

February 13, 2017

Field Safety Notice

Product code: SUN-1KR5
Product name: RESIST-3 O.K.N K-set
Reference: 1KR5K1618

Type of action:

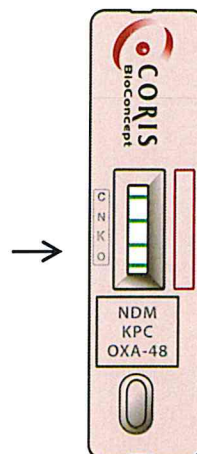
- Advice regarding the use of the device

Details on affected devices:

RESIST-3 O.K.N. cassette, K-15R5, with the lot number 1KR5K1618

Description of the problem:

There is a slight shift between the test lines OXA-48 (O) and KPC (K) of the strip and the labeled inscription on the cassette (see arrow). Both test lines of strip are slightly lower than the letters 'O' and 'K' labeled on the cassette.



There is a risk of confusing the KPC line with the OXA-48 line when only the KPC signal is readable after the test.

The performance of the test is not altered at all and we guarantee that this lot meets our quality standards.

Advise on action to be taken by the user:

To facilitate interpretation of the result, it is recommended to indicate the position of the KPC green line before starting the test.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Contact information:

This action reflects Coris BioConcept's commitment to high quality standards and ensuring that our products fully meet your expectations.

If you have any questions or comments arising from this customer communication, please contact us at:

Client Care
Coris BioConcept
Science Park CREALYS
Rue Jean Sonet 4A
5032 - GEMBLOUX - BELGIUM
TEL : + 32(0)81.719.917
FAX : +32(0)81.719.919
e-mail : client.care@corisbio.com
www.corisbio.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Signature

Coralie MISSON
QA Manager



CUSTOMER REPLY FORM

(Field Safety Notice letter dated February 10, 2017)

RESIST-3 O.K.N K-set

Product code : SUN-1KR5 – Lot number : 1KR5K1618

Please complete and return this form by email (client.care@corisbio.com) or by FAX (+32 81 719 919) as confirmation that you have received this notification.

Acknowledgement of receipt

Facility name and address:	
Reply confirmation completed by:	
Title:	

We have received the above mentioned letter and have disseminated this information to our staff and to other accounts.

Signature / date:
REQUIRED FIELD
