Biocartis Field Safety Notice
Biocartis Reference: BC-012798 Rev. 1
Date: September 11, 2019

For the Attention of the Laboratory Director

URGENT – Field Safety Notice

Idylla™ ctNRAS-BRAF Mutation Test
Issue: Incorrect expiry date on product label

Product Name	Idylla™ ctNRAS-BRAF Mutation Test
Device Identifier	
REF	A0090/6
GTIN	15415219000710
Production Identifier (Lot. No.)	00003867 00003939 00004216 00004270
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Biocartis has identified that the labeling of the above listed lots (see Production Identifier) of Idylla™ ctNRAS-BRAF Mutation Test cartridges contains an incorrect expiry date. Due to this labeling error, Biocartis has initiated a Field Safety Corrective Action to prevent further use of the impacted Idylla™ ctNRAS-BRAF Mutation Test cartridges.

Problem Description

After receiving a customer complaint for incorrect labeling, Biocartis has identified that four (4) lots of Idylla™ ctNRAS-BRAF Mutation Test cartridges have been labeled with an incorrect expiry date. The shelf life of the concerned product was erroneously set to twelve (12) months instead of to the currently claimed shelf life of nine (9) months. The impacted lots are listed in Table 1 below, together with the incorrect expiry dates (as marked on the product label) and the actual (correct) expiry dates.

Table 1: Overview expiry dates of impacted Idylla™ ctNRAS-BRAF Mutation Test cartridges

Lot. No.	Expiry date on label (incorrect)	Correct expiry date
00003867	2019-07-18	2019-04-14
00003939	2019-12-06	2019-09-02
00004216	2020-05-29	2020-02-24
00004270	2020-07-08	2020-04-04

Potential risk

Two of the affected lots (00003867, 00003939), which were distributed to the market, could potentially have been used beyond their claimed shelf life of nine (9) months (see Table 1).

Although the claimed shelf life of the Idylla™ ctNRAS-BRAF Mutation Test has not been extended to twelve (12) months, available stability data demonstrates that the product performance remains within acceptance criteria after twelve (12) months of storage. In addition, Biocartis has tested performance of the retained cartridges from the oldest impacted lot (00003867) after thirteen (13) months of storage. All tested cartridges provided a correct result (i.e. correct call). This indicates that there is no increased risk of generating incorrect results with the impacted Idylla™ ctNRAS-BRAF Mutation Test cartridges, when used between nine (9) and twelve (12) months of storage.

Actions to be taken by the customer

1) Please stop using **all** your remaining Idylla™ ctNRAS-BRAF Mutation Test cartridges from the lots listed in Table 1 and destroy them.
2) Please return the completed 'Acknowledgement of Receipt' form in Appendix 1 of this Field Safety Notice to Biocartis to confirm the destruction of the impacted Idylla™ ctNRAS-BRAF Mutation Test cartridges.
3) Results generated with impacted Idylla™ ctNRAS-BRAF Mutation Test cartridges, beyond the nine (9) months shelf life and before receipt of this Field Safety Notice, can be considered valid. There is no need to re-test patient samples due to this labeling error.

Actions taken by Biocartis NV

1) Biocartis has notified local Regulatory Authorities of this Field Safety Corrective Action.
2) The root cause of the event has been identified, and immediate actions have been taken to prevent that any remaining non-conforming product is distributed to the market. Implementation of corrective actions is ongoing to prevent recurrence of the event.
3) Biocartis will replace, free of charge, all Idylla™ ctNRAS-BRAF Mutation Test cartridges for which Biocartis receives confirmation of destruction through means of the completed Appendix 1 of this Field Safety Notice.

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Communication of this Field Safety Notice

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.

Completion of the 'Acknowledgement of Receipt' form

Due to regulatory reasons, completion of the 'Acknowledgement of Receipt' form (Appendix 1 of this Field Safety Notice) is required. Please complete and sign the attached 'Acknowledgement of Receipt' form by September 20, 2019 and email it to hotline@biocartis.com.

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 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,

[redacted]

Biocartis NV

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URGENT – Field Safety Notice: Idylla™ ctNRAS-BRAF Mutation Test

Appendix 1

Acknowledgement of Receipt

Please complete this form and return it by email to: hotline@biocartis.com

1) We hereby confirm that:

- We have read and understood the Biocartis Field Safety Notice dated September 11, 2019, with reference BC-012798.
- We have taken the requested actions as mentioned in such Field Safety Notice.
- We hereby confirm that we have destroyed all our available stock of Idylla™ ctNRAS-BRAF Mutation Test cartridges of the affected lots, as registered in Table 3, in accordance with local regulations and our internal laboratory procedures.

Organization Name and Address:	
Completed by Name and Title:	
Signature:	
Telephone:	
Email:	
Date response completed:	

Table 2: Contact details customer

2) Product information to complete if you received Idylla™ ctNRAS-BRAF Mutation Test cartridges of the affected lots 00003867, 00003939, 00004216, 00004270:

	Idylla™ ctNRAS-BRAF Mutation Test (REF# A0090/6)			
Lot number(s)	**00003867**	**00003939**	**00004216**	**00004270**
Quantity of cartridges received				
Quantity of cartridges used				
Quantity of cartridges not used and destroyed				

Table 3: Registration of used cartridges