

20/02/2024

Declaration letter

Product code: K-15R13 Product name : RESIST ACINETO Reference : Declaration letter_NC2688

Type of action:

- Device exchange
- Device destruction

Details on affected devices:

Batches 50102I2305 & 50485K2321 of RESIST ACINETO (ref. K-15R13) are affected.

Description of the problem:

Batches 50102I2305 & 50485K2321 of RESIST ACINETO give a non-specific signal on the OXA-40/58 test line when the test is performed with a sample containing a high concentration of the OXA-23 analyte. Both line OXA-23 and OXA-40/58 are therefore regarded as positive.

The analysis of this problem led to the conclusion that the manufacturer of the OXA-23 specific antibody provided Coris BioConcept with a non-compliant batch of antibodies leading to this non specific signal. More precisely, some aliquots within the same batch shown lower quality than expected. This exceptional case could not be highlighted during our quality controls because the non-compliant aliquots were not within those sampled for the income QC.

Following the analysis that demonstrated the evidence of the root cause of this problem, Coris BioConcept has already decided to :

- replace the former OXA-23 specific antibody manufacturer with a new one that will apply stricter quality controls on the antibodies before their release for production.
- adapt the QC procedure

Action to be taken by the user:

All the remaining tests of RESIST ACINETO belonging to batches 50102I2305 and 50485K2321 must be discarded

Please send confirmation to Coris BioConcept claiming that :

- you have received the mentioned letter and have disseminated this information to your staff and to other accounts using the CUSTOMER REPLY FORM attached to this letter
- the destruction has been carried out using the F-CUS-13-05 form.

Transmission of this statement :

This statement should be communicated to everyone who needs to know within your organization or any organization where potentially affected devices have been transferred.

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

Please remain informed of this notice and resulting actions for an appropriate period of time to ensure corrective actions are effective.

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

Contact reference person:

M. LAMBOT Michel - Client Care

Coris BioConcept

CREALYS Science Park

Rue Guillaume Fouquet, 11

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.

Gustin Yves

QA Manager

CUSTOMER REPLY FORM

(Declaration letter dated (DATE) 26.02.2024.

RESIST ACINETO

Product code : (K-15R13)

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.

- We do not have any of the potentially affected devices in our inventory
- We do have potentially affected devices in our inventory

Facility name and address:	BIOMAX d.o.o., PERJAVIČKA PUTINA 5 10030 ZAGREB
Reply confirmation completed by:	NO DOKO
Title:	ACCOUNT MANAGER

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

Signature / date:
REQUIRED FIELD

No Doko J, 26.02.2024.

BIOMAX D.O.O
ZAGREB