Biocartis Field Safety Notice
Biocartis Reference: BC-023637
Date: May 27, 2024

For the Attention of the Laboratory Director

URGENT – Field Safety Notice

Idylla™ EGFR Mutation Test

Risk of False Positive Results for S768I mutation

Product Name	Idylla™ EGFR Mutation Test
Device Identifier **REF** **GTIN**	 A0060/6 15415219111157
Production Identifier (Lot. No.)	**N/A**
Type of Action	Advice by the manufacturer on interpretation of test results

Dear Valued Customer,

Biocartis has initiated a Field Safety Corrective Action, related to the Idylla™ EGFR Mutation Test, based upon a complaint received from the field and subsequent Incident reporting. Please read the following information and implement the recommended actions appropriately within your organization.

Problem Description

Biocartis has identified the potential for False Positive (FP) results to be generated for the S768I target when using the Idylla™ EGFR Mutation Test, when tests are conducted with low sample input.

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Potential Risk

In the event of a False Positive result for the S768I target, generated by the Idylla™ EGFR Mutation Test following low sample input, it is possible that incorrect patient management decisions may be made based upon this result. Biocartis has therefore decided to notify customers of the risk of FP results through a Field Safety Corrective Action (FSCA).

No other Biocartis Idylla™ IVD products are within the scope of this Field Safety Notice, nor are any other mutation targets tested for by this product; this failure mode is unique to the S768I target for the Idylla™ EGFR Mutation Test.

Notice to Customers

Customers are therefore advised of the following:

Caution must be taken in interpreting positive S768I results generated from the Idylla™ EGFR Mutation Test in the following circumstances:

- A positive result for the S768I mutation is generated, and
- The Cq value for the EGFR control is ≥21.9

Should an S768I mutation be identified with the Cq of the EGFR control be ≥21.9, we recommend retesting of the patient sample using higher sample input. Should a subsequent retest with the higher sample input provide a negative ("no mutation detected") result for the S768I target, this result can be considered as the final result.

The above information shall be incorporated into an update of the IFU, as follows:

- Cq of EGFR Control (Section 10.1.4) shall be updated, with the following caution being added:

"In case an S768I mutation is detected and the Cq of the EGFR control is ≥ 21.9, it is recommended to retest the patient sample using a higher sample input. For more information, see Section 11 Limitations."

- Limitations (Section 11) shall be updated, with the following additional limitation being listed:

"*There is potential for S768I calls to generate false positive results in the event of low sample input. Therefore, we recommend caution be taken in interpreting positive S768I results in the following circumstances:*

- *An S768I mutation is detected, irrespective of the presence of other EGFR mutations, and*
- *The Cq value for the EGFR control is ≥21.9.*

Should the above be identified, we recommend retesting the patient sample(s) using a higher sample input. Should a subsequent retest give a positive result for the S768I target meeting the above criteria, please contact your Biocartis representative for further support. However, should a subsequent retest with the higher sample input give a negative ("no mutation detected") result for the S768I target, this result can be considered as the final result."

Action to be taken by the customer

1) Please read the above warning, incorporating this into your testing procedures, and contact Biocartis if you have any questions.
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 to hotline@biocartis.com) by June 10th, 2024.
3) Please forward this information to all individuals and departments within your organization that have received or used, or continue to receive and use, this product. If you are not the end user, please forward this Field Safety Notice to the device end user. Please maintain awareness of this Field Safety Notice and its contents for an appropriate period to ensure the effectiveness of the Corrective Action.

Action taken by Biocartis

1) Biocartis has notified the relevant Regulatory Authorities of this Field Safety Corrective Action.
2) The Idylla™ EGFR Mutation Test IFU is currently being updated to reflect the additional limitation and caution detailed within this Field Safety Notice.

We sincerely 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 Biocartis Customer Support (email: hotline@biocartis.com) or your local Biocartis representative.

Yours faithfully,

Karlien Hermans
Head of Quality and Regulatory Affairs
Biocartis

BIOCARTIS

URGENT – Field Safety Notice: Idylla™ EGFR Mutation Test

Appendix 1

Acknowledgement of Receipt

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 May 27, 2024, with reference BC-023637.

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