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To the attn. of the Laboratory Director

Address line 1

Address line 2

Address line 3

Address line 4

URGENT VOLUNTARY FIELD SAFETY NOTICE:
IDYLLA™ KRAS MUTATION TEST lots 2207 and 2208

Field safety corrective action

Mechelen, August 4, 2015

Dear Sir, dear Madam,

Affected products:

Biocartis informs you of the voluntary recall of Idylla™ KRAS Mutation Test cartridges produced in lots 2207 and 2208.

Product description	Lot reference	Manufacturing Date
Idylla™ KRAS Mutation Test CE-IVD	00002207	2015-06-24
	00002208	2015-06-26

Problem description:

The recall is a result of an investigation initiated after a false negative result was obtained during initial laboratory verification testing in a Belgian clinical laboratory. A "No mutation detected in KRAS codon 12, 13, 59, 61, 117, 146" result was reported on a reference material of Horizon, containing 5 % allelic frequency of G12A, using the Idylla™ KRAS Mutations Test. Investigational testing performed by Biocartis confirmed the increased risk of false negative results obtained for G12A and G12S mutations on reference samples containing 5 % allelic frequency using Idylla™ KRAS Mutation Test lots 2207 or 2208. The likelihood that such an increased false negative result is generated on G12S and G12A mutations at 5% allelic frequency on a clinical sample is assumed to be below 0.5%. Although Biocartis is not aware of any patient management case resulting in false negative results using the Idylla™ KRAS Mutation Test, Biocartis takes the quality of its products very seriously and has therefore, as a precautionary measure, decided to voluntarily recall both lots 2207 and 2208.

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Please note that if a KRAS mutation has been reported using Idylla™ KRAS Mutation Test cartridges of lots 2207 or 2208, this result should be considered as valid.

The increased occurrence of false negatives on G12A and G12S has been investigated. The raw data analysis of the tests does not indicate any issue related to the Idylla instrumentation or to the software. Within lot 2207 and 2208 cartridges a slight difference in their reproducibility performance characteristics is found.

Biocartis is working on a solution to provide customers with a reliable KRAS Mutation test on short notice. An improvement has been identified and will be further evaluated. Biocartis will inform you about the new delivery date of the Idylla™ KRAS Mutation Test.

Advise on action to be taken by the user:

- *Please forward this field safety notice to any health care professionals within your organization that needs to be aware of this notice and to any third party where the product may have been used. Please provide Biocartis with details of any product that have been distributed to any third party organizations.*
- *Identify and quarantine the unused cartridges as identified in this document.*
- *Re-test by an alternative validated method all samples used for patient management that reported a 'No mutation detected in KRAS codon 12, 13, 59, 61, 117, 146'.*
- *Please complete the attached Confirmation Form (Appendix 1) and either fax it back to Biocartis to the attention of Mr. Chris Heymans, Head of Quality on +32 (0)15 632 692 or email to customerservice@biocartis.com with a CC to cheymans@biocartis.com.*
- *Return all unused cartridges: Please contact Mr. Joris De Pauw in our Customer Service department who will arrange the pick-up and credit for your returned product. Contact details email customerservice@biocartis.com or by phone +32 (0) 15 632 888 (for this occasion exceptional open from 8 AM until 8 PM CET).*

We regret any inconvenience this action may have caused and would appreciate your understanding as we have taken this action in the interest of patient safety. Biocartis has informed your national competent authority about this field safety corrective action.

If you have any questions or need further assistance with this field safety notice please contact the following: customerservice@biocartis.com or by phone +32 (0) 15 632 888.

Yours Sincerely,

Chris Heymans
Head of Quality Biocartis

Appendix 1: Confirmation of Receipt of Field Safety Notice

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Appendix 1

Confirmation of Receipt of Field Safety Notice

Biocartis NV: URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED
Type of Action: Product Recall

Please complete this form and return a copy either by FAX or email to confirm that you have received this confirmation, once all information has been gained.
FAX +32 (0)15 632 692 or email to customerservice@biocartis.com

Customer Name and Address: (Please Print)	
Reply confirmation completed by: (Please Print Name)	
Title: (Please Print)	
Telephone Number:	
Email :	

We confirm:

1. We have read the Field Safety notice.
2. We have taken the requested actions as mentioned in the notification letter.

We have some of the affected stock: YES / NO
IF YES: We have the following unused product that requires to be returned:

Product	Lot Number:	Quantity (number of cartridges):