ABACUS Diagnostica

FSN Ref: 004

Date: 28/11/2022

Urgent Field Safety Notice

GenomEra® GBS Assay Kit

For Attention of: Distributors and end users of the GenomEra® GBS Assay Kit

1. GenomEra® GBS Assay Kit
The GenomEra® GBS assay, performed on the GenomEra CDX system, is a qualitative *in vitro* diagnostic (IVD) nucleic acid test for the detection of group B Streptococcus (*Streptococcus agalactiae*, GBS) from: (i) Vaginal-rectal swab samples collected into Copan ESwab® transport medium from pregnant intrapartum or antepartum women.; and from: (ii) Enrichment broth cultures from vaginal-rectal swab samples collected from antepartum women. Cultures are performed by incubating the swab samples preferably for 4 h or 18–24 h, or until growth is detected, in selective enrichment broth medium.
1.1. Primary clinical purpose of device(s)
GenomEra GBS assay testing is indicated for rapid identification of antepartum and intrapartum GBS colonization. Intrapartum GenomEra GBS results are useful in identifying candidates for intrapartum antibiotic prophylaxis when administration of intravenous antibiotics is not delayed pending results.
1.2. Device Catalogue number(s)
CDX-60-01-20 and CDX-60-01-40
1.3. Affected serial or lot number range
Based on the investigation, the issue does not directly relate to any particular GenomEra GBS Assay Kit lots, but rather to the Copan ESwab Collection Kit, Catalogue number No. 480CE, hereafter referred as ESwab 480CE, to be used with the kit.

2. Reason for Field Safety Corrective Action (FSCA)
2.1. Description of the product problem
Abacus Diagnostica Oy has received a customer complaint concerning increasing number of borderline results with GenomEra GBS Assay Kit lots 16025 and 16026. Based on the investigation, the root cause of the increased number of borderline results is incompatibility of the GenomEra GBS Assay Kit with certain ESwab 480CE lots, including at least the following lot numbers: 220835800, 220895600 212737400. The effect also applies to GenomEra GBS Assay Kit lots16028, 16029, and 16030. Please be informed that based on the investigation the issue is not limited to ESwab catalogue number 480CE, but the ESwab Liquid Amies Medium in general. Please be informed that the issue is only related to vaginal-rectal swab samples from pregnant intrapartum or antepartum women collected directly into ESwab 480CE transport medium. This issue does not concern the enrichment broth cultures from vaginal-rectal swab samples collected from antepartum women.

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Please also be informed that this issue is limited to the use of ESwab together with the GenomEra GBS Assay Kit and does not indicate any particular defect in the ESwab 480CE itself.

2.2. Hazard giving rise to the FSCA

Hazard to patient: Borderline or delayed result may lead to delayed patient treatment.

2.3. Probability of problem arising

No incidents or false negative results have been reported but based on the customer complaint received, the number of borderline results is increasing above the level described in the instructions for use.

3. Type of Action to mitigate the risk

3.1. Action To Be Taken by the User

☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☒ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Based on the investigations performed and assessment of all the data available, Abacus Diagnostica Oy has decided to perform a corrective action by updating the kit lot specific cut-off calculation procedure to reduce the number of borderline results.

Due to the updated kit lot specific cut-off calculation procedure, the kit lot-specific values for the following GenomEra® GBS Assay Kit lots have been re-adjusted and shall be updated to the GenomEra software: 16025, 16026, 16028, 16029 and 16030.

Advise on action to be taken by the user:

- Please download the new lot code with re-adjusted cut-off values before continuing the use of GenomEra® GBS Assay Kit, lots 16025, 16026, 16028, 26029, 16030, see the rework instructions in 2022-11-28_FSN_004_End User Reply Form
- Please check your stock of the GenomEra® GBS Assay Kits and perform the rework as instructed in 2022-11-28_FSN_004_End User Reply Form
- Please confirm the downloading of the re-adjusted cut-offs by filling up and returning the form 2022-11-28_FSN_004_End User Reply Form.

Based on the investigations performed by the manufacturer, the borderline results related to this specific issue are negative. The sensitivity of the assay is not affected and hence the positive cases should be correctly detected.

3.2. By when should the action be completed?	Before continuing the use of the GenomEra® GBS Assay Kit lots 16025, 16026, 16028, 16029 and 16030.

3.3. Particular considerations for: IVD
Is follow-up of patients or review of patients' previous results recommended?

No, manufacturer is not aware of any incorrect results. Borderline results must be retested and hence the result may be delayed, or result is not obtained before parturition.

3.4. Is customer Reply Required?	Yes

3.5. Action Being Taken by the Manufacturer

☐ Product Removal ☒ On-site device modification/inspection
☐ Software upgrade ☒ IFU or labelling change
☐ Other ☐ None

Manufacturer has been investigating the issue in close collaboration with the manufacturer of the ESwab 480CE (Copan, Italy). Based on the investigations performed, the issue does not relate to PCR-reaction, but rather to a specific fluorescence signal measurement. The root cause for the signal decrease has been identified and confirmed before performing Field Safety Corrective Action.

The field safety corrective action taken is to update the kit lot-specific cut-off calculation procedure and re-adjust the cut-off values of GenomEra® GBS Assay Kit lots 16025, 16026, 16028, 26029 and 16030 to reduce the number of borderline results.

The updated cut-off calculation is used by the manufacturer starting from GenomEra® GBS Assay Kit lot 16031.

3.6. By when should the action be completed?	Action has been completed.

4. General Information	
4.1. FSN Type	Update
4.2. Further advice or information already expected in follow-up FSN? *	No, the FSCA is completed.
4.3. Manufacturer information	
Company Name	Abacus Diagnostica Oy
Address	Tykistökatu 4 D, FI-20520 Turku, Finland
4.4. The Competent (Regulatory) Authority of the country in which the device has been used has been informed about this communication to customers by Abacus Diagnostica Oy.	
4.5. List of attachments/appendices:	2022-11-28_FSN_004_End User Reply Form, 2022-11-28_FSN_004_Distributor Reply Form
4.6. Name/Signature	Elina Tuomola, Quality and Regulatory Director
	

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. 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.

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Please accept our sincere apology for all the inconvenience this unfortunate situation brings to you.

If you have any questions or concerns, please do let us know.

Contact reference person:
Elina Tuomola
Quality and Regulatory Director

Mobile: +358 40 3549732
vigilance@uniogen.com

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[redacted]

End User Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	004
FSN Date*	28/11/2022
Product/ Device name*	GenomEra® GBS Assay Kit
Product Code(s)	CDX-60-01-20 and CDX-60-01-40
Batch/Serial Number (s)	16025, 16026, 16028, 26029, 16030

2. End User Details	
Laboratory/Health Care Unit Name*	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email to your local distributor	
Deadline for returning the End User reply form*	2/12/2022

4. End User	
☐	*I confirm the receipt, the reading, and understanding of the Field Safety Notice
☐	*I have downloaded the re-adjusted GenomEra® GBS Assay Kit lot codes to the GenomEra software according to the rework instructions provided
☐	*I have checked my stock of the GenomEra® GBS Assay Kits and, using a marker, drawn over the barcodes on the Assay Kit labels according to the rework instructions provided
Print Name*	End User name here:
Signature*	End User sign Here:
Date *	

Mandatory fields are marked with *

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[redacted]

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

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

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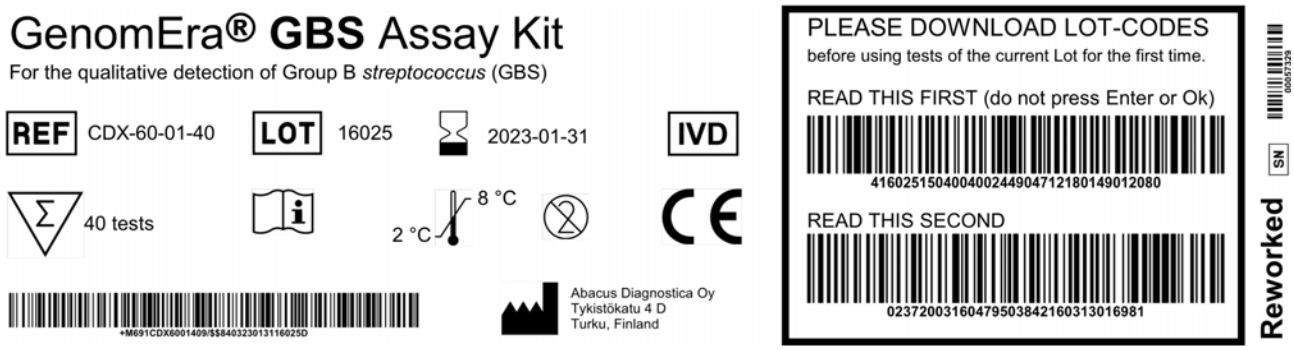
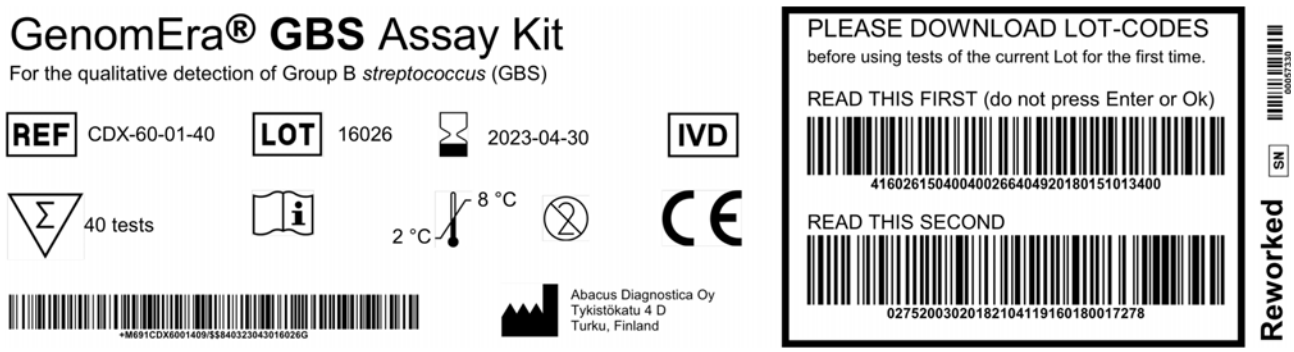
REWORK INSTRUCTIONS

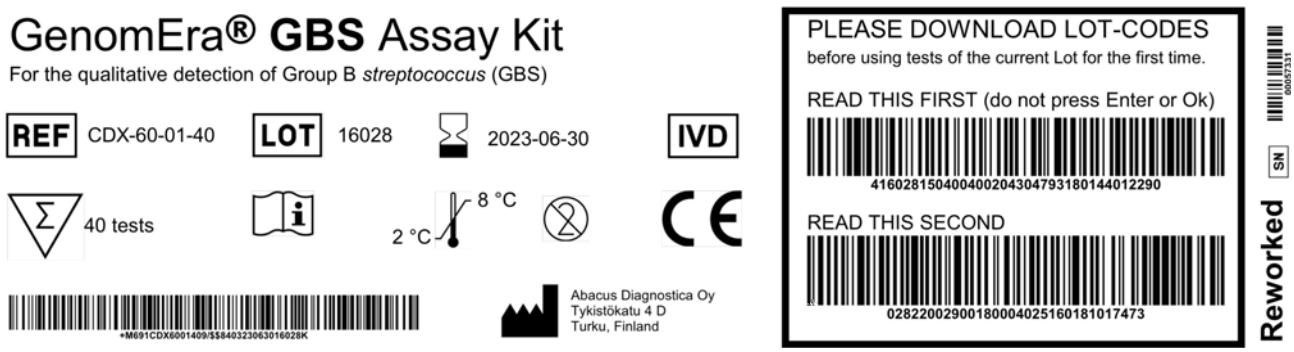
Updating the kit lot specific cut-off values:

Download the updated GenomEra® GBS lot information into the GenomEra® software by reading the new lot codes provided below.

1. Click the ‘Lot parameters’ button in the ‘Main menu’ tab.
2. Use the hand-held barcode reader to download the new lot code into the text box.
3. Do this individually for **all five** lot codes provided







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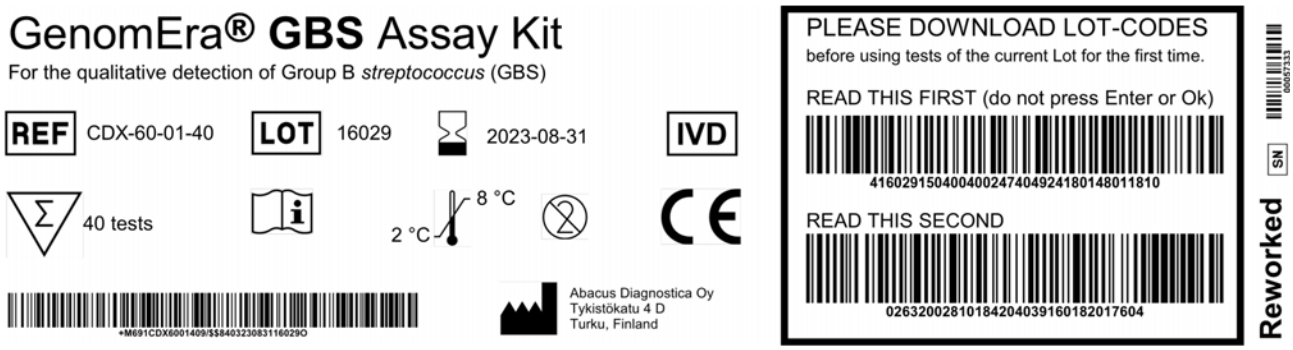

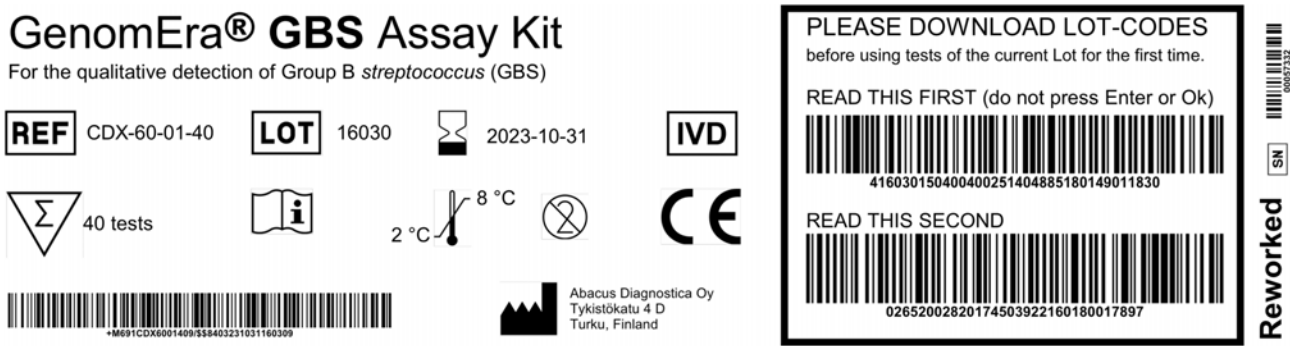

Rework for kits in stock:

Check your stock of the GenomEra® GBS Assay Kits. To prevent accidental reloading of the old lot codes, make the lot code on every GBS Assay Kit label unreadable by drawing over it with a thick black marker as shown in the picture below.

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Further measures:

Henceforth, the GenomEra® GBS kits delivered to End Users will have the updated lot code information in the Assay Kit label.

- The updated labels of the affected kit lots (16025, 16026, 16028, 16029, and 16030) can be recognized from the '**Reworked**' note on the label.
- The updated cut-off calculation is used by the manufacturer starting from GenomEra® GBS Assay Kit lot 16031.

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