37/IVD/13/74
76.	ASPERGILLUS	K021	GalM Ag EIA (Cat. No. K021)	DE/CA37/IVD/13/78

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Represented in the EC by Polmed.de
Steinacker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279

Vertretung und Repräsentanz Polmed.de D-73773 Aichwald Steinacker 5

Date: **January 01, 2020**

Polmed.de

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
282710-2019-AQ-MCW-FINAS

Initial certification date:
14 February 2019

Valid:
14 February 2019 - 14 February 2022

This is to certify that the management system of

XEMA Co, LTD

bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.

Place and date:
Moscow, 14 February 2019

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

For the issuing office:
DNV GL – Business Assurance
Trekhprudny per. 9 build. 2, office 406,
Moscow, Russian Federation

S. Groubine

Serguei Groubine
Management Representative

Certificate No: 282710-2019-AQ-MCW-FINAS
Place and date: Moscow, 14 February 2019

Appendix to Certificate

XEMA Co, LTD
Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
XEMA Co, LTD	bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264	Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.
XEMA Co, LTD (Production site)	Trubetskaya str., 2B, Balashikha, Moscow region, Russian Federation, 125000	Design and development, manufacturing and sales of in vitro tests for food and feed control, clinical and veterinary diagnostics and forensic investigations.

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:	Initial certification date:	Valid:
53899-2009-AQ-MCW-FINAS	22 May 2009	22 January 2019 - 30 April 2021

This is to certify that the management system of

XEMA CO., LTD.

bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:
DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.

Place and date:
Moscow, 22 January 2019

For the issuing office:
DNV GL – Business Assurance
Trekhprudny per. 9 build. 2, office 406,
Moscow, Russian Federation

S. Groubine

Serguei Groubine
Management Representative

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

Certificate No: 53899-2009-AQ-MCW-FINAS
Place and date: Moscow, 22 January 2019

Appendix to Certificate

XEMA CO., LTD.
Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
XEMA CO., LTD.	bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264	DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.
XEMA Co., LTD (production site)	Trubetskaya str., 2B, Balashikha, Moscow region, Russian Federation, 125000	DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

Manufacturer: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Product Category(ies): **In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: SH1974310

Valid from: 2019-10-24
Valid until: 2022-09-12

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

Model(s): **For Detail Models see attachment**

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

For the product(s)/product category (ies):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Redi Blood Glucose Monitoring System,
On Call Redi II Blood Glucose Test Strips,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Platinum Blood Glucose Monitoring System,
On Call Platinum Blood Glucose Test Strips,
On Call Chosen Blood Glucose Monitoring System,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
D-ONE Blood Glucose Monitoring System,
D-ONE Blood Glucose Test Strips,
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Toxoplasma IgG EIA Test Kit,
Toxoplasma IgM EIA Test Kit,
Rubella IgG EIA Test Kit,
Rubella IgM EIA Test Kit,
CMV IgG EIA Test Kit,

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Product Service

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Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

CMV IgM EIA Test Kit,

Total PSA EIA Test Kit,

PT Coagulation Monitoring System (CCM-121),

PT Coagulation Test Strips (CCS-121),

Cholesterol Monitoring System (CCM-111),

CHOL Total Cholesterol Test Devices (CCS-111),

TRIG Triglycerides Test Devices (CCS-112),

HDL High Density Lipoprotein Test Devices (CCS-113),

3-1 Lipid Panel Test Devices (CCS-114),

Cholesterol CTRL Control Devices,

Cholesterol Monitoring System (CCM-101),

CHOL Total Cholesterol Test Strips (CCS-101),

PT/INR Monitoring System (CCM-151),

PT/INR Test Strips (CCS-151),

Hemoglobin Testing System (CCM-141),

Hemoglobin Test Strips (CCS-141),

hCG Pregnancy Rapid Test Cassette (Urine),

Pregnancy Rapid Test Midstream,

On Call Extra Mobile Blood Glucose Monitoring System (OGM-281)

On Call Sure Blood Glucose Monitoring System (OGM-211)

On Call Sure Sync Blood Glucose Monitoring System (OGM-212)

On Call Sure Blood Glucose Test Strips (OGS-211)

On Call GU Dual Blood Glucose & Uric Acid Monitoring System (OGM-201)

On Call Blood Uric Acid Test Strips (OGS-201)

LH Ovulation Rapid Test Cassette (Urine)

Ovulation Rapid Test Midstream

Ovulation & Pregnancy Test Combo Pack

On Call Extra Voice Blood Glucose Monitoring System (OGM-291)

Early Detection Pregnancy Test

Digital Pregnancy Test

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