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,

Jeroen Poels
IVD Competent Authority

Digitally signed by Monastîrschii Viorica
Date: 2021.12.09 14:06:56 EET
Reason: MoldSign Signature
Location: Moldova

Rue Juliette Wytsmanstraat 14
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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)**
- **O157 Coli-Strip (C-1011)**
- **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)**
- **BL-RED 25 (RED-0001)**
- **Adenovirus Positive Control (C-1082)**
- **RSV Positive Control (C-1086)**
- **Influenza A Positive Control (C-1090)**
- **E. coli O157 Positive Control (C-1091)**
- **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 21st of March, 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

RESIST-4 O.K.N.V.

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- 58R8/EN/02

***In vitro* rapid diagnostic test for the detection of OXA-48, KPC, NDM and VIM carbapenemases in bacterial culture**

FOR IN VITRO DIAGNOSTIC USE **EN**
FOR PROFESSIONAL USE ONLY
References: K-15R8, 2x20 cassettes, buffer, 20 tubes and droppers

I. INTRODUCTION

Carbapenemase-producing organisms (CPO) and more particularly carbapenem-resistant Enterobacteriaceae (CRE) represent a major public health concern worldwide due to their broad spectrum of resistance to antibiotics including, besides carbapenems, most classes of antimicrobial agents, and thus leaving very few options for the management of infected patients. Besides CREs, CPOs also include nonfermenting gram-negative bacilli (NFGNB), such as *Pseudomonas aeruginosa* and *Acinetobacter baumannii* that exhibit resistance not only to beta lactam and other groups of antibiotics, but also to carbapenems. The rapid spread of CPOs or of the genes encoding these resistances has led to nosocomial outbreaks and endemic situations in several countries in Europe and elsewhere worldwide.
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. NDM and KPC represent two of the most increasing and prevalent carbapenemases in many countries. On the other hand, class D OXA-48 type carbapenemases represent the most challenging resistance mechanism to detect for clinical laboratories. VIM is not only present in Enterobacteriaceae but is also highly prevalent in non-fermenter bacteria. Rapid identification of those carbapenemases is of upmost importance to improve both patient therapy and control of the spread of such antibiotic resistance in hospitals.
Confirmatory phenotypic tests using combination disks with specific inhibitors already exist for detection of selected types of carbapenemases including class A (KPC) and class B (VIM, IMP, NDM) carbapenemases; however, these tests are time-consuming and require an extra additional day following antimicrobial susceptibility testing results. Moreover, phenotypic colorimetric assays are in some instances not sensitive enough for the detection of low-activity carbapenemases such as OXA-48. Several molecular assays based on different formats also allow detection of carbapenemases. These tests are expensive, time-consuming and can only be performed in dedicated environment and by skilled personnel, hence limiting their generalized use.

II. PRINCIPLE OF THE TESTS

These tests are ready to use and are based on a membrane technology with colloidal gold nanoparticles. Our kit is aimed to the detection of carbapenemases from a single bacterial colony isolate of Enterobacteriaceae or NFGNB growing on agar plate.
Each pouch contains 2 lateral-flow cassettes for the identification of (i) KPC and OXA-48 and (ii) NDM and VIM. These two devices are aimed at the detection of KPC, OXA-48, NDM and VIM carbapenemases on a single colony of bacterial isolates growing on agar plate resuspended in the provided buffer.
Identification of KPC and OXA-48. A nitrocellulose membrane is sensitized with:
(1) a monoclonal antibody directed against the KPC carbapenemase (bottom K line)
(2) a monoclonal antibody directed against the OXA-48 carbapenemase (middle O line)
(3) a control capture reagent (upper C line).
Three different colloidal gold nanoparticles conjugates are dried on a membrane: a conjugate directed against the KPC carbapenemase, a conjugate directed against the OXA-48 carbapenemase, and a control conjugate.

Identification of NDM and VIM. A nitrocellulose membrane is sensitized with:
(1) a monoclonal antibody directed against the NDM carbapenemase (bottom N line),
(2) a monoclonal antibody directed against the VIM carbapenemase (middle V line),
(3) a control capture reagent (upper C line).
Three different colloidal gold nanoparticles conjugates are dried on a membrane: a conjugate directed against the NDM carbapenemase, a conjugate directed against the VIM carbapenemase, and a control conjugate.

When the provided buffer containing the resuspended bacteria comes into contact with the strip, the solubilised conjugates migrate with the sample by passive diffusion and conjugates and sample material come into contact with the immobilized respective antibodies that are adsorbed onto the nitrocellulose strip. If the sample contains a KPC, OXA-48, NDM or VIM carbapenemase, the respective complexes made of the conjugates and either KPC, or OXA-48, or NDM or VIM will remain bound to their respectives specific lines (KPC, K line; OXA-48, O line; NDM, N line, VIM, V line). The migration continues by passive diffusion and both conjugates and sample material come into contact with the (upper) line control reagent that binds a control conjugate (line C), thereby producing a red line.
The result is visible within 15 minutes in the form of red lines on the strip.

III. REAGENTS AND MATERIALS

1. RESIST-4 O.K.N.V. (2x20 cassettes)
20 sealed pouches containing two lateral-flow cassettes 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)

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.

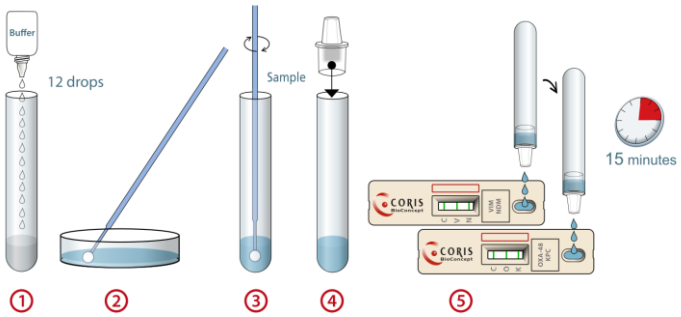
VII. SPECIMEN HANDLING AND COLLECTION

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/RESIST-4-OKNV.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:
Performance claims with regard to samples types other than bacterial colonies have not been established. We recommend the use of fresh bacterial colonies for optimal test performance.

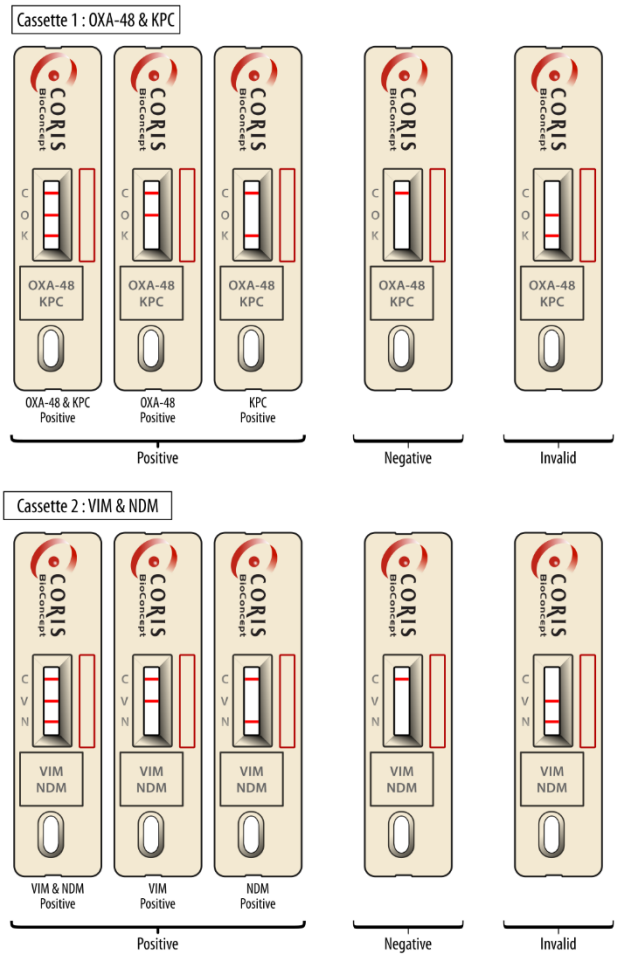
1. Prepare one semi-rigid tube and add **12** drops of LY-A buffer in the tube.
2. Harvest bacteria by taking one colony with a disposable bacteriological loop and dip the loop in the bottom of the semi-rigid tube containing the buffer.
3. Stir thoroughly before removing the loop
4. Insert tightly the 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 each of the two cassettes labeled (i) KPC and OXA-48 and (ii) NDM and VIM. Alternatively, add 100µl with a micropipette to both cassettes
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 for each of the two cassettes:
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 one of the Test lines position (OXA-48 or KPC) on cassette labelled (i) KPC and OXA-48, or at one of the Test lines position (VIM or NDM) on cassette labelled (ii) NDM and VIM. Intensity of the test line may vary according to the quantity of antigens as well as of the variant type present in the sample. Any reddish-purple Test line (OXA-48, KPC, NDM and VIM), even weak, should be considered as a positive result.
If a positive test line appears beside of the O mark, the sample contains OXA-48 or OXA-48-like variant, beside of K mark, the sample contains KPC, beside of N mark , the sample contains NDM and beside of V mark, VIM is present in the sample. Combinations of positive test lines can occur. In this case the sample contains the combination of several carbapenemases.
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 positions (O, K, N, V). It should not be regarded as a positive result.



X. PERFORMANCE

A. Detection Limit

The detection limit determined with purified recombinant proteins of OXA-48, KPC, NDM and VIM have been evaluated at 0.125 ng/ml, 0.625 ng/ml, 0,25 ng/ml and 0.23 ng/ml, respectively.

B. Prospective study (based on RESIST-3 O.K.N. *K*-SeT kit)

The OXA-48 and KPC cassette test was validated by comparison with reference molecular method (validated multiplex PCR including sequencing) in the National Reference Laboratory for Multidrug-Resistant Gram Negative Bacilli (Belgium) in a prospective study performed on 173 non duplicated, consecutive suspected CPE clinical isolates referred from July to September 2016.

Molecular method OXA-48 test	Positive	Negative	Total
Positive	69	0	69
Negative	0	104	104
Total	69	104	173

		95 % Confidence Interval [1]
Sensitivity:	100 %	(95.7 to 100 %)
Specificity:	100 %	(97.2 to 100 %)
Positive Predictive value:	100 %	(95.7 to 100 %)
Negative predictive value:	100 %	(97.2 to 100 %)
Agreement:	100 %	(173/173)

Molecular method KPC test	Positive	Negative	Total
Positive	9	0	9
Negative	0	164	164
Total	9	164	173

		95 % Confidence Interval [1]
Sensitivity:	100 %	(68.4 to 100 %)
Specificity:	100 %	(98.2 to 100 %)
Positive Predictive value:	100 %	(68.4 to 100 %)
Negative predictive value:	100 %	(98.2 to 100 %)
Agreement:	100 %	(173/173)

C. Validation on collection of reference strains

The VIM and NDM cassette test was validated by comparison with reference molecular method in the National Reference Laboratory for Multidrug-Resistant Gram Negative *Bacilli* (Belgium) in a retrospective study.

Molecular method NDM test	Positive	Negative	Total
Positive	24	0	24
Negative	0	95	95
Total	24	95	119

		95 % Confidence Interval [1]
Sensitivity:	100 %	(82.8 to 100 %)
Specificity:	100 %	(95.2 to 100 %)
Positive Predictive value:	100 %	(82.8 to 100 %)
Negative predictive value:	100 %	(95.2 to 100 %)
Agreement:	100 %	(119/119)

[1] Newcombe, Robert G. "Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods," *Statistics in Medicine,* **17**, 857-872 (1998).

Molecular method VIM test	Positive	Negative	Total
Positive	38	0	38
Negative	1*	80	81
Total	39	80	119

*: the false-negative result is a ***P. aeruginosa*** colony harboring VIM-5 and NDM-1 genes. This colony was detected as NDM-positive but VIM-negative. The production of VIM-5 was not assessed.

		95 % Confidence Interval [1]
Sensitivity:	97.4 %	(84.9 to 99.9 %)
Specificity:	100 %	(94.3 to 100 %)
Positive Predictive value:	100 %	(88.6 to 100 %)
Negative predictive value:	98.8 %	(92.4 to 99.9 %)
Agreement:	99.2 %	(118/119)

D. 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. Write the lot number of the kit concerned
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	Batch code
	Consult instructions for use	②	Do not reuse
	Keep dry		Use by
DIL SPE	Diluent specimen	CONT NaN_3	Contains Sodium azide