Urgent Field Safety Notice
Novodiag CarbaR+

FIELD SAFETY NOTICE (FSN) DETAILS

Manufacturer:	Mobidiag, Ltd. Keilaranta 16 A FI-02150 Espoo Finland Phone: +358-10-5050 770 support.mob@hologic.com http://www.mobidiag.com
SRN:	*FI-MF-000001215*
Manufacturer's FSN reference number:	ID 2022-086
FSN date:	31-JAN-2023
Required action type:	Prohibition of use

PRODUCT DETAILS

Catalogue number:	NVD-CRB-012
Name:	**Novodiag® CarbaR+**
Basic UDI-DI:	643004176B0015M4
Version(s):	Version 2
UDI-DI(s):	06430041761778
Affected lot(s)/ serial number(s):	Kit lot 00241726 (Cart lot 00241466) (Exp date 18-MAY-2023) Kit lot 00442558 (Cart lot 00442365) (Exp date 08-JUN-2023) Kit lot 00542815 (Cart lot 00542611) (Exp date 14-SEP-2023)
UDI-PI(s):	N/A

ISSUE DETAILS

Description:	The Novodiag® CarbaR+ test (NVD-CRB-012) version 2 (V2) has been recently shown to not perform according to its specifications. This might have resulted in situations in where some false positive results have been obtained from clinical samples. The Novodiag® CarbaR+ test is diagnostic test that is intended for screening carbapenem and/or colistin resistance markers in conjunction with other clinical and laboratory findings. • KPC • NDM • IMP • OXA-23 • OXA-24 • OXA-48/181 • OXA-51 (detected only when the promoter ISAbal is present) • OXA-58 • VIM • MCR-1 The potential patient impact of a false positive result depends on the usage (patient screening or patient carriage monitoring) and sample type (rectal swab or bacterial pure cultures) In both screening and patient monitoring applications, with rectal swab as a primary sample, a false positive with Novodiag CarbaR+ could lead to unnecessary patient isolation and, in the occasion of an infection later on, potentially also to empiric treatment with antibiotics targeted against carbapenemase-producing bacteria. When bacterial pure culture is used as a primary sample, the risk of false positive with Novodiag CarbaR+ is low as the pure cultures are usually based on selection of phenotypically carbapenem-resistant strains. If pure cultures were obtained without preselection with selective culture media, a false positive result with Novodiag CarbaR+ could potentially lead to treatment with antibiotics targeted against carbapenemase-producing bacteria.
Potential hazard(s) and harm(s) associated to the issue:	Potential harms related to false positive results is unnecessary isolation and epidemiological assessment, and/or adverse events associated with antibiotic treatment for carbapenemase producing strains.

ACTIONS TO BE TAKEN BY THE FIELD SAFETY NOTICE RECIPIENT

Description:	Mobidiag is requesting to discontinue the use of the Novodiag CarbaR+ V2 and discard any remaining inventory assays according to local regulations. Customers have been asked to contact Mobidiag's representative for further information. In addition, Mobidiag recommends that the patients/samples that fulfil all the following four criteria will be retested by another molecular method or bacterial culture with antibiogram: 1. Sample from the patient has been tested positive with Novodiag® CarbaR+ assay for one or more of the carbapenem and/or colistin resistance markers. 2. The test result of carbapenem or colistin resistance has not been confirmed with another method such as measurement of minimal inhibitory concentration (MIC) of a carbapenem or colistin. 3. The test result indicating carbapenem and/or colistin resistance has been communicated to the clinic or physician. 4. Another bacterial culture sample with the same matrix and request type has not been received from the patient. 5. Based on the information available from the patient, it cannot be excluded that the Novodiag® CarbaR+ result has been used for decision regarding antibiotic use or isolation. If the retest does not identify the same carbapenem and/or colistin resistance markers as seen in the first test result, it is possible (although not evident) that the first result was false positive. In this case, the laboratory should give the clinician this information without any unnecessary delay to enable reassessment of the need for antibiotic use, possible isolation procedures, or testing for potential other causes for the symptoms of the patient. Customers are asked to contact Mobidiag's representative for further information. Complete the customer acknowledge form on page 5 and return it to the specified recipient no later than *10-FEB-2023.*

FIELD SAFETY NOTICE DISTRIBUTION

We ask you to bring this Field Safety Notice to the attention of all persons within your organization who need to be aware of the issue described in it.

FURTHER ASSISTANCE

If you need further assistance or information regarding the issue described in this FSN please don't hesitate to contact your local Mobidiag representative or the local Mobidiag office on:

Mobidiag (HQ) +358 10 5050 789 support.mob@hologic.com	**Mobidiag UK** 08000323318 support_UK.mob@hologic.com
Mobidiag France +33 1 88 88 02 52 support_fr.mob@hologic.com	**Mobidiag Sweden** +358 10 5050 789 scandinavia.support.mob@hologic.com

Mobidiag confirms that all relevant regulatory agencies have been informed of these field safety corrective actions.

Sincerely,

Electronically signed by:
Timo Soininen
Person Responsible for Regulatory Compliance

Urgent Field Safety Notice 31-JAN-2023

Novodiag® CarbaR+ V2

ACKNOWLEDGEMENT

We kindly ask you to confirm receipt of this Field Safety Notice by filling and returning this form in any of the following methods:

1) by mail to: Mirka Oksman Manager, Quality Assurance
Mobidiag Oy
Keilaranta 16 A
FI-02150 Espoo
FINLAND

2) as an email attachment to: Mirka.oksman@hologic.com

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UDI-PI(s):	N/A
Company/laboratory:	
Address:	
Contact person:	
Direct phone number:	
Email address:	
Acknowledgement:	I acknowledge receipt of this Field Safety Notice and that I have understood the information provided in it.
Date:	
Signature:	