
Advisory notice**GenomEra® GSB Assay Kit**

Date: 02-12-2021
Attention: Customers

Details on affected devices:
GenomEra® GSB Assay Kit, lot 16025

Description of the problem:

Dear Customer,

We have become aware that the number of borderline results has increased with the GenomEra® GSB Assay Kit, lot 16025. To investigate the issue the final release test of the kit lot was thoroughly evaluated. The kit lot fulfills the acceptance criteria, but an increase in Europium background signal can be detected when compared to the previous kit lots. The kit lot -specific cut-off determination takes the background signal into account but based on the investigation the correction has not been sufficient. Thereby, based on the assessment of all the data available, Abacus Diagnostica Oy has decided to re-adjust the kit lot -specific cut-off value to reduce the number of borderline results.

According to the instruction for use, in case the borderline results the assay should be repeated by preparing a new sample. Thereby, due to the increased number of borderline results, the number of repeated tests, and thereby the risk of delayed result has increased.

Abacus Diagnostica Oy is not aware of any report of injury attributed to this defect. The investigation for the root cause of the increased number of borderline results is still on-going.

Advise on action to be taken by the user:

- Please do not use the GenomEra® GSB Assay Kit, lot 16025, with the original kit lot -specific cut-offs due to increased risk of borderline results
- Please download the new lot code with re-adjusted cut-off values before continuing the use of GenomEra® GSB Assay Kit, lot 16025, see attached
- Please confirm the downloading of the re-adjusted cut-offs by replying to e-mail vigilance@abacusdiagnostica.com

Contact reference person:

Elina Tuomola
Quality and Regulatory Director



Signature


Attachment: updated kit lot –specific labels with updated kit lot -specific cut-offs.

GenomEra® GBS Assay Kit

For the qualitative detection of Group B *streptococcus* (GBS)

REF CDX-60-01-40


LOT 16025

 2023-01-31

IVD

 40 tests



2 °C  8 °C 

CE



*M591CDX6001409538403235131160250



Abacus Diagnostica Oy
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Turku, Finland

PLEASE DOWNLOAD LOT-CODES
before using tests of the current Lot for the first time.

READ THIS FIRST (do not press Enter or Ok)



416025150400400244904712180149012080

READ THIS SECOND



02372003160479503842160274016979



SN