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: 2022.04.27 15:36:22 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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tel.: + 32 2 642 53 94
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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.

CORIS BioConcept

EC Declaration of Conformity according to Annex III of the IVDD

This is to certify that following IVD products:

- **Rota-Strip (C-1001)**
- **Adeno-Strip (C-1002)**
- **40/41 Adeno-Strip (C-1003)**
- **Combi-Strip & Combi K-SeT (C-1004; K-1204; K-1504)**
- **Crypto-Strip (C-1005)**
- **RSV Respi-Strip & RSV K-SeT (C-1006; K-1206; K-1506)**
- **Adeno Respi-Strip & Adeno Respi K-SeT (C-1009; K-1209; K-1509)**
- **Influ A+B K-SeT (K-1212; K-1512)**
- **Giardia-Strip & Giardia K-SeT (C-1013; K-1213; K-1513)**
- **Legionella *K*-SeT (K-1215; K-1515)**
- **GastroVir-Strip & GastroVir K-SeT (C-1016; K-1216; K-1516)**
- **Crypto/Giardia Duo-Strip (C-1018)**
- **Pylori-Strip & Pylori K-SeT (C-1019; K-1219; K-1519)**
- **C.diff-Strip & Clostridium K-SeT (C-1020; K-1220; K-1520)**
- **Strep-A Respi-Strip (C-1022)**
- **P. aeruginosa mexQ-TesT (C-3806)**
- **Proguanil / Malarone™-Strip; Proguanil-Strip (C-10T1; C-40T1)**
- **Mefloquine / Lariam™-Strip; Mefloquine-Strip (C-10T2; C-40T2)**
- **HAT Sero K-SeT (K-12S2; K-15S2)**
- **OXA-48 K-SeT (K-15R1)**
- **KPC K-SeT (K-15R2)**
- **RESIST-3 O.O.K. K-SeT (K-15R4)**
- **RESIST-3 O.K.N. K-SeT (K-15R5)**
- **RESIST-4 O.K.N.V. (K-15R8)**
- **OXA-23 K-SeT (K-15R7)**
- **RESIST-5 O.O.K.N.V. (K-15R9)**
- **IMP *K*-SeT (K-15R10)**
- **BL-RED 25 (RED-0001)**
- **Adenovirus Positive Control (C-1082)**
- **RSV Positive Control (C-1086)**
- **Influenza A Positive Control (C-1090)**
- **Influ A&B Control Test (C-1092)**
- **Giardia Lamblia Control Test (C-1093)**
- **Pylori Positive Control (C-1099)**
- **Strep-A Positive Control (P-1022)**
- **Negative Control (CTR-1000)**

are manufactured and sold by **Coris BioConcept**
Science Park CREALYS
Rue Jean Sonet 4A - 5032 Gembloux - BELGIUM

These products:

1. Belong to the Class "Others/General" as they are not for self-testing and do not belong to List A or List B of Annex II of IVDD (98/79 EC).
2. Comply with all Essential Requirements (Annex I) of the IVDD (98/79 EC)
3. This compliance has been properly documented using a checklist created from Annex I and III of the IVDD, linked to all supporting Technical Documentation. This documentation included both product specific and process (Quality System) specific documents.
4. Have a Quality System in place based ISO 13485
5. This Declaration is issued by Coris BioConcept and has unlimited time validity.
6. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

For Coris BioConcept, made in Gembloux the 2^{sd} of October, 2019

T. Leclipteux
C.E.O

C. Misson
QA Manager

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

Certificate of Analysis

Phone: +32 81 719 917 Fax: +32 81 719 919 E-mail: info@corisbio.com www.corisbio.com **Ref: F-SRV-11-01v5**

Description	Code	Lot number	Packaging date	Expiry date	Quality control
O.K.N.V.I. RESIST-5	K-15R11/TB	46322K2129	29/11/2021	10/04/2023	Accepted

Date of delivery: 10/12/2021 Customer: SANMEDICO SRL

All these products have been manufactured and tested according to our Standard Operating Procedures.
Coris BioConcept has a Quality System in place based on ISO 13485.

This lot is released for shipment and sale.

Date: 10/12/2021 **Approved by Q.A.**

This document has been produced electronically and is valid without a signature

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.

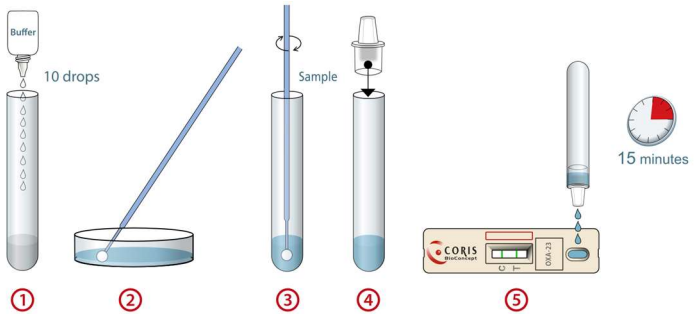
VII. SPECIMEN HANDLING AND COLLECTION

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.

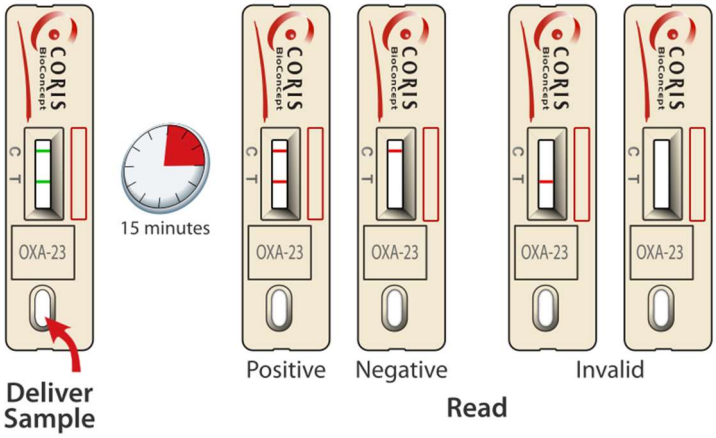
IX. INTERPRETING RESULTS

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

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2. If possible, keep the sample in the appropriate storage condition during the complaint management
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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.

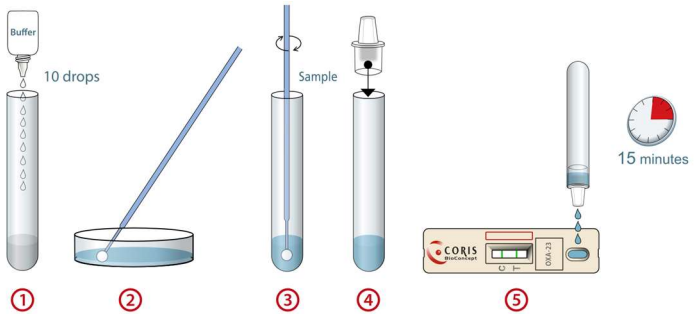
VII. SPECIMEN HANDLING AND COLLECTION

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.

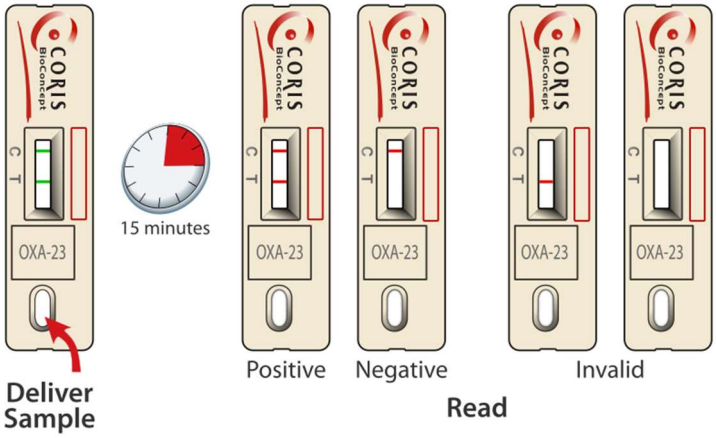
IX. INTERPRETING RESULTS

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

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
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W. **P. Bogaerts, S. Evrard, G. Cuzon, TD. Huang, T. Naas and Y. Glupczynski** Specificity of the OXA-48 immunochromatographic K-SeT for the detection of OXA-48 like in Shewanella spp. 26th European Congress of Clinical Microbiology and Infectious Diseases, Infectious Amsterdam April 09 – 12, 2016

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.

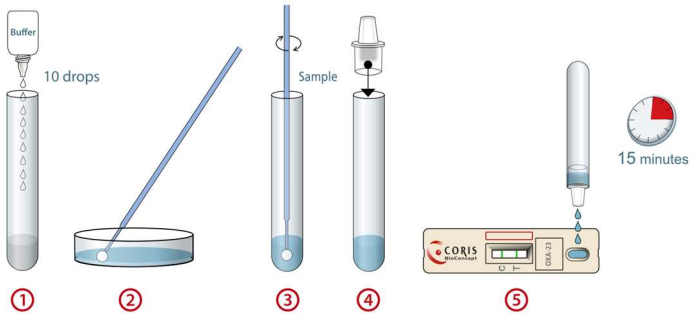
VII. SPECIMEN HANDLING AND COLLECTION

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.

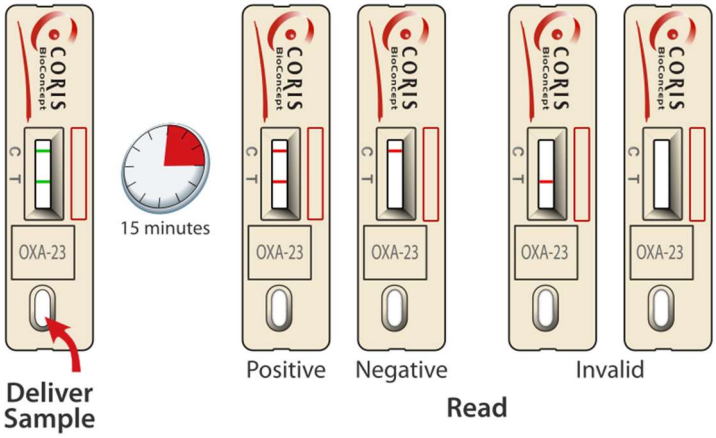
IX. INTERPRETING RESULTS

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

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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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

Innovative solutions
for effective diagnostics

Rapid testing for
antibiotic resistance
markers and
infectious diseases

Product Catalogue

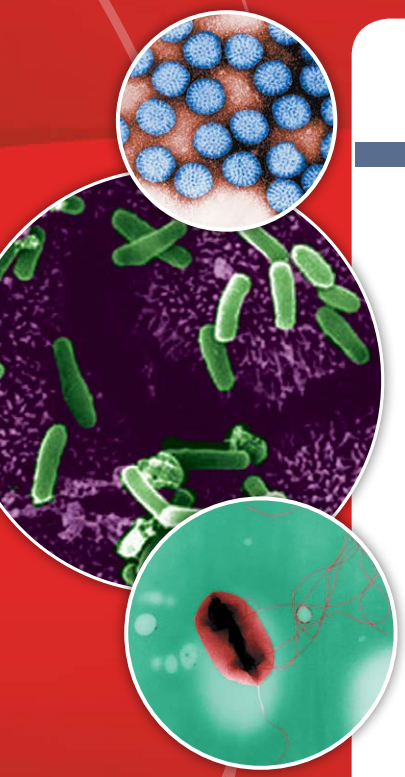
CORIS
BioConcept

www.corisbio.com

R·E·D

Electrochemical in vitro rapid detection test of resistance to third-generation cephalosporins by hydrolysis.

PRODUCT NAME	DESCRIPTION	CODE
BL-RED 25	25 RED-sensors, BL-Reagent, PP-Buffer	**RED-0001**



Immunochromatographic Tests

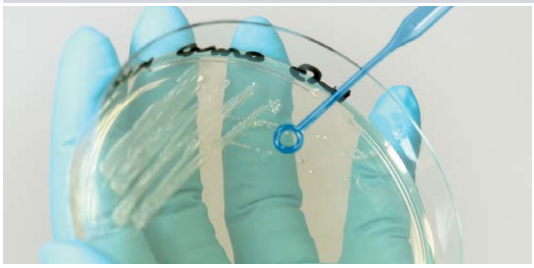
ENTERIC

PATHOGEN	PRODUCT NAME	DESCRIPTION	CODE
Adenovirus	Adeno-Strip	25 strips, buffer	**C-1002**
Adenovirus 40/41	40/41 Adeno-Strip	25 strips, buffer	**C-1003**
Clostridium difficile	C. diff-Strip	25 strips, buffer	**C-1020**
	Clostridium *K*-SeT	20 cassettes, buffer	**K-1220**
	Clostridium *K*-SeT with collection set	20 cassettes, 20 faecal sampling systems	**K-1520**
Cryptosporidium	Crypto-Strip	25 strips, buffer	**C-1005**
Cryptosporidium & Giardia	Crypto/Giardia Duo-Strip	25 strips, buffer	**C-1018**
Giardia	Giardia-Strip	25 strips, buffer	**C-1013**
	Giardia *K*-SeT	20 cassettes, buffer	**K-1213**
	Giardia *K*-SeT with collection set	20 cassettes, 20 faecal sampling systems	**K-1513**
Rotavirus	Rota-Strip	25 strips, buffer	**C-1001**
Rotavirus & Adenovirus	Combi-Strip	25 strips, buffer	**C-1004**
	Combi *K*-SeT	20 cassettes, buffer	**K-1204**
	Combi *K*-SeT with collection set	20 cassettes, 20 faecal sampling systems	**K-1504**
Rotavirus & Adenovirus 40/41	GastroVir-Strip	25 strips, buffer	**C-1016**
	Gastro Vir *K*-SeT	20 cassettes, buffer	**K-1216**
	Gastro Vir *K*-SeT with collection set	20 cassettes, 20 faecal sampling systems	**K-1516**

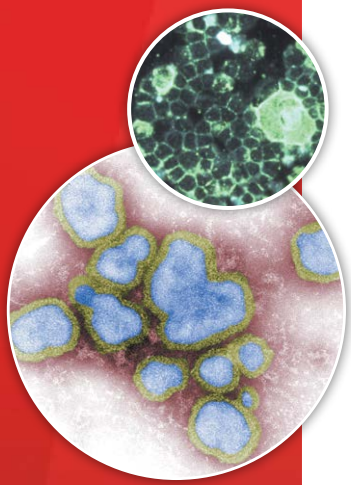
R·E·S·I·S·T

Antibiotic resistance is a growing and major global health concern.
For a precise and rapid identification: the new RESIST range !

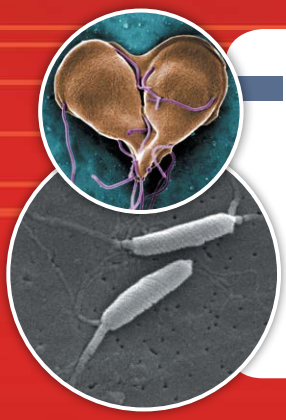
TARGET	PRODUCT NAME	DESCRIPTION	CODE
OXA-48	OXA-48 *K*-SeT	20 cassettes, buffer 20 tube-droppers	**K-15R1**
KPC	KPC *K*-SeT	20 cassettes, buffer 20 tube-droppers	**K-15R2**
OXA-48 & OXA-163 & KPC	RESIST-3 O.O.K. *K*-SeT	20 cassettes, buffer 20 tube-droppers	**K-15R4**
OXA-48 & KPC & NDM	RESIST-3 O.K.N. *K*-SeT	20 cassettes, buffer 20 tube-droppers	**K-15R5**
OXA-48 & KPC NDM & VIM	RESIST-4 O.K.N.V.	2x20 cassettes, buffer 20 tube-droppers	**K-15R8**
OXA-23	OXA-23 *K*-SeT	20 cassettes, buffer, 20 tubes-droppers	**K-15R7**
OXA-48 & OXA-163 & KPC NDM & VIM	RESIST-5 O.O.K.N.V.	2x20 cassettes, buffer, 20 tube-droppers	**K-15R9**



RESPIRATORY

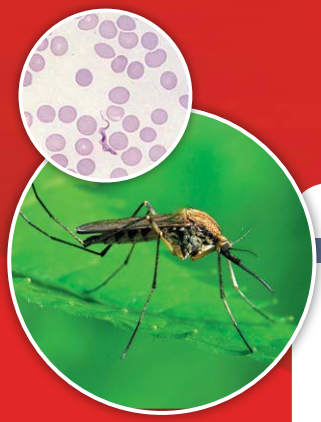


PATHOGEN	PRODUCT NAME	DESCRIPTION	CODE
Influenza A & B Viruses	Influ A+B K-SeT	20 cassettes, buffer	**K-1212**
	Influ A+B K-SeT with collection set	20 cassettes, buffer, 20 swabs, 20 tube-droppers	**K-1512**
Legionella pneumophila	Legionella K-SeT	20 cassettes, 20 transfer pipettes	**K-1215**
	Legionella K-SeT with controls	20 cassettes, 20 transfer pipettes, positive and negative controls	**K-1515**
Respiratory Adenovirus	Adeno Respi-Strip	25 strips, buffer	**C-1009**
	Adeno Respi *K*-SeT	20 cassettes, buffer	**K-1209**
	Adeno Respi *K*-SeT with collection set	20 cassettes, buffer, 20 swabs 20 tube-droppers	**K-1509**
Respiratory Syncytial Virus	RSV Respi-Strip	25 strips, buffer	**C-1006**
	RSV *K*-SeT	20 cassettes, buffer	**K-1206**
	RSV *K*-SeT with collection set	20 cassettes, buffer, 20 swabs 20 tube-droppers	**K-1506**
Streptococci (Group A)	Strep-A Respi-Strip	25 tests, dilution buffer, extraction buffer	**C-1022**



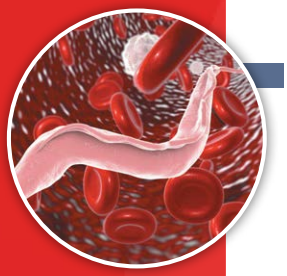
GASTRIC

PATHOGEN	PRODUCT NAME	DESCRIPTION	CODE
Helicobacter pylori	Pylori-Strip	25 strips, buffer	C-1019
	Pylori *K*-SeT	20 cassettes, buffer	K-1219
	Pylori *K*-SeT with collection set	20 cassettes, 20 faecal sampling systems	K-1519



DRUG

DRUG	PRODUCT NAME	DESCRIPTION	CODE
Proguanil	Proguanil-Strip	20 strips	C-10T1
Mefloquine	Mefloquine-Strip	20 strips	C-10T2



SEROLOGICAL

PATHOGEN	PRODUCT NAME	DESCRIPTION	CODE
Human African Trypanosomiasis*	HAT Sero K-SeT	40 cassettes, buffer, heparinized capillary tubes	K-12S2
	HAT Sero K-SeT with collection set	40 cassettes, buffer, heparinized tubes, blood lancets, alcohol prep pads	K-15S2

Immunochromatographic Test for Veterinary

PATHOGEN	PRODUCT NAME	DESCRIPTION	CODE
Rotavirus ***Cryptosporidium parvum*** ***Escherichia coli F5*** **Coronavirus**	Quatro Vet Uni-Strip	10 individual pouches with 4 strips, buffers, sampling devices (tests tubes, loops, tube holder)	C-1540

*** : On demand**

Company Profile

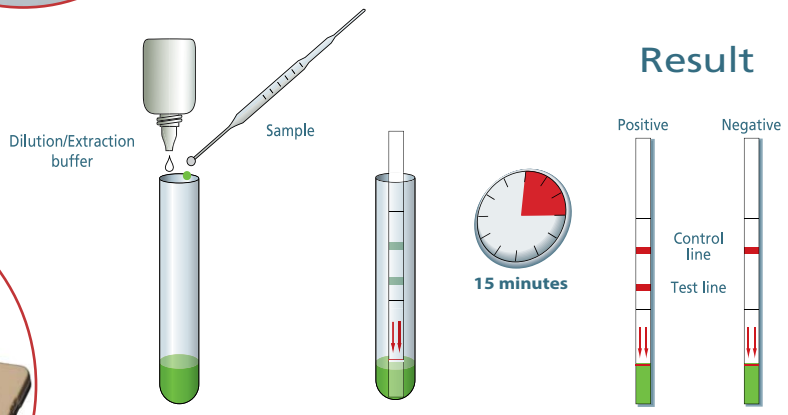
Coris BioConcept is a leading expert in the field of immunochromatographic (IC) and oligochromatographic (OC) technologies. Based in Belgium and established in 1996, the company develops, produces and markets rapid diagnostic kits for the detection of human respiratory and gastro-enteric infectious pathogens (bacteria, viruses and parasites) and for the detection of antibiotic resistance markers (RESIST range). These rapid tests are extensively used in microbiology laboratories worldwide.

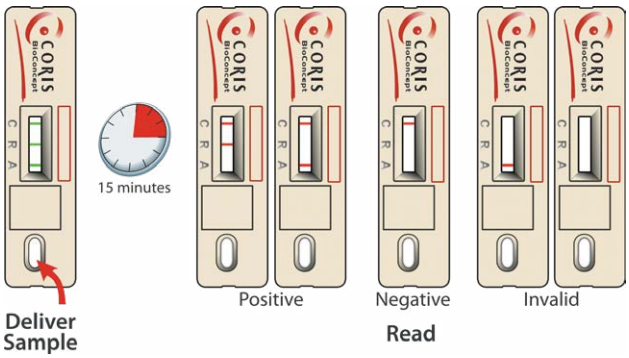
To complement this extensive range of fast and accurate lateral flow tests, the company has developed an innovative fully automated platform that performs multiplex PCR amplification and detection on a microfluidic cartridge (TRAPIST® system). This molecular multiplex platform allows syndromic diagnostic approach for the clinical management of main human infections and resistance to antibiotics.

Coris BioConcept is continually involved in collaborative projects with Belgian and European Research Institutes, laboratories and companies for the development of breaking new solutions.

This R&D expertise is ideally suited for "on-demand" production of innovative solutions in a rapidly changing world that calls for cutting edge biotechnology to take us forward into a healthy future.

All Coris BioConcept's products fulfil the CE marking requirements and the company is also certified ISO 13485.





Distributed by:

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