

For the Attention of the Laboratory Director

URGENT – Field Safety Notice

Idylla™ EGFR Mutation Test Update of the Instructions for Use

Product Name	Idylla™ EGFR Mutation Test
Device Identifier	
REF	A0060/6
GTIN	05415219111150
Production Identifier (Lot. No.)	NA
Type of Action	Advice by manufacturer on the use of device

Dear Valued Customer,

Biocartis has initiated a Field Safety Corrective action related to the Idylla™ EGFR Mutation Test Instructions for Use based on market feedback.

Problem Description

The Idylla™ EGFR Mutation Test Instructions for Use (IFU) has been updated based on customer feedback and a request received from the Australian regulator - Therapeutic Goods Administration (TGA).

Since these IFU updates are intended to reduce a risk of potential misinterpretation of the product claims and eventually unintentional misuse of the product, Biocartis has decided to notify the customers of the IFU limitations section (Section 11) update through a Field Safety Corrective Action.

The amendments included in the IFU provide additional clarification on the use of the Idylla™ EGFR Mutation Test, and the impact of sample quality and/or quantity on the claimed limit of detection (LOD).

The following changes to the Idylla™ EGFR Mutation Test IFU have been implemented to clarify product limitations listed in "Section 11 – Limitations":

1) The limitation

"The Idylla™ EGFR Mutation Test is not to be used for diagnosis of NSCLC, or for monitoring purposes."
has been rephrased and replaced by:

"The Idylla™ EGFR Mutation Test is not to be used for diagnosis of NSCLC. The Idylla™ EGFR Mutation Test is to be used for patients at diagnosis and is not intended for use in a monitoring or progression setting".

2) A limitation has been added.

"No mutation detected" result does not rule out the presence of a mutation that may be present, but the presence is below the detection limits of the Test. In cases of sub-optimal quality and quantity (see Table 6 and Table 7) there is a possibility that mutations close to the LOD may be missed."

3) A limitation has been added to uniform the IFU content worldwide.

"Performance characteristics do not preclude false positive or false negative results. The patient's mutation status has to be considered by a physician, alongside other disease factors to make a therapy decision."

4) Minor clarifications and corrections have been made (typos corrected, standards updated and clarification of a COSMIC ID in Table 6).

Actions to be taken by the customer

- 1) Please read through the updated IFU and contact Biocartis if you have any questions. Electronic versions of the revised IFU are available for downloading on www.biocartis.com/ifu by using a keycode indicated on the product box and pouch label.
- 2) To confirm receipt and understanding of this Field Safety Notice, please complete and sign the attached 'Acknowledgement of Receipt' form in Appendix 1 and return it to Biocartis (via email hotline@biocartis.com) by 9 March 2020.
- 3) Please forward this information to all individuals and departments within your organization that have received or used this product. If you are not the end user, please forward this Field Safety Notice to the device end user. Please maintain the awareness of this Field Safety Notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

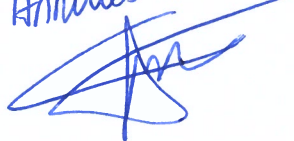
Actions taken by Biocartis NV

- 1) Biocartis has notified the relevant Regulatory Authorities of this Field Safety Corrective Action.
- 2) The Idylla™ EGFR Mutation Test IFU has been updated to reflect the changes described in this Field Safety Notice.

We apologize for any inconvenience this may cause and thank you in advance for your understanding and support.

If you need any further information or assistance concerning this notice, please contact the Biocartis hotline (Phone: +32 (0) 15 632 800 between 9h00 and 17h00 CEST; e-mail: hotline@biocartis.com) or your local Biocartis representative.

Yours sincerely,

*on behalf of
Annelies Laniers*


Marijke De Wit

Head of Quality
Biocartis NV

URGENT – Field Safety Notice: Idylla™ EGFR Mutation Test

<p>Appendix 1</p> <p>Acknowledgement of Receipt</p>
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Please complete this form and return it via email to: hotline@biocartis.com

I hereby confirm that:

- I have read and understood the Biocartis Field Safety Notice dated February 12, 2020, with reference BC-013089.
- I have read the updated Idylla™ EGFR Mutation Test Instructions for Use.

Laboratory name:	
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date: