Biocartis Field Safety Notice
Biocartis Reference: BC-011091
Date: August 20, 2018

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For Attention of the Laboratory Director

URGENT – Field Safety Notice

Idylla™ Instrument

Issue: Defective part built in the Idylla™ Instrument

Product Name	**Idylla™ Instrument**
Device Identifier	
REF	**P0010**
GTIN	**05415219000119**
Production Identifier (Serial No.)	**00001764, 00001767, 00001769, 00001770**
SW Version	**ISW/25.0 or ISW/26.0**
Type of Action	**Service intervention**

Dear Valued Customer,

Biocartis has identified an issue with the Idylla™ Instruments listed above (See production Identifier), which could introduce some risks when using these affected Idylla™ Instruments for diagnostic purposes.

Description of situation

During manufacturing of Idylla™ Instruments, a defective part has been introduced in a limited number of Idylla™ Instruments. The defective part concerns the Front-End Manifold (referred to as 'FEM') driver which is part of the fluid module of the Idylla™ Instrument.

An investigation was started immediately. We would like to inform you on the preliminary results:

- One specific lot of FEM drivers displayed a defect. This lot of defective parts was immediately put in quarantine.
- Suspected Idylla™ Instruments in the process of manufacturing and QC testing were immediately put in quarantine.
- Four Idylla™ Instruments, as listed above, were released to the market with the defective part built in the fluid module of the instruments.

Potential risk

When an Idylla™ Cartridge is introduced in an Idylla™ Instrument with the defective part, the Idylla™ Instrument can dock on the Idylla™ Cartridge. However, the defective FEM driver of the Idylla™ Instrument will have a suboptimal connection with the docked Idylla™ Cartridge.

This defect could have following effects:

- System errors or invalid results generated, hence no result obtained and sample loss;
- A dosing inaccuracy within the Idylla™ BRAF Mutation Test leading to potential false negative results.

Actions taken by Biocartis NV

1) All suspected Idylla™ Instruments were quarantined to prevent further distribution;

2) Our Customer Service department will reach out to you to organize the service intervention of affected Idylla™ Instrument(s).

Actions to be taken by the customer of an Idylla™ Instrument with serial number 00001764, 00001767, 00001769 or 00001770

1) Immediately **stop using the affected Idylla™ Instrument(s)** (listed above) for **diagnostic purposes**;

2) If a '**No mutation detected in BRAF codon 600**' result was obtained for diagnostic purposes with an affected Idylla™ Instrument, this **result should not be considered for patient management**. In addition, the concerned patient sample(s) require(s) **re-testing** on an Idylla™ Instrument not impacted by this issue.

3) **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 notice to the device end user.

   Please, maintain the awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

4) Due to regulatory reasons, **completion of the Acknowledgement of Receipt (Appendix 1) is required**. Please, complete and sign the attached Acknowledgement of Receipt form by August 27, 2018, and email to *customersupport@biocartis.com (CC: cheymans@biocartis.com) or fax to +32 (0)15 632 692.*

   The undersigned confirms that the appropriate Regulatory Agencies have been notified of this notice.

5) You can continue using all Idylla™ Cartridges, including Idylla™ BRAF IVD Mutation tests, with an Idylla™ Instrument which is not listed as impacted;

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 Mr. Chris Heymans (Phone: +32 (0) 475 694 684; e-mail: cheymans@biocartis.com) or your local Biocartis representative.

Yours sincerely,

P. O.

Chris Heymans

Head of Quality
Biocartis NV

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URGENT – Field Safety Notice: Idylla™ Instrument

Appendix 1

Acknowledgement of Receipt

Please complete this form and return it by email or fax by August 27, 2018:

email: customersupport@biocartis.com (CC: cheymans@biocartis.com)

Fax: +32 (0)15 632 692

I hereby confirm that I have received, read and understood the Urgent Field Safety Notice dated August 20, 2018. We have taken the necessary actions as suggested by this notice.

Laboratory name:	
Address:	
Contact name:	Title:
Email address:	Phone number:
Provide: Serial Number(s) of the affected Idylla™ instrument(s): _____	
Idylla™ BRAF IVD Mutation tests were run on an affected Idylla™ Instrument and generated a 'No mutation detected in BRAF codon 600' result? ☐ Yes / ☐ No	
'No mutation detected in BRAF codon 600' results generated with the affected Idylla™ Instrument were used for patient management: ☐ Yes / ☐ No	
Signature:	Date:

Table 1: contact details customer

If you have performed patient sample testing with Idylla™ BRAF IVD Mutation tests on an affected Idylla™ Instrument and obtained a 'No mutation detected in BRAF codon 600' result , please complete also the Appendix 2 form.

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Appendix 2
Confirmation of Results of Retesting

Please complete this form and return it by email or fax at your earliest convenience:

email: customersupport@biocartis.com (CC: cheymans@biocartis.com)

Fax: +32 (0)15 632 692

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

Table 2: contact details customer

Please complete Table 3 after retesting patient samples which obtained a 'No mutation detected in BRAF codon 600' result on an affected Idylla™ Instrument.

ID of cartridge* initially reporting 'No mutation detected in BRAF codon 600'	Date of retesting	Serial No. of Idylla™ Instrument used for retesting	ID of cartridge* used for retesting	Result of retesting

Table 3: Results of retesting

** Cartridge ID number can be found on the bottom of the cartridge.*