RESIST-BC

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IFU-57S01/TB/V01

Reagents kit for blood culture CPE detection with RESIST kits

FOR IN VITRO DIAGNOSTIC USE ***EN***
FOR PROFESSIONAL USE ONLY
Reference: S-1001
Reagents for 20 tests: 1x RBCL solution, 1x MS buffer and 1x Washing buffer

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I. INTRODUCTION

Bloodstream infections caused by Carbapenemase-producing Enterobacteriaceae (CPE) are often detected after 16 to 72 hours by standard methods, leading to inappropriate treatments and increased mortality. A new procedure to allow the use of RESIST IVD tests has been developed for detecting CPE directly from positive blood culture bottles. It can be performed in any microbiology laboratory to help clinicians to rapidly identify patients with these difficult-to-treat bloodstream infections for better management.

II. PRINCIPLE OF THE KIT

The reagents of the kit are ready to use and are intended for preparation of blood cultures before performing a RESIST test.
The purpose of the kit is to treat the red blood cells from blood cultures in order to release a bacterial extract suitable for the detection of carbapenemases by any kit from the RESIST range.
It can be used with all RESIST kits for the analysis of OXA-48, KPC, NDM, VIM and IMP carbapenemases from positive clinical blood cultures (not validated for OXA-163, OXA-23).

III. REAGENTS AND MATERIALS

1. **RBCL solution (4 mL)**

Red blood cell lysis solution containing a detergent and ProClin™ 200

2. **MS buffer vial (0.20 mL)**

Salts solution containing ProClin™ 200

3. **Washing buffer vial (20 mL)**

Phosphate saline buffered to pH 7.5 and ProClin™ 200

4. **Instruction for use (1)**

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.
- Vials must be opened with care.
- Avoid touching liquids with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- Do not mix up the steps with the RBCL solution, the MS buffer and the Washing buffer.
- The technician performing the test must be accustomed to handling the provided reagents.
- The quality of the reagents cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under the required conditions as indicated in the insert.

V. WASTE DISPOSAL

- Dispose of used gloves, safety glasses and 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

- Any reagent in the kit may be kept at between 15 °C and 30 °C (room temperature) and used until the shelf-life date indicated on the packaging. Once opened, the vials of reagents are stable up to the expiry date indicated on the packaging.
- Avoid freezing reagents.
- **Note:** If the RBCL solution is cloudy due to precipitation of the main reagent, incubate at 40°C and shake the vial regularly for 15 minutes.

VII. SPECIMEN HANDLING AND COLLECTION

Blood culture specimens to be tested should be obtained and handled by standard microbiological methods.
Blood culture bottles tested and validated with Coris BioConcept RESIST kits are: BD Bactec™ or BACT/ALERT®. No performance claims have been established with respect to sample types other than these blood culture bottles.

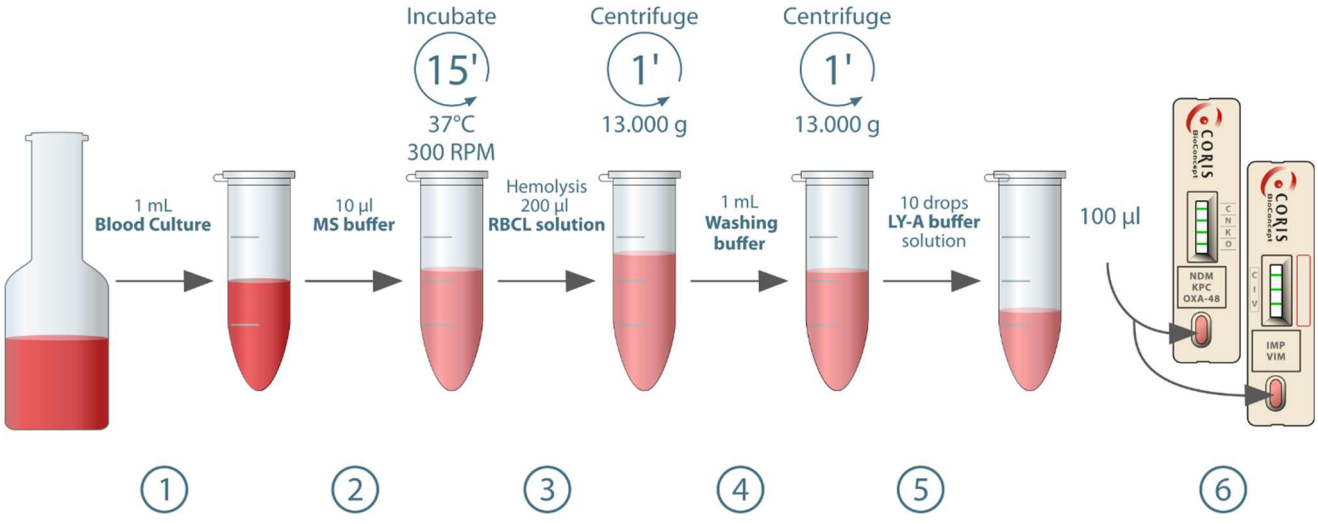
VIII. PROCEDURE

PREPARATION OF THE TEST:

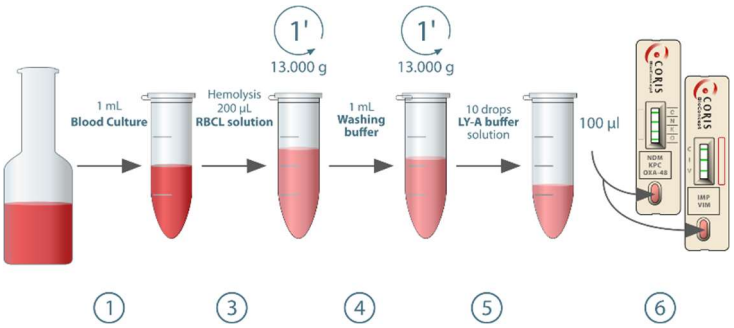
Indicate the patient's name or specimen number on microcentrifuge tube

SPECIMEN PREPARATION PROCEDURE:

1. Collect 1mL from a positive blood culture bottle, and dispense in a microcentrifuge tube
2. Add 10µl of MS buffer and incubate the mixture for 15 minutes at 37°C with stirring at 300 RPM
3. After incubation, add 200 µl of RBCL solution, mix by repeated inversions or with a vortex for a few seconds and immediately centrifuge at 13,000 g for 1 minute
4. Discard the supernatant and wash the pellet with 1 mL of washing buffer. Centrifuge at 13,000 g for 1 minute
5. Discard the supernatant and add 10 drops of LY-A buffer (provided in the RESIST kit) to the pellet
6. Resuspend the pellet and pipette 100µL to perform the RESIST test according to the manufacturer's recommendations.
   Allow to react for 15 minutes maximum and read the result.



Optional: a short procedure has been designed exclusively for detection of OXA-48 and KPC positive strains**, excluding metallo-β-lactamases (MBLs)**.
Incubation in MS buffer for 15 minutes can be avoided. Proceed directly to step 3, i.e, treatment of the sample with the RBCL solution.



IX. INTERPRETING RESULTS

The results have to be interpreted as indicated in the instruction for use of the Coris BioConcept RESIST Kits.

X. PERFORMANCE

A. Retrospective study based on RESIST-3 O.K.N. *K*-SeT (short procedure)

Molecular method OXA-48 test	Positive	Negative	Total
Positive	82	0	82
Negative	0	88	88
Total	82	88	170

		95% Confidence Interval[1]
Sensitivity:	100%	(94.4 to 100%)
Specificity:	100%	(94.8 to 100%)
Positive predictive value:	100%	(94.4 to 100%)
Negative predictive value:	100%	(94.8 to 100%)
Agreement:	100%	(170/170)

Molecular method KPC test	Positive	Negative	Total
Positive	18	0	18
Negative	0	152	152
Total	18	152	170

		95% Confidence Interval[1]
Sensitivity:	100%	(78.1 to 100%)
Specificity:	100%	(96.9 to 100%)
Positive predictive value:	100%	(78.1 to 100%)
Negative predictive value:	100%	(96.9 to 100%)
Agreement:	100%	(170/170)

Molecular method NDM test	Positive	Negative	Total
Positive	32	0	32
Negative	0	138	138
Total	32	138	170

		95% Confidence Interval[1]
Sensitivity:	100%	(86.7 to 100%)
Specificity:	100%	(96.6 to 100%)
Positive predictive value:	100%	(86.7 to 100%)
Negative predictive value:	100%	(96.6 to 100%)
Agreement:	100%	(170/170)

B. Retrospective study based on RESIST-4 O.K.N.V. *K*-SeT (advanced procedure)

Molecular method VIM test	Positive	Negative	Total
Positive	49	0	49
Negative	0	3	3
Total	49	3	52

		95% Confidence Interval[1]
Sensitivity:	100%	(95.7 to 100%)
Specificity:	100%	
Positive predictive value:	100%	(95.7 to 100%)
Negative predictive value:	100%	
Agreement:	100%	(52/52)

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

C. Retrospective study based on IMP *K*-SeT (advanced procedure)

Molecular method IMP test	Positive	Negative	Total
Positive	10	0	10
Negative	0	0	0
Total	10	0	10

		95% Confidence Interval[1]
Sensitivity:	100%	(65.5 to 100%)
Specificity:	nd	
Positive predictive value:	100%	(65 to 100%)
Negative predictive value:	nd	
Agreement:	100%	(10/10)

XI. LIMITS OF THE KIT

This Reagent Kit must only be used with one of the Coris BioConcept RESIST range of kits. It is an aid in the rapid identification of bacterial resistance to carbapenemases.
The RESIST test is qualitative and cannot predict the quantity of enzymes present in the sample. The clinical presentation and other test results must be taken into consideration to establish the diagnosis. A positive test does not rule out the possibility of other mechanisms of antibiotic resistance.

XII. TECHNICAL PROBLEMS / COMPLAINTS

If you have a technical problem or if the performance does not correspond to that indicated in this package insert:

1. Record the lot number of the kit concerned.
2. If possible, keep the sample in the appropriate storage conditions during claim handling.
3. Contact Coris BioConcept (client.care@corisbio.com) or your local distributor.

XIII. BIBLIOGRAPHIC REFERENCES

A. Hamprecht A, Vehreschild JJ, Seifert H, Saleh A. Rapid detection of NDM, KPC and OXA-48 carbapenemases directly from positive blood cultures using a new multiplex immunochromatographic assay. PLoS One. 2018 Sep 14;13 (9):e0204157
B. S. Tsiplakou, V. Papaioannou, E. Koiliari, D. Stefani and M. LelekisA. Saleh, S. Göttig and A. Hamprecht E0141 – Trends in resistance mechanisms of carbapenem resistant Klebsiella pneumoniae blood isolates during a two-year period in a tertiary care Hellenic hospital
28th European Congress of Clinical Microbiology and Infectious Diseases, Infectious Diseases April 21 – 24, 2018
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D. A. Saleh, S. Göttig and A. Hamprecht Multiplex immunochromatographic detection of OXA-48, KPC and NDM carbapenemases: impact of the inoculum, antibiotics and agar
J Clin Microbiol. 2018 Feb 14. pii: JCM.00050-18.

Last update 28 JUNE 2021

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		Do not reuse
	Keep dry		Use by
DIL SPE	Specimen Diluent	CONT ProClin	Contains Proclin200

Danger
H315; H318; H412
P264; P273; P280; P302+P352; P332+P313; P362+P364; P305+P351+P338; P310; P501
EUH 208 – 'Contains ProClin® 200. May produce an allergic reaction'
Causes skin irritation. Causes serious eye damage. Harmful to aquatic life with long lasting effects. Wash hands thoroughly after handling. Avoid release to the environment. Wear protective gloves/eye protection. IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/ attention. Take off contaminated clothing and wash it before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor if ingested. Dispose of contents/container in accordance with local/regional/national/international regulations.