WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

CORIS BioConcept
Mr Leclipteux
Parc Scientifique CREALYS
Rue Jean Sonet 4
B-5032 GEMBLOUX

Quality of Medical Laboratories

date: 28/03/2017
your ref.:
our ref.: WIV/IVD/303-16
annex(es):

contact: Jeroen Poels
tel.: + 32 2 642 53 94
fax: + 32 2 642 56 45
e-mail: jeroen.poels@wiv-isp.be
IVD@wiv-isp.be

SUBJECT: IVD Notification

Dear Mr Leclipteux,

Please find enclosed the original notification form for the CE marked in vitro diagnostic medical devices, notified to the Belgian Competent Authority. This notification form is an acknowledgement of your declaration that the in vitro diagnostic medical devices, mentioned hereunder, fully comply with the Directive 98/79 of the European Parliament and of the Council. Be aware that it is an offence to place on the market non-complying devices bearing the CE marking. This form does not represent an accreditation or approval by the Belgian Competent Authority.

Please inform us of any changes (change of company information, change of address, significant change of product, change of certificate) and of the discontinuation of the product.

For the products listed hereunder, the Belgian Competent Authority for in vitro diagnostic medical devices has entered the data referred to in point (a), and if applicable point (b), of Article 12(1) of Directive 98/79/EC into Eudamed in accordance with the Annex to Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed).

Sincerely yours,

Digitally signed by Monastîrschii Viorica
Date: 2022.07.26 16:39:43 EEST
Reason: MoldSign Signature
Location: Moldova

Jeroen Poels
IVD Competent Authority

Rue Juliette Wytsmanstraat 14
1050 Brussels | Belgium
T + 32 2 642 51 11 | F + 32 2 642 50 01
info@iph.fgov.be | www.iph.fgov.be

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e-mail: jeroen.poels@wiv-isp.be
IVD@wiv-isp.be

Re: notification of IVD products according to the directive 98/79

Competent Authority: BE/CA02

Manufacturer: CORIS BioConcept,
Parc Scientifique CREALYS
Rue Jean Sonet 4
B-5032 GEMBLOUX
BELGIUM

Date of registration: 24/09/2016

Type of IVD: Instruments/ reagents for professional use

IVD	GMDN code	Registration number
Adeno-Strip (C-1002/C-1003)	41274	BE-CA02-001-01
Crypto-Strip (C-1005)	30675	BE-CA02-002-01
Combi-Strip (C-1004)	38442	BE-CA02-003-01
Rota-Strip (C-1001)	30815	BE-CA02-004-01
RSV Respi-Strip (C-1006)	30814	BE-CA02-005-02
Adeno Respi-Strip (C-1009)	41274	BE-CA02-093-02
Influ-A Respi-Strip (C-1010)	30813	BE-CA02-094-02
Adeno Uni-Strip (C-1502)	41274	BE-CA02-675-03
Influ-A Respi Uni-Strip (C-1510)	30813	BE-CA02-676-03
40/41 Adeno Uni-Strip (C-1503)	41274	BE-CA02-677-03
Crypto Uni-Strip (C-1505)	30675	BE-CA02-678-03
Combi Uni-Strip (C-1504)	38442	BE-CA02-679-03
Rota Uni-Strip (C-1501)	30815	BE-CA02-680-03
RSV Uni-Strip (C-1006)	30814	BE-CA02-681-03
Adeno Respi Uni-Strip (C-1509)	41274	BE-CA02-682-03
0157 Coli-Strip (C-1011)	37727	BE-CA02-683-03
O157 Coli Uni-Strip (C-1511)	37727	BE-CA02-684-03
Giardia-Strip & Giardia Uni-Strip (C-1013/C-1513)	36173	BE-CA02-838-03

RSV Positive Control (C-1086)	42248	BE-CA02-338-04
Influ A+B Respi Strip (C-1012)	30813	BE-CA02-019-05
Influ A+B Uni-Strip (C-1512)	30813	BE-CA02-020-05
Gastro Vir-Strip (C-1016) Gastro Vir Uni-Strip (C-1516)	30815 41274	BE-CA02-016-06
Rota-CIT (C-1201)	30815	BE-CA02-257-06
Adeno-CIT (C-1202)	38442	BE-CA02-258-06
Combi-CIT (C-1204)	38442	BE-CA02-259-06
Crypto-CIT (C-1205)	30675	BE-CA02-260-06
RSV-Respi-CIT (C-1206)	30814	BE-CA02-261-06
Adeno-Respi-CIT (C-1209)	38442	BE-CA02-262-06
Influ A Respi-CIT (C-1210)	30813	BE-CA02-263-06
O157 Coli-CIT (C-1211)	37727	BE-CA02-264-06
Influ A & B Respi-CIT (C-1212)	30813	BE-CA02-265-06
Giardia-CIT (C-1213)	36173	BE-CA02-266-06
GastroVir^{COLOR}-CIT (C-1216)	38442	BE-CA02-267-06
Adeno 40/41 CIT (C-1203)	38442	BE-CA02-268-06
Control Test Influ A & B (C-1092)	41758	BE-CA02-026-07
Control Test Adeno 40/41(C-1083)	41273	BE-CA02-027-07
Control Test Giardia (C-1093)	38442	BE-CA02-028-07
Influenza A positive control (C-1090)	41758	BE-CA02-040-07
Crypto/Giardia Duo-Strip, Crypto/Giardia Uni-Strip, Crypto/Giardia-CIT	30675 36173	BE-CA02-001-08
Leishmania OligoC- Test (C-3405 (20 tests), C-3705 (10 tests))	38442	BE-CA02-172-08
T. cruzi OligoC- Test (C-3404 (20 tests), C-3704 (10 tests))	38442	BE-CA02-173-08
Pylori-Strip (C-1019 (25 tests)), Pylori Uni-Strip (C-1519 (10 single tests)), Pylori -CIT (C-1219 (20 single tests))	30825	BE-CA02-174-08
Negative Control (CTR-1000)	38442	BE-CA02-175-08
GastroVir Control Test (C-1096)	38442	BE-CA02-297-08
Pylori Positive Control (C-1099)	38442	BE-CA02-298-08
Legionella V-Test (10 tests (C-1815); 20 tests(C-1915))	30692	BE-CA02-299-08
RSV K-SeT (K-1506, K-1206)	49500	BE-CA02-216-10
Combi K-SeT (K-1504, K-1204)	48235	BE-CA02-217-10
Pylori K-SeT (K-1519, K-1219)	30825	BE-CA02-218-10
Adeno Respi K-SeT (K-1509, K-1209)	49856	BE-CA02-268-10
Influ-A K-SeT (K-1510, K-1210)	49150	BE-CA02-269-10
Giardia K-SeT (K-1513, K-1213)	52249	BE-CA02-270-10
P.aeruginosa mexQ-TesT (C-3806)	51266	BE-CA02-271-10
Proguanil / Malarone - Strip (C-10T1), Proguanil - Strip (C-40T1)	38442	BE-CA02-012-11
PG Uni-Strip (C-45T1)	38442	BE-CA02-013-11
Mefloquine / Lariam - Strip (C-10T2), Mefloquine - Strip (C-40T2)	38442	BE-CA02-014-11
MQ Uni-Strip (C-45T2)	38442	BE-CA02-015-11
Clostridium K-SeT (K-1220, K-1520, 56001044, 56001056)	30714	BE-CA02-146-11
GastroVir *K*-SeT (K-1516, K-1216)	30815	BE-CA02-188-12
C.diff-Strip (C-1020)	30714	BE-CA02-189-12
E.coli O157 Positive Control (C-1091)	44023	BE-CA02-190-12
Legionella Card letitest (56001036, 56001048)	30692	BE-CA02-191-12
HAT Sero *K*-SeT (K-12S2, K-15S2)	38442	BE-CA02-261-12
Influ A+B *K*-SeT (K-1212, K-1512)	30813	BE-CA02-262-12

Helicobacter pylori Strip letitest (56001033, 56001051)	30825	BE-CA02-263-12
Helicobacter pylori Card letitest (56001034, 56001050, 56102001)	30825	BE-CA02-264-12
Influenza A+B Strip letitest (56001035, 56001047)	30813	BE-CA02-265-12
RSV Strip letitest (56001041, 56001045)	30814	BE-CA02-266-12
RSV Card letitest (56001042, 56001046, 56101003)	30814	BE-CA02-267-12
Legionella GDT letitest (56001037, 56001049)	30692	BE-CA02-268-12
Adenovirus 40/41 Strip letitest (56001027, 56001054)	41274	BE-CA02-269-12
Gastrovir Strip letitest (56001030, 56001055)	30815	BE-CA02-270-12
C. difficile Ag Card letitest (56001044, 56001056)	30714	BE-CA02-271-12
Adeno Respiratory Strip letitest (56001026)	41274	BE-CA02-272-12
Giardia Card letitest (56001032)	36173	BE-CA02-273-12
Giardia Strip letitest (56001031)	36173	BE-CA02-274-12
Cryptosporidium / Giardia Combo Strip letitest (56001029)	30675	BE-CA02-275-12
Cryptosporidium Strip letitest (56001028)	30675	BE-CA02-276-12
Adeno Respiratory Card letitest (56001025)	41274	BE-CA02-109-13
Rotavirus/Adenovirus Combo Strip letitest (56001038)	41274	BE-CA02-110-13
Rotavirus/Adenovirus Combo Card letitest (56001039)	41274	BE-CA02-111-13
Rotavirus Strip letitest (56001040)	30815	BE-CA02-112-13
Influenza A+B Card letitest (56001052, 56101002)	30813	BE-CA02-434-13
Adeno 40 Positive Control (C-1082)	41273	BE-CA02-435-13
Strep-A letitest (56001063)	30710	BE-CA02-150-14
Strep-A Respi-Strip (C-1022)	30710	BE-CA02-199-14
Legionella *K*-SeT (K-1215, K-1515)	30692	BE-CA02-200-14
OXA-48 *K*-SeT (K-15R1)	33359	BE-CA02-001-15
STREP-A Positive Control (P-1022)	30710	BE-CA02-002-15
Strep-A Card letitest (56101001)	30710	BE-CA02-054-15
OXA-48 Card letitest (56001065)	33359	BE-CA02-199-15
KPC *K*-SeT (K-15R2)	33359	BE-CA02-200-15
KPC *K*-SeT letitest (56001066)	33359	BE-CA02-345-15
NDM *K*-SeT (K-15R6)	61275	BE-CA02-303-16
RESIST-3 O.O.K. *K*-SeT (K-15R4)	61275	BE-CA02-304-16
RESIST-3 O.K.N. *K*-SeT (K-15R5)	61275	BE-CA02-305-16

Jeroen Poels
IVD Competent Authority

This notification contains **3** pages and replaces the certificate issued 17/05/2016.

Certificate BE21/819944231.00

The management system of

Coris BioConcept

Science Park CREALYS - Rue Jean Sonet 4A
5032 Gembloux, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, development, manufacture and distribution of in vitro diagnostic tests for the detection of pathogens in the diagnosis of respiratory, gastric, enteric and parasitic diseases, the detection of resistance to antibiotics and the detection in urine of therapeutics, used for the treatment of these infectious diseases.
Distribution of instrument for electrochemical detection to be used with Coris' kit.

This certificate is valid from 21 August 2021 until 20 August 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 7 April 2021.
Recertification audit due before 20 July 2024.

Multiple certificates have been issued for this scope.
The main certificate is numbered BE21/819944231.00.

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Accreditation Number
005-QMS
EN ISO/IEC 17021-1:2015

Coris BioConcept

ISO 13485:2016
EN ISO 13485:2016

Issue 3

Detailed scope

Design, development, manufacture and distribution of in vitro diagnostic tests for the detection of pathogens in the diagnosis of respiratory, gastric, enteric and parasitic diseases, the detection of resistance to antibiotics and the detection in urine of therapeutics, used for the treatment of these infectious diseases.

Distribution of instrument for electrochemical detection to be used with Coris' kit.

Additional facilities

Science Park CREALYS - Rue Jean Sonet 29, 5032 Gembloux, Belgium

Accreditation Number

005-QMS
EN ISO/IEC 17021-1:2015

Science Park CREALYS
Rue Jean Sonet 4A
5032 - GEMBLOUX - BELGIUM
TEL : + 32(0)81.719.917
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e-mail : info@corisbio.com
http://www.corisbio.com

STATEMENT

We, **CORIS BIOCONCEPT** having a registered office at SCIENCE PARK CREALYS, Rue Jean Sonet 4A, 5032 Gembloux, BELGIUM 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/EC.

For the purpose of business development and tender participation, 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.

Gembloux, June 26th, 2019

CORIS BIOCONCEPT
RUE JEAN SONET 4A
BE-5032 GEMBLOUX

Thierry LECLIPTEUX
CEO & CSO

Legionella *K*-SeT

www.corisbio.com

Manufacturer:

Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
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BELGIUM
Tel.: +32(0)81.719.917
Fax: +32(0)81.719.919
info@corisbio.com

Produced in BELGIUM

IFU-5815/TB/06

***In vitro* rapid diagnostic test for the detection of *Legionella pneumophila* LPS antigen in urine samples**

FOR IN VITRO USE **EN**

FOR PROFESSIONAL USE ONLY

References: K-1215, 20 tests per kit
K-1515, 20 tests per kit, controls supplied

(EN) For Instructions For Use in your language : (FR) Pour obtenir les notices dans la langue de votre choix : (ES) Para las instrucciones de uso en su idioma : (PT) Para Instruçoes de Uso na sua lingua : (IT) Per le Istruzioni di Uso nella sua lingua : (DE) Für Gebrauchsanleitungen in Ihrer Sprache : (SV) För bruksanvisning på ditt språk:	
www	website: ifu.corisbio.com key-code: cor58151
Tel.	(EU) +800 135 79 135 (non-EU) +31 20 794 7071 (CA) +1 855 805 8539 (AR, CO, UY, AU, NZ) +800 135 79 135

I. INTRODUCTION

Legionellosis is a serious pneumonia caused by bacteria of the genus *Legionella* assigned to the family *Legionellaceae*. This family now includes 48 species and over 60 serogroups. Approximately 20 species are implicated in human disease. The overwhelming majority of *Legionella* infections are caused by *Legionella pneumophila*. Legionnaires' disease is the major clinical manifestation of *Legionella* infection although extra-pulmonary infection and non-pneumonic disease like Pontiac fever occur. The name *Legionella pneumophila* was derived from the dramatic outbreak at the 1976 American Legion Convention in Philadelphia. *Legionella pneumophila* is responsible for approximately 90% of infections, and of these, over 80% are due to a single serogroup, serogroup 1. *Legionella* bacteria are small faintly staining Gram-negative rods with polar flagella. *Legionella* bacteria have a widespread distribution in both natural and manmade aquatic habitats. They are readily found in fresh water, cooling towers and potable water systems. The organisms can survive in a wide range of conditions, and temperature is a critical determinant for *Legionella* proliferation. Nosocomial infection is particularly associated with colonization of hospital hot water system by *Legionella.*

The incubation period of Legionnaires' disease after being exposed to the bacteria is from two to ten days. Most patients who are admitted to the hospital develop high fever often higher than 39.5°C (103°F). Cough can be the first sign of a lung infection. Other common symptoms include headaches, muscle aches, chest pain, and shortness of breath. Gastrointestinal symptoms are common.

Legionnaires' disease (LD) is not contagious. The disease is transmitted by aerosol, and there is no evidence for direct person-to-person transmission. Person at risk are those whose immune system is compromised, including transplant recipients, the elderly, cigarette smokers, or those showing chronic obstructive pulmonary disease or chronic renal disease.

Diagnosis of legionellosis can be difficult because signs and symptoms are non-specific and do not distinguish *L. pneumophila* infections from other common causes of pneumonia. *L. pneumophila* infections are considered to be fairly common but they are probably underdiagnosed and under-reported. The underdiagnosis of legionellosis can in part be attributed to the need for rapid, specific and sensitive diagnostic testing methods.

The Legionella *K*-SeT detects soluble antigen from *L .pneumophila* serogroup 1 in urine.

II. PRINCIPLE OF THE TEST

This is a ready-to-use membrane test based on colloidal gold particles. This test allows detection of *Legionella pneumophila* LPS in urine samples. Legionella *K*-SeT sensitivity and specificity come from monoclonal and polyclonal anti-*Legionella* antibodies. Some antibodies are conjugated to colloidal gold particles and dried on a conjugate absorbant pad. Each strip is sensitized with anti- *Legionella* antibodies at the upper line and with a control antibody at the bottom (migration control) line

When the urine sample migrates, conjugate is rehydrated and migrates along with the sample. If *L. pneumophila* urinary antigens are present in the sample, a complex between the anti-*L. pneumophila* conjugates and the *L. pneumophila* antigens is formed that will be caught by the specific anti-*L. pneumophila* reagent coated on the stick. Results appear in 15 minutes in the form of a red line that develops on the strip.

The solution continues to migrate to encounter a control reagent that binds the control conjugate, thereby producing a second red (migration control) line.

III. REAGENTS AND MATERIALS

1. Legionella *K*-SeT (20)

Sealed pouches containing one device and one desiccant. Each device contains one sensitized strip.

2. Instruction for use (1)

3. Disposable transfer pipettes (20)

Fixed volume (100 µL) transfer pipettes used for sample delivery into the device.

4. Materials supplied with K-1515

Positive control (0.8 mL; SUN-3P15): *L. pneumophila* extract

Negative control (1 mL; CTR-1000): Heat-inactivated *S. pyogenes* bacteria suspension.

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- All reagents are for *in vitro* diagnostic use only.
- Pouch must be opened with care
- Avoid touching nitrocellulose with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- Green lines indicate immunoreagents adsorption sites. Green colour disappears during the test.
- Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in the insert.

V. WASTE DISPOSAL

- Dispose of gloves, test tubes and used devices in accordance with GLP.
- Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

VI. STORAGE

- An unopened pouch may be kept at between 4 and 30°C and used until the shelf-life date indicated on the packaging. Once the pouch is opened, run the test immediately.
- Avoid freezing devices and buffer.

VII. SPECIMEN HANDLING AND COLLECTION

Specimens to be tested should be obtained and handled by standard methods for the collection of urine sample. Urine specimens should be collected in standard containers. The use of boric acid as preservative has been validated on the Legionella *K*-SeT.

Urine sample specimens must be tested as soon as possible after they are collected. If necessary, they can be stored at 2-8°C for up to 1 week or at -10°C to -20°C for longer periods of time.

Although it requires added processing time, the antigens present in the urine can be concentrated with a disposable concentrator (Miniplus) or a centrifugation system (Centricon).

VIII. PROCEDURE

PREPARATIONS OF THE TEST:

Allow kit components, in unopened packaging, and specimens to reach room temperature (15-30°C) before performing a test.

Open the pouch and remove the device. Once opened, run the test immediately. Indicate the patient's name or specimen number on the device (one device per sample).

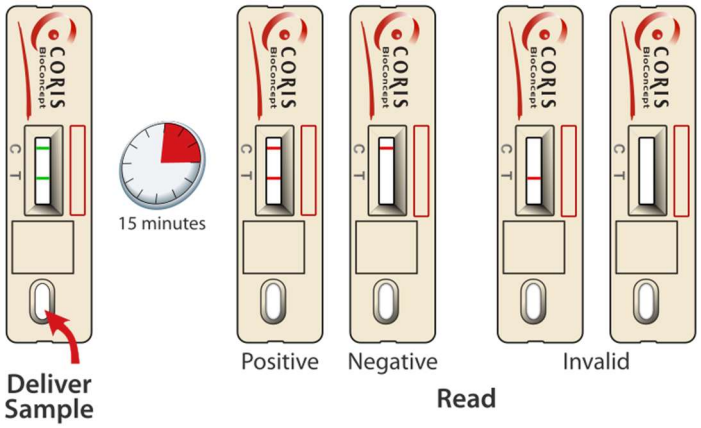
SPECIMEN PREPARATION PROCEDURE:

1. Swirl urine gently to mix before testing
2. Slowly dispense 100µL of urine sample into the sample well of the device as illustrated below (Use provided disposable transfer pipette or use a lab pipette to take 100 µL)
3. Leave to react for 15 minutes. The results are observed in the reading window. Positive results may be reported sooner the moment the test and control lines become visible.

The result must be read on still wet strip.

IX. INTERPRETING RESULTS

The results are to be interpreted as follows:



Negative test result: a reddish-purple line appears across the central reading window at the Control line (C) position. No other band is present.

Positive test result: in addition to a reddish-purple band at the Control line (C), a visible reddish-purple band appears at the Test line position (T). Intensity of the test line may vary according to the quantity of antigens found in the sample. Any reddish-purple line (T), even weak, should be considered as a positive result.

Invalid test result: The absence of a Control line indicates a failure in the test procedure. Repeat invalid tests with a new test device.

Note: during the drying process, after 60 minutes, a very faint shadow may appear at the Test line position. It should not be regarded as a positive result.

X. QUALITY CONTROL

In accordance with Good Laboratory Practices, we recommend to check the test's performance regularly according to the laboratory's requirements.

Positive and Negative Controls (provided in the kit K-1515) can be run as a quality control to demonstrate a positive or negative reaction in order to ensure that test reagents are working and the test is correctly performed. Positive and negative controls must be used as a urine sample (see VIII).

XI. PERFORMANCES

A. Sensitivity – Specificity

The kit was evaluated on 85 clinical samples in a National Reference Laboratory in Spain. 30 urine samples from patients with LD defined by clinical and radiological signs of pneumonia and microbiologically confirmed were studied. EIA method was used as laboratory evidence. Urine samples from patients with respiratory tract infections other than *Legionella* infections were tested in a similar manner to test the specificity of the kit.

EIA Legionella *K*-SeT	Positive	Negative	Total
Positive	27	0	27
Negative	3	55	58
Total	30	55	85

		95 % Confidence Interval[1]
Sensitivity:	90.0 %	(72.3 to 97.4 %)
Specificity:	100 %	(91.9 to 100 %)
Positive Predictive value:	100 %	(84.5 to 100 %)
Negative predictive value:	94.8%	(84.7 to 98.7 %)
Agreement:	96.5 %	(82/85)

B. Repeatability and reproducibility

To check intra-batch accuracy (repeatability), same positive and negative urine samples have been processed 15 times on kits of the same production batch in the same experimental conditions. The samples produced the expected results in 100% of cases.

To check inter-batch accuracy (reproducibility), same samples (positive and negative) were processed on kits from three different production batches. The samples produced the expected results in 100% of cases.

C. Interference

Cross-reactivity to urines spiked with the following pathogens was tested and found to be negative: Adenovirus, *Aspergillus niger, Candida albicans, Haemophilus influenzae,* Influenza A, Influenza B, *Moraxella catarrhalis, Mycoplasma pneumonia, Nocardia asteroides, Parainfluenzae,* Rhinovirus, RSV, *Staphylococcus aureus*, *Streptococcus pneumonia, Streptococcus pyogenes, Campylobacter jejuni, Clostridium difficile, E.coli* (different strains), *Enterobacter cloacae, Enterococcus faecalis, Escherichia hermanni, Helicobacter pylori, Klebsiella pneumoniae, Legionella bozemanii (sg1), Legionella longbeachae, Neisseria meningitidis, Proteus mirabilis, Salmonella enteritidis, Shigella flexneri, Staphylococcus epidermidis, Yersinia enterocolitica* (types 3,9), HMPV, *Streptococcus (Group B, C, F, G), Streptococcus mutans, Vibrio parahemolyticus, Ureaplasma urealyticum, Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium tuberculosis, Serratia marcescens, Pseudomonas aeruginosa, Shigella sonnei, Campylobacter coli, S. typhimurium, Vibrio parahemolyticus, Neisseria meningitidis (sg C), Mycoplasma hominis.*

The blood naturally present in urine (microhematuria conditions) doesn't affect test performances. However, bloody specimens (at 0.1% whole blood) may fail to flow properly causing smears and inconclusive test results.

XII. LIMITS OF THE KIT

The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.

A positive test does not rule out the possibility that other pathogens may be present.

Kit test is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titres below the reagent's sensitivity threshold. If a sample is given a negative result despite the observed symptoms, a culture should be started to check the sample.

XIII. TECHNICAL PROBLEMS / COMPLAINTS

If you encounter a technical problem or if performances do not correspond with those indicated in this package insert:

1. Record the kit batch number
2. If possible, keep the clinical sample in the freezer during the complaint management
3. Contact Coris BioConcept (client.care@corisbio.com) or your local distributor

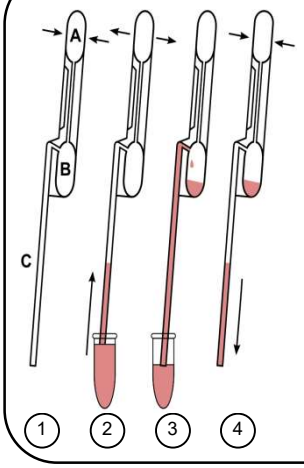
XIV. BIBLIOGRAPHIC REFERENCES

A. **B. M.W. Diederen**; *Legionella spp. and Legionnaires'disease*; J. Inf. 2008 56:1-12, 2008

B. **J.H. Helbig et al.**; *Pan-European study on culture-proven Legionnaires' Disease*; Eur. J. Clin. Microbiol. Infect. Dis. 2002 21:710-716, 2002

C. **B.S. Fields et al.**; *Legionella and Legionnaires'Disease : 25 years of investigation*; Clin. Microbiol. Rev. 2002 15: 506-526, 2002

How to use the disposable transfer pipette



1) Squeeze firmly the upper bulb (A).

2) Insert the tip (C) of the transfer pipette into the urine sample and release the pressure on the upper bulb (A) in order to let the liquid be drawn into the tip C.

3) Be sure tip C is completely filled. Volume of tip C is 100 µL. All liquid in excess will move to into bulb B.

4) Move the transfer pipette above the device sample well and squeeze the upper bulb A to push the liquid present in tip C into the device. Make sure that the tip C is completely discharged and that all the excess liquid in bulb B remains in the bulb. Never press on bulb B

5) Discard the transfer pipette. Use only one transfer pipette per urine specimen.

Last update: 20 JUNE 2022

REF	Catalogue number		Manufacturer
IVD	*In vitro* diagnostic medical device		Temperature limits
Σ	Contains sufficient for <n> tests	LOT	Lot number
	Consult instructions for use		Do not reuse
	Keep dry		Use by
		CONT NaN_3	Contains Sodium azide

OXA-23 *K*-SeT

Manufacturer:

Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
B – 5032 GEMBLOUX
BELGIUM
Tel.: +32(0)81.719.917
Fax: +32(0)81.719.919
info@corisbio.com

Produced in BELGIUM

www.corisbio.com
IFU-58R7/EN/02

***In vitro* rapid diagnostic test for the detection of OXA-23 carbapenemase in bacterial culture**

FOR IN VITRO DIAGNOSTIC USE **EN**
FOR PROFESSIONAL USE ONLY
References: K-15R7, 20 cassettes, buffer, 20 tubes and droppers

I. INTRODUCTION

Acinetobacter baumannii is an important opportunistic and multidrug-resistant Gram-negative bacterium responsible for nosocomial infections in health facilities. If left untreated, this infection can lead to septicemia and death. The carbapenem-hydrolysing oxacillinases (OXAs) are the most commonly reported carbapenem-resistance determinants in *Acinetobacter* spp., particularly in *A. baumannii*. Among the OXAs, OXA-23 is the most prevalent carbapenem-resistance determinant in *A. baumannii* isolates.
OXA-23 has been detected in other bacterial species as chromosomal (*P. mirabilis,* Bonnet et al 2002 and Osterblad et al 2016; *A. radioresistans*) or plasmidic gene (*E. coli*, La et al, 2014), which can constitute reservoirs for horizontal transmission of this resistance factor (Poirel et al 2016). The detection of this resistance factor OXA-23, not only in resistant species but also in carrier species, is therefore of paramount importance in the control of antibiotic resistance in the hospital.
Nowadays, definitive confirmation of OXA-23 relies on molecular amplification analysis and DNA sequencing. These tests are expensive and can only be performed in dedicated environment and by skilled staff, hence limiting their more generalized usage.
The development of new rapid diagnostic tests to track antimicrobial resistance patterns is considered as one of the priority core action by international experts and health authorities.
The OXA-23 K-SeT test aimed at a rapid identification of the OXA-23 carbapenemase (and variants of the OXA-23 group) ensures effective treatment of patients and prevention of spread of OXA-23 *Acinetobacter* spp. carrier, especially in hospitals.

II. PRINCIPLE OF THE TEST

This test is ready to use and is based on a membrane technology with colloidal gold nanoparticles. A nitrocellulose membrane is sensitized with a monoclonal antibody directed against one epitope of the OXA-23 carbapenemase. Another monoclonal antibody directed against a second epitope of the OXA-23 carbapenemase is conjugated to colloidal gold particles. This conjugate is dried on a membrane.
This test is aimed at the detection of OXA-23 like carbapenemases in a single bacterial colony growing on agar plate. The sample must be diluted in the dilution buffer supplied with the test. When the provided buffer containing the resuspended bacteria comes into contact with the strip, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample material come into contact with the anti-OXA-23 antibody that it is adsorbed onto the nitrocellulose strip. If the sample contains the OXA-23 carbapenemase, the conjugate–OXA-23 complex will remain bound to the anti-OXA-23 antibody adsorbed onto the nitrocellulose and a red line will develop. Solution continues to migrate to reach a second reagent (control reagent) that binds the migration control conjugate, thereby producing a red control line that confirms that the test is valid. Result is visible within 15 minutes.

III. REAGENTS AND MATERIALS

1. OXA-23 *K*-SeT (20)
20 sealed pouches containing one device and one desiccant. Each device contains one sensitized strip.
2. LY-A buffer vial (15 mL)
Saline solution buffered to pH 7.5 containing TRIS, NaN_3 (<0,1%) and a detergent.
3. Instruction for use (1)
4. Semi-rigid disposable collection tubes with droppers (20)
5.

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- All reagents are for *in vitro* diagnostic use only.
- Pouch must be opened with care.
- Avoid touching nitrocellulose with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- Green lines indicate immunoreagents adsorption sites. Green colour disappears during the test.
- Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in the insert.

V. WASTE DISPOSAL

- Dispose of gloves, swabs, test tubes and used devices in accordance with GLP.
- Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

VI. STORAGE

- An unopened pouch may be kept at between 4 and 30°C and used until the shelf-life date indicated on the packaging. Once the pouch is opened, run the test immediately.
- Avoid freezing devices and buffer.

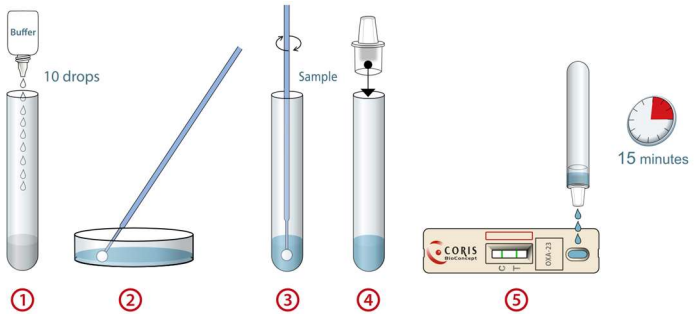
VII. SPECIMEN HANDLING AND COLLECTION

Specimens to be tested should be obtained and handled by standard microbiological methods.
Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.
Culture media tested and validated with Coris BioConcept RESIT kits are listed on the website: https://www.corisbio.com/Products/Human-Field/OXA-23/FAQ.php

VIII. PROCEDURE

PREPARATIONS OF THE TEST:
Allow kit components, in unopened packaging, and specimens (in case the plate containing colony to be tested was kept at 4°C) to reach room temperature (15-30°C) before performing a test.
Open the pouch and remove the device. Once opened, run the test immediately. Indicate the patient's name or specimen number on the device (one device per sample).
SPECIMEN PREPARATION PROCEDURE:
We recommend the use of fresh bacterial colonies for optimal test performance.

1. Prepare one semi-rigid tube provided in the kit and add **10** drops of LY-A buffer in the tube.
2. Harvest bacteria by taking one colony with a disposable bacteriological loop and dip the loop in the bottom of the semi-rigid tube containing the buffer.
3. Stir thoroughly before removing the loop
4. Insert tightly the dropper on the semi-rigid tube.
5. Vortex the preparation to homogenize. The entire bacterial colony must be suspended into the buffer.
6. Invert the test tube and add slowly **3** drops of diluted sample into the sample well of the cassette. Alternatively, add 100µl with a micropipette into the sample well of the cassette.
7. Allow to react for 15 min max and read the result.



Positive results may be reported as soon as the test and control lines become visible.
Do not take the appearance of new lines into account after the reaction time is passed.
The result must be read on still wet strip.

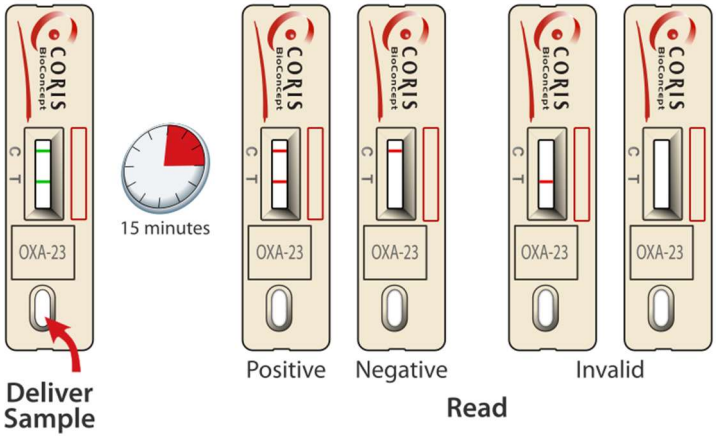
IX. INTERPRETING RESULTS

The results are to be interpreted as follows:

Negative test result: a reddish-purple line appears across the central reading window at the Control line (C) position. No other band is present.

Positive test result: in addition to a reddish-purple band at the Control line (C), a visible reddish-purple band appears at the Test line position (T). Intensity of the test line may vary according to the quantity of antigens present in the sample. Any reddish-purple line (T), even weak, should be considered as a positive result.

Invalid test result: The absence of a Control line indicates a failure in the test procedure. Repeat invalid tests with a new test device.
Note: during the drying process, a very faint shadow may appear at the Test line position. It should not be regarded as a positive result.



X. PERFORMANCE

A. Detection Limit

The detection limit was determined with a purified recombinant OXA-23 protein and has been evaluated at 0,156 ng/mL.

B. Validation on collection of reference strains

The OXA-23 *K*-SeT was evaluated on a collection of 108 clinical isolates of carbapenem-resistant *Acinetobacter* spp. fully characterized resistance mechanisms to beta-lactams by phenotypic and molecular tests (Germany).

108 strains	**35 strains** tested positive with the OXA-23 *K*-SeT	**35 strains** carrying OXA-23 carbapenemase	*Acinetobacter baumannii, Acinetobacter pittii, Acinetobacter nosocomialis, Acinetobacter radioresistens*
	73 strains tested negative with the OXA-23 *K*-SeT	**68 strains** carrying a non-OXA-23 carbapenemase	OXA-40, OXA-51, OXA-58, OXA-143, OXA-235
		5 strains carrying class B carbapenemases	Including VIM-2, NDM-1, NDM-2

A second evaluation was retrospectively performed on 448 clinical strains of *Acinetobacter spp*. and 14 oxacillinase-producing Gram-negative bacteria collected in Belgium and in Italy between 2008 and 2018 with an agreement of 100 % versus real-time PCR and molecular sequencing. see Riccobono, 2019

	Italy	Belgium	Total	Test OXA-23 K-SeT
$bla_{OXA\text{-}23\text{-}like}$	170	137	307	307 +
$bla_{OXA\text{-}24\text{-}like}$	5	25	30	negative
$bla_{OXA\text{-}58\text{-}like}$	1	30	31	negative
IS*Aba1* $bla_{OXA\text{-}51\text{-}like}$	11	0	11	negative
$bla_{OXA\text{-}23\text{-}like}$ + $bla_{OXA\text{-}58\text{-}like}$	5	2	7	7 +
$bla_{OXA\text{-}23\text{-}like}$ + IS*Aba1* $bla_{OXA\text{-}51\text{-}like}$	4	0	4	4 +
$bla_{OXA\text{-}23\text{-}like}$ + bla_{NDM}	0	3	3	3 +
$bla_{OXA\text{-}58\text{-}like}$ + bla_{VIM}	0	1	1	negative
bla_{NDM}	0	13	13	negative
$bla_{OXA\text{-}143\text{-}like}$	0	1	1	negative
bla_{IMP}	0	3	3	negative
bla_{VIM}	0	1	1	negative
bla_{GES}	0	1	1	negative
$bla_{OXA\text{-}48\text{-}like}$	0	2	2	negative
$bla_{OXA\text{-}198\text{-}like}$	0	1	1	negative
non-carbapenemase producer	0	46	46	negative
Total	196	266	462	321 +

C. Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 15 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.
To check inter-batch accuracy (reproducibility), some samples (positive and buffer) were processed on kits from three different production batches. All results were confirmed as expected.

XI. LIMITS OF THE KIT

The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.
A positive test does not rule out the possibility that other antibiotic resistance mechanisms may be present.

XII. TECHNICAL PROBLEMS/COMPLAINTS

If you encounter a technical problem or if performances do not correspond with those indicated in this package insert:

1. Record the kit batch number
2. If possible, keep the sample in the appropriate storage condition during the complaint management
3. Contact Coris BioConcept (client.care@corisbio.com) or your local distributor

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Last update: 27 NOVEMBER 2019

REF	Catalogue number		Manufacturer
IVD	*In vitro* diagnostic medical device		Temperature limits
Σ	Contains sufficient for <n> tests	LOT	Lot number
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DIL SPE	Diluent specimen	CONT NaN_3	Contains Sodium azide

OXA-23 *K*-SeT

Manufacturer:

Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
B – 5032 GEMBLOUX
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OXA-23 has been detected in other bacterial species as chromosomal (*P. mirabilis,* Bonnet et al 2002 and Osterblad et al 2016; *A. radioresistans*) or plasmidic gene (*E. coli*, La et al, 2014), which can constitute reservoirs for horizontal transmission of this resistance factor (Poirel et al 2016). The detection of this resistance factor OXA-23, not only in resistant species but also in carrier species, is therefore of paramount importance in the control of antibiotic resistance in the hospital.
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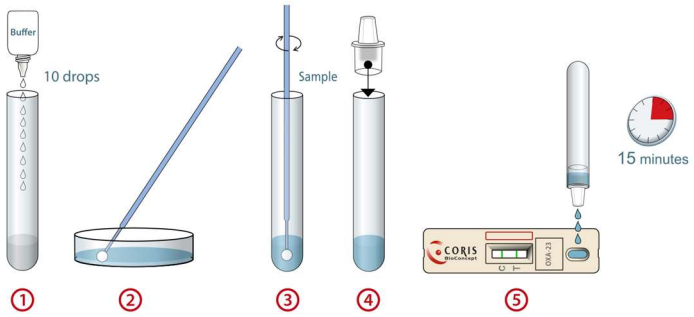

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The results are to be interpreted as follows:

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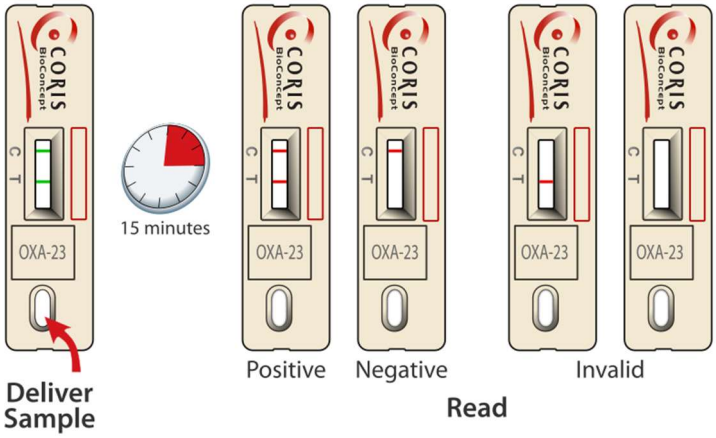

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	73 strains tested negative with the OXA-23 *K*-SeT	**68 strains** carrying a non-OXA-23 carbapenemase	OXA-40, OXA-51, OXA-58, OXA-143, OXA-235
		5 strains carrying class B carbapenemases	Including VIM-2, NDM-1, NDM-2

A second evaluation was retrospectively performed on 448 clinical strains of *Acinetobacter spp*. and 14 oxacillinase-producing Gram-negative bacteria collected in Belgium and in Italy between 2008 and 2018 with an agreement of 100 % versus real-time PCR and molecular sequencing. see Riccobono, 2019

	Italy	Belgium	Total	Test OXA-23 K-SeT
$bla_{OXA\text{-}23\text{-}like}$	170	137	307	307 +
$bla_{OXA\text{-}24\text{-}like}$	5	25	30	negative
$bla_{OXA\text{-}58\text{-}like}$	1	30	31	negative
IS*Aba1* $bla_{OXA\text{-}51\text{-}like}$	11	0	11	negative
$bla_{OXA\text{-}23\text{-}like}$ + $bla_{OXA\text{-}58\text{-}like}$	5	2	7	7 +
$bla_{OXA\text{-}23\text{-}like}$ + IS*Aba1* $bla_{OXA\text{-}51\text{-}like}$	4	0	4	4 +
$bla_{OXA\text{-}23\text{-}like}$ + bla_{NDM}	0	3	3	3 +
$bla_{OXA\text{-}58\text{-}like}$ + bla_{VIM}	0	1	1	negative
bla_{NDM}	0	13	13	negative
$bla_{OXA\text{-}143\text{-}like}$	0	1	1	negative
bla_{IMP}	0	3	3	negative
bla_{VIM}	0	1	1	negative
bla_{GES}	0	1	1	negative
$bla_{OXA\text{-}48\text{-}like}$	0	2	2	negative
$bla_{OXA\text{-}198\text{-}like}$	0	1	1	negative
non-carbapenemase producer	0	46	46	negative
Total	196	266	462	321 +

C. Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 15 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.
To check inter-batch accuracy (reproducibility), some samples (positive and buffer) were processed on kits from three different production batches. All results were confirmed as expected.

XI. LIMITS OF THE KIT

The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.
A positive test does not rule out the possibility that other antibiotic resistance mechanisms may be present.

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Last update: 27 NOVEMBER 2019

REF	Catalogue number		Manufacturer
IVD	*In vitro* diagnostic medical device		Temperature limits
Σ	Contains sufficient for <n> tests	LOT	Lot number
	Consult instructions for use		Do not reuse
	Keep dry		Use by
DIL SPE	Diluent specimen	CONT NaN_3	Contains Sodium azide

OXA-23 *K*-SeT

Manufacturer:

Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
B – 5032 GEMBLOUX
BELGIUM
Tel.: +32(0)81.719.917
Fax: +32(0)81.719.919
info@corisbio.com

Produced in BELGIUM

www.corisbio.com
IFU-58R7/EN/02

***In vitro* rapid diagnostic test for the detection of OXA-23 carbapenemase in bacterial culture**

FOR IN VITRO DIAGNOSTIC USE **EN**
FOR PROFESSIONAL USE ONLY
References: K-15R7, 20 cassettes, buffer, 20 tubes and droppers

I. INTRODUCTION

Acinetobacter baumannii is an important opportunistic and multidrug-resistant Gram-negative bacterium responsible for nosocomial infections in health facilities. If left untreated, this infection can lead to septicemia and death. The carbapenem-hydrolysing oxacillinases (OXAs) are the most commonly reported carbapenem-resistance determinants in *Acinetobacter* spp., particularly in *A. baumannii*. Among the OXAs, OXA-23 is the most prevalent carbapenem-resistance determinant in *A. baumannii* isolates.
OXA-23 has been detected in other bacterial species as chromosomal (*P. mirabilis,* Bonnet et al 2002 and Osterblad et al 2016; *A. radioresistans*) or plasmidic gene (*E. coli*, La et al, 2014), which can constitute reservoirs for horizontal transmission of this resistance factor (Poirel et al 2016). The detection of this resistance factor OXA-23, not only in resistant species but also in carrier species, is therefore of paramount importance in the control of antibiotic resistance in the hospital.
Nowadays, definitive confirmation of OXA-23 relies on molecular amplification analysis and DNA sequencing. These tests are expensive and can only be performed in dedicated environment and by skilled staff, hence limiting their more generalized usage.
The development of new rapid diagnostic tests to track antimicrobial resistance patterns is considered as one of the priority core action by international experts and health authorities.
The OXA-23 K-SeT test aimed at a rapid identification of the OXA-23 carbapenemase (and variants of the OXA-23 group) ensures effective treatment of patients and prevention of spread of OXA-23 *Acinetobacter* spp. carrier, especially in hospitals.

II. PRINCIPLE OF THE TEST

This test is ready to use and is based on a membrane technology with colloidal gold nanoparticles. A nitrocellulose membrane is sensitized with a monoclonal antibody directed against one epitope of the OXA-23 carbapenemase. Another monoclonal antibody directed against a second epitope of the OXA-23 carbapenemase is conjugated to colloidal gold particles. This conjugate is dried on a membrane.
This test is aimed at the detection of OXA-23 like carbapenemases in a single bacterial colony growing on agar plate. The sample must be diluted in the dilution buffer supplied with the test. When the provided buffer containing the resuspended bacteria comes into contact with the strip, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample material come into contact with the anti-OXA-23 antibody that it is adsorbed onto the nitrocellulose strip. If the sample contains the OXA-23 carbapenemase, the conjugate–OXA-23 complex will remain bound to the anti-OXA-23 antibody adsorbed onto the nitrocellulose and a red line will develop. Solution continues to migrate to reach a second reagent (control reagent) that binds the migration control conjugate, thereby producing a red control line that confirms that the test is valid. Result is visible within 15 minutes.

III. REAGENTS AND MATERIALS

1. OXA-23 *K*-SeT (20)
20 sealed pouches containing one device and one desiccant. Each device contains one sensitized strip.
2. LY-A buffer vial (15 mL)
Saline solution buffered to pH 7.5 containing TRIS, NaN_3 (<0,1%) and a detergent.
3. Instruction for use (1)
4. Semi-rigid disposable collection tubes with droppers (20)
5.

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- All reagents are for *in vitro* diagnostic use only.
- Pouch must be opened with care.
- Avoid touching nitrocellulose with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- Green lines indicate immunoreagents adsorption sites. Green colour disappears during the test.
- Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in the insert.

V. WASTE DISPOSAL

- Dispose of gloves, swabs, test tubes and used devices in accordance with GLP.
- Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

VI. STORAGE

- An unopened pouch may be kept at between 4 and 30°C and used until the shelf-life date indicated on the packaging. Once the pouch is opened, run the test immediately.
- Avoid freezing devices and buffer.

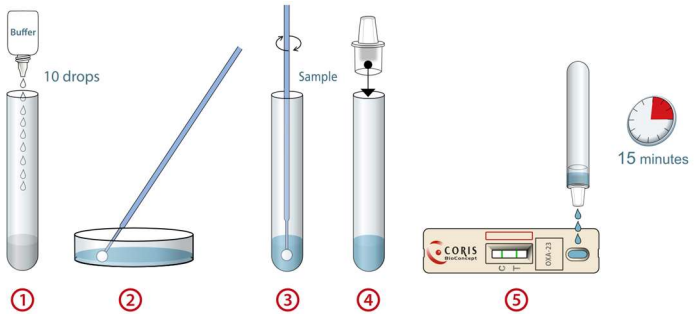
VII. SPECIMEN HANDLING AND COLLECTION

Specimens to be tested should be obtained and handled by standard microbiological methods.
Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.
Culture media tested and validated with Coris BioConcept RESIT kits are listed on the website: https://www.corisbio.com/Products/Human-Field/OXA-23/FAQ.php

VIII. PROCEDURE

PREPARATIONS OF THE TEST:
Allow kit components, in unopened packaging, and specimens (in case the plate containing colony to be tested was kept at 4°C) to reach room temperature (15-30°C) before performing a test.
Open the pouch and remove the device. Once opened, run the test immediately. Indicate the patient's name or specimen number on the device (one device per sample).
SPECIMEN PREPARATION PROCEDURE:
We recommend the use of fresh bacterial colonies for optimal test performance.

1. Prepare one semi-rigid tube provided in the kit and add **10** drops of LY-A buffer in the tube.
2. Harvest bacteria by taking one colony with a disposable bacteriological loop and dip the loop in the bottom of the semi-rigid tube containing the buffer.
3. Stir thoroughly before removing the loop
4. Insert tightly the dropper on the semi-rigid tube.
5. Vortex the preparation to homogenize. The entire bacterial colony must be suspended into the buffer.
6. Invert the test tube and add slowly **3** drops of diluted sample into the sample well of the cassette. Alternatively, add 100µl with a micropipette into the sample well of the cassette.
7. Allow to react for 15 min max and read the result.



Positive results may be reported as soon as the test and control lines become visible.
Do not take the appearance of new lines into account after the reaction time is passed.
The result must be read on still wet strip.

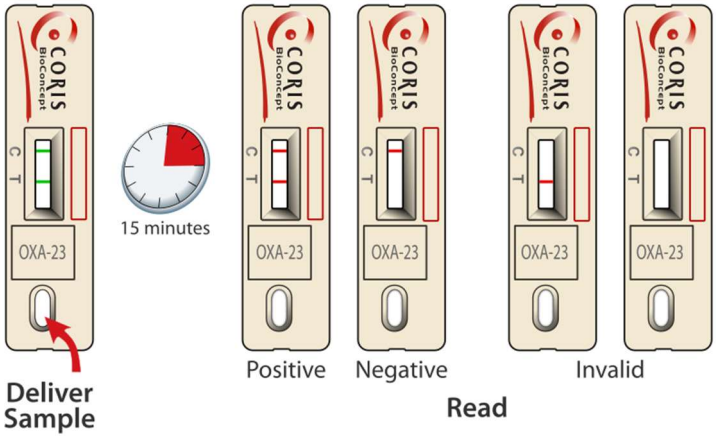
IX. INTERPRETING RESULTS

The results are to be interpreted as follows:

Negative test result: a reddish-purple line appears across the central reading window at the Control line (C) position. No other band is present.

Positive test result: in addition to a reddish-purple band at the Control line (C), a visible reddish-purple band appears at the Test line position (T). Intensity of the test line may vary according to the quantity of antigens present in the sample. Any reddish-purple line (T), even weak, should be considered as a positive result.

Invalid test result: The absence of a Control line indicates a failure in the test procedure. Repeat invalid tests with a new test device.
Note: during the drying process, a very faint shadow may appear at the Test line position. It should not be regarded as a positive result.



X. PERFORMANCE

A. Detection Limit

The detection limit was determined with a purified recombinant OXA-23 protein and has been evaluated at 0,156 ng/mL.

B. Validation on collection of reference strains

The OXA-23 *K*-SeT was evaluated on a collection of 108 clinical isolates of carbapenem-resistant *Acinetobacter* spp. fully characterized resistance mechanisms to beta-lactams by phenotypic and molecular tests (Germany).

108 strains	**35 strains** tested positive with the OXA-23 *K*-SeT	**35 strains** carrying OXA-23 carbapenemase	*Acinetobacter baumannii, Acinetobacter pittii, Acinetobacter nosocomialis, Acinetobacter radioresistens*
	73 strains tested negative with the OXA-23 *K*-SeT	**68 strains** carrying a non-OXA-23 carbapenemase	OXA-40, OXA-51, OXA-58, OXA-143, OXA-235
		5 strains carrying class B carbapenemases	Including VIM-2, NDM-1, NDM-2

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Last update: 27 NOVEMBER 2019

REF	Catalogue number		Manufacturer
IVD	*In vitro* diagnostic medical device		Temperature limits
Σ	Contains sufficient for <n> tests	LOT	Lot number
	Consult instructions for use		Do not reuse
	Keep dry		Use by
DIL SPE	Diluent specimen	CONT NaN_3	Contains Sodium azide