



For Attention of: Laboratory Director

URGENT – Field Safety Notice

Potential incorrect results for Idylla™ MSI Test

Product Commercial Name	Idylla™ MSI Test
Model/Catalog Number (REF)	A0100/6
UDI-DI	15415219000550
Lot. No. / Serial No.	00006938
SW Version	N/A

Primary Clinical Purpose of Device

The Idylla™ MSI Test is intended to provide information on microsatellite instability for use by qualified health care professionals in accordance with professional guidelines, and is not directly conclusive or prescriptive for labeled use of any specific therapeutic product. The Idylla™ MSI Test should not be used for diagnosis of colorectal cancer.

Dear Valued Customer,

Biocartis has identified an increased risk for incorrect results associated with specific cartridges from Idylla™ MSI Test Lot 00006938. Our records indicate that your institution may be in possession of one or more affected cartridges.

Please read the following information carefully and execute the appropriate recommended actions within your institution. Please also complete and return the Acknowledgement of Receipt included in Appendix 1 of this Field Safety Notice by 18Jun2026 and send it to vigilance@biocartis.com.

Problem description

Following the investigation of a complaint concerning an increased frequency of inaccurate MSI results, Biocartis identified a manufacturing deviation affecting 46 cartridges from lot 00006938. Only the cartridge serial numbers (IDs) listed in Table 1 and Tabel 2 are affected by this issue. All other cartridges from lot 00006938, which are not included in Table 1 or Table 2, are not impacted by this deviation and can be safely used for testing.

Table 1: IDs of affected cartridges – not yet identified at customers

69380604	69380611
69380605	69380612
69380606	69380613
69380607	69380614
69380608	69380615
69380609	
69380610	

Table 2: ID of affected cartridges – yet identified at customers.

69380600	69380627	69380634	69380641	69380649
69380601	69380628	69380635	69380642	69380650
69380602	69380629	69380636	69380644	69380651
69380603	69380630	69380637	69380645	69380652
69380624	69380631	69380638	69380646	69380653
69380625	69380632	69380639	69380647	69380654
69380626	69380633	69380640	69380648	

Impact

The manufacturing deviation may affect the scores of the Idylla™ MSI biomarkers used to generate the final cartridge call. Depending on the true status of the 7 Idylla™ MSI markers in the sample tested, this may result in either a false-positive MSI-H or a false-negative MSS cartridge result.

Actions to be taken by the customer

Please identify whether you are in possession of any Idylla™ MSI cartridge(s) listed in Table 1 or Table 2 in your inventory or processed on your Idylla™ System. Follow the applicable instructions below and complete Appendix 1. Note that the Cartridge ID is located on the pouch label.

If you are **not** in possession of any affected cartridge(s):

Complete and return the Acknowledgement of Receipt form (Appendix 1) to vigilance@biocartis.com by 18Jun2026, confirming that no affected cartridges are in your possession.

If you **are** in possession of one or more affected cartridges from Table 1 or Table 2:

Cartridge not yet processed: Discard the cartridge(s) immediately. Do not use.

Cartridge already processed: Retest using a cartridge not listed in Table 1 or Table 2.

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In all cases, complete and sign the Acknowledgement of Receipt form (Appendix 1) to confirm the performed actions and return it to vigilance@biocartis.com by 18Jun2026.

Action taken by Biocartis

- Biocartis has informed the relevant Regulatory Authorities about this Field Safety Notice.
- Biocartis is investigating the root cause and assessing appropriate steps to prevent reoccurrence of the issue.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

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

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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 idyllasupport@biocartis.com or your local Biocartis representative (Key Account Manager or Molecular Diagnostic Specialist).

Yours sincerely,

Steve Chatters
VP, Regulatory & Clinical Affairs & Quality Assurance

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Appendix 1
Acknowledgement of Receipt

Please complete this form and return it to vigilance@biocartis.com

<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.		
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	I do not have any affected devices as per Table 1.		
<input type="checkbox"/>	I have affected, unused, devices and destroyed these.	Qty:	Cartridge IDs:
		Date (DD/MM/YY):	
	Optional Comment:		
<input type="checkbox"/>	Cartridges were already used, and I retested with another cartridge and includes the results (MSS vs MSI-H) obtained with affected and new cartridge.	Cartridge IDs:	Results:
<input type="checkbox"/>	Results generated with the affected device(s) were used for patient management.	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Laboratory name:			
Address:			
Contact name:		Title:	
Email address:		Phone number:	
Signature:		Date:	

It is important that your organisation takes the actions detailed in the FSN and confirms you have received the FSN.

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Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.