Biocartis Field Safety Notice
Biocartis Reference: BC-024217
Date: 09Dec2024

For the Attention of the Laboratory Director

URGENT – Field Safety Notice

Idylla™ Instruments with a potential of false-positive results for Idylla™ MSI Test

Product Name	Idylla™ Instrument
Device Identifier:	
REF	P0010
UDI-DI	05415219000119
Production Identifier (Lot. No., Ser. No.))	**See Appendix 1 and 2**
Type of Action	Field Safety Corrective Action

Dear Customer,

Biocartis has initiated a Field Safety Corrective Action, related to the Idylla™ Instrument. This is based upon review of Idylla™ MSI Test performance in the field following customer feedback regarding false-positive MSI-H results. Please read the following information carefully and implement the appropriate recommended actions within your institution. Please also complete and return the Acknowledgement of Receipt included in Appendix 3 of this Field Safety Notice by 16Dec2024 and send it to vigilance@biocartis.com .

Problem Description

As an investigation outcome of customer feedback, Biocartis identified that false-positive MSI-H test results could be, or could have been, generated by the Idylla™ MSI Test at your laboratory for the Idylla™ Instruments listed in Appendix 1 and 2. The root cause identified for the potential false-positive MSI-H result(s) is a combination of an Instrument with higher than expected fluorescence signal intensity readout and high temperature and humidity levels at the location where the Idylla™ Instrument is installed.

Impact

In rare cases, the performance of the Idylla™ MSI Test may be impacted for the Idylla™ Instrument(s) listed in Appendixes 1 and 2. Running the Idylla™ MSI Test on an impacted Idylla™ Instrument in elevated temperature or humidity conditions could lead to "MSI-H" (Microsatellite Instability-High) status being reported for samples that are actually "MSS" (Microsatellite Stable).

It is important to note that this issue does not impact reported MSS results, nor MSI-H results with six or seven positive identified biomarkers (as depicted on the result report), which remain reliable and accurate.

Following a thorough analysis of the impact of this issue on the other assays performed on Idylla™, Biocartis has determined that there is no significant change in patient risk associated with any other Idylla™ Test.

Actions taken by Biocartis

1. Local Regulatory Authorities have been informed of this notice.
2. A service intervention for the Instrument(s) listed in Appendix 1 will be performed.
3. Following an assessment of Idylla™ MSI Test run data for Appendix 2 Instrument(s), a service intervention may be performed.
4. A Biocartis representative will contact you and provide details on when and how the (potential) service intervention will be performed.

Actions to be taken by the customer

1. Until your Instrument, listed in **Appendix 1,** is serviced, please move forward with the option that applies to your situation:

   - In case you have another Instrument available that is not listed in Appendix 1 or 2, use that Instrument to run the Idylla™ MSI Test and discontinue running the Idylla™ MSI Test on the listed Instrument(s).

   - In case you do not have another Instrument available and your Idylla™ Instrumentation is connected to Idylla™ Explore, you can continue running Idylla™ MSI Test on the listed Instrument(s). A dedicated Biocartis support team will monitor your test results to identify potential false-positive MSI-H results. In case a potential false-positive is detected, Biocartis will notify you within 3 business days of the test being performed; therefore, MSI-H test results should not be reported or relied on before this time period.

   - In case you do not have another Instrument available and your Idylla™ Instrumentation is not connected to Idylla™ Explore, you can continue running Idylla™ MSI Test on the listed Instrument(s). Please download the Assay Log files from any MSI-H test result(s) with five or fewer positive biomarkers from the Console and send them to Idyllasupport@biocartis.com.

     Information on how to download assay log files can be found in the Idylla™ Operator Manual or contact Idyllasupport@biocartis.com. A dedicated Biocartis support team is in place to assess whether potential false-positive MSI-H test results have been obtained. A reply with the outcome of the assessment will be sent within 3 business days. The MSI-H test results should not be reported or relied on before this reply. MSI-H results which identify six or seven

positive biomarkers in the result report remain reliable and accurate and can be reported or relied upon.

2. To assess whether your instrument listed in **Appendix 2** needs a service intervention, MSI data will have to be generated or retrieved from your instrument.
   - If your Instrumentation is connected to Idylla™ Explore, a dedicated Biocartis support team will monitor your test results and will contact you if a service intervention is needed or not once sufficient data are generated. In the meantime, in case a potential false-positive is detected, Biocartis will notify you within 3 business days of the test being performed; therefore MSI-H test results should not be reported or relied on before this time period.
   - If your Instrumentation is not connected to Idylla™ Explore, you are kindly requested to download assay log files from the last 15 valid MSI runs from your Console and send them to Idyllasupport@biocartis.com. Information on how to download assay log files can be found in the Idylla™ Operator Manual or contact Idyllasupport@biocartis.com. Based on these runs, it will be possible to define the next actions for your Instrument(s). You will be notified within 3 business days after the assay log files have been received, what the additional actions may entail. MSI-H test results should not be reported or relied on before this reply.
3. If you are not the Idylla™ user, please forward this notice to the Idylla™ end user or Idylla™ supervisor and provide Biocartis with the correct contact details for our record keeping.
4. Completion of the Acknowledgement of Receipt (Appendix 3) is required for compliance. Please complete and sign the attached Acknowledgement of Receipt form by 16Dec2024 and send it to vigilance@biocartis.com or your local Biocartis representative.

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 (email: Idyllasupport@biocartis.com) or your local Biocartis representative.

Thank you for your prompt attention to this matter.

Yours sincerely,

W. Michael Korn, M.D.
Chief Medical and Scientific Officer

BIOCARTIS

Appendix 1

List of impacted Idylla™ Instruments

Table 1 lists all impacted Idylla™ Instruments within the scope of this Field Safety Notice.

Table 1: List of impacted Idylla™ Instruments							
00000673	00002264	00002736	00002993	00003208	00003284	00003369	00003448
00000716	00002265	00002750	00002997	00003210	00003285	00003370	00003450
00000734	00002270	00002751	00003005	00003211	00003290	00003371	00003451
00000765	00002277	00002756	00003007	00003212	00003291	00003372	00003452
00000853	00002278	00002759	00003009	00003213	00003292	00003373	00003454
00000871	00002285	00002760	00003014	00003214	00003293	00003374	00003455
00000903	00002290	00002762	00003018	00003218	00003294	00003380	00003459
00001000	00002302	00002763	00003025	00003219	00003296	00003381	00003460
00001027	00002310	00002773	00003041	00003222	00003297	00003382	00003461
00001129	00002331	00002779	00003042	00003223	00003298	00003383	00003462
00001170	00002335	00002780	00003061	00003224	00003299	00003384	00003463
00001241	00002336	00002788	00003062	00003225	00003300	00003385	00003464
00001307	00002341	00002789	00003069	00003229	00003301	00003386	00003465
00001325	00002347	00002791	00003078	00003230	00003302	00003387	00003468
00001468	00002353	00002797	00003079	00003231	00003305	00003388	00003470
00001492	00002358	00002801	00003084	00003232	00003307	00003389	00003471
00001528	00002359	00002802	00003086	00003233	00003308	00003390	00003472
00001582	00002361	00002810	00003088	00003236	00003310	00003393	00003473
00001592	00002364	00002812	00003098	00003237	00003311	00003394	00003475
00001594	00002381	00002813	00003100	00003239	00003312	00003395	00003476
00001601	00002382	00002814	00003108	00003240	00003313	00003396	00003477
00001604	00002387	00002822	00003116	00003241	00003314	00003397	00003480
00001608	00002389	00002837	00003131	00003242	00003315	00003399	00003481
00001644	00002392	00002841	00003146	00003243	00003316	00003400	00003484
00001666	00002396	00002854	00003148	00003244	00003317	00003401	00003485
00001670	00002397	00002866	00003156	00003245	00003319	00003402	00003487
00001676	00002400	00002867	00003157	00003246	00003321	00003404	00003488
00001677	00002411	00002868	00003158	00003247	00003322	00003405	00003489
00001714	00002437	00002892	00003163	00003249	00003323	00003406	00003493
00001776	00002462	00002896	00003164	00003251	00003324	00003407	00003495
00001847	00002470	00002898	00003166	00003257	00003326	00003408	00003496
00001850	00002501	00002899	00003167	00003258	00003328	00003409	00003499

Table 1: List of impacted Idylla™ Instruments							
00001873	00002505	00002923	00003168	00003259	00003329	00003410	00003500
00001934	00002510	00002932	00003170	00003260	00003330	00003411	00003501
00002091	00002570	00002934	00003172	00003263	00003334	00003412	00003502
00002121	00002669	00002937	00003173	00003267	00003335	00003413	00003503
00002149	00002704	00002940	00003174	00003270	00003337	00003414	00003506
00002189	00002705	00002944	00003177	00003272	00003339	00003416	00003507
00002207	00002714	00002952	00003178	00003273	00003340	00003417	00003509
00002218	00002717	00002954	00003181	00003274	00003341	00003418	00003510
00002243	00002718	00002967	00003182	00003276	00003365	00003420	00003511
00002248	00002724	00002985	00003190	00003278	00003366	00003421	00003516
00002249	00002726	00002986	00003201	00003279	00003367	00003422	
00002254	00002728	00002989	00003204	00003280	00003368	00003446	

Appendix 2

List of potentially impacted Idylla™ Instruments

Table 2 lists all Idylla™ Instruments within the scope of this Field Safety Notice that are potentially impacted. With data of previously or additionally generated MSI runs, Biocartis will be able to assess whether the Instrument needs a service intervention.

Table 2: List of potentially impacted Idylla™ Instruments

00000520	00000959	00001131	00001304	00001364	00002062	00002663	00003543
00000578	00000979	00001133	00001310	00001365	00002083	00002664	00003546
00000668	00000981	00001138	00001312	00001369	00002084	00002700	00003547
00000691	00000984	00001139	00001315	00001403	00002103	00002713	00003548
00000710	00000990	00001144	00001326	00001491	00002109	00002732	00003549
00000717	00000991	00001146	00001329	00001545	00002223	00002761	00003551
00000742	00001023	00001150	00001335	00001622	00002250	00002882	00003556
00000743	00001025	00001157	00001345	00001648	00002272	00002936	00003557
00000763	00001045	00001166	00001347	00001649	00002274	00002956	00003558
00000764	00001060	00001202	00001349	00001689	00002289	00002974	00003591
00000827	00001075	00001240	00001350	00001722	00002405	00002976	00003592
00000832	00001079	00001264	00001351	00001753	00002409	00003022	
00000843	00001094	00001297	00001352	00001827	00002454	00003040	
00000863	00001114	00001299	00001353	00001856	00002480	00003159	
00000915	00001116	00001302	00001355	00001869	00002497	00003238	
00000928	00001117	00001303	00001356	00001940	00002561	00003513	

Appendix 3

Acknowledgement of Receipt

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

I hereby confirm that:

- I have read, understood and implemented actions requested in thisBiocartis Field Safety Notice dated 09Dec2024.

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