

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 dyllasupport@biocartis.com.

Information on how to download assay log files can be found in the Idylla™ Operator Manual or contact dyllasupport@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

Appendix 1

List of impacted Idylla™ Instruments

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

| | | | | | | | |
|----------|----------|----------|----------|----------|----------|----------|----------|
| 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 |

| | | | | | | | |
|----------|----------|----------|----------|----------|----------|----------|----------|
| 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 this Biocartis Field Safety Notice dated 09Dec2024.

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