FSN Ref: 005

Date 22-02-2023:

# Urgent Field Safety Notice

# GenomEra® CDX System

**For Attention of:** Distributors and end users of the GenomEra® CDX System CDX-10-020

| **1. GenomEra® CDX System** |
|---|
| GenomEra CDX is a molecular diagnostics analyzer consisting of an integrated thermal cycler and a fluorometer capable of time-resolved and prompt measurement. The Instrument is used to run analyte specific, ready-to-use GenomEra® Test Chips that have been developed for the detection of specific DNA or RNA in different direct clinical or cultured sample matrices. The Instrument is operated via the GenomEra CDX Software.<br>GenomEra CDX System consists of the GenomEra CDX molecular diagnostics analyzer and the GenomEra CDX Software. |
| 1.1. Primary clinical purpose of device(s) |
| The GenomEra CDX System does not have a clinical purpose. Clinical purpose depends on the GenomEra Assay Kit used in the closed system in which only the GenomEra Assay Kits can be run. |
| 1.2. Device Catalogue number(s) |
| CDX-10, CDX-10-020 |
| 1.3. Affected serial or lot number range |
| GenomEra CDX molecular diagnostics analysers with serial numbers:<br>20110028, 20120036, 20120038, 20120063, 20120064, 20130076, 20200151, 20200156, 20200161, 20200164, 20200178, 20200192 |

| **2. Reason for Field Safety Corrective Action (FSCA)** |
|---|
| 2.1. Description of the product problem |
| The parameter set for the Terbium/Europium leakage has been erroneously set as zero during the service performed by the manufacturer after July 2020. As a consequence, the leaked Terbium signal detected in the Europium channel is not corrected appropriately. The leaked signal may be falsely interpreted as amplification in Eu channel which may impact the result reported for the analyte labelled with Eu.<br>*(Note: Abacus Diagnostica merged into Uniogen Oy December 31, 2022).* |

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2.2. Hazard giving rise to the FSCA

Uniogen noticed this error in the specified devices during internal check when designing the next user interface software. The possible impact was analysed and is summarized for each assay kit in the table below.

Hypothetical impact on result interpretation:

| **GenomEra Assay Kit** | **Catalogue number** | **Impact on result** |
|---|---|---|
| GenomEra MRSA/SA AC Assay Kit | CDX-30-05-20, CDX-30-05-40 | False MRSA-positive result |
| GenomEra MRSA/SA Multi Swab Assay Kit | CDX-30-02-20 | False MRSA-positive result |
| GenomEra *C. difficile* Assay Kit | CDX-40-01-20, CDX-40-01-40 | No impact |
| GenomEra GBS Assay Kit | CDX-60-01-20, CDX-60-01-40 | No impact |
| GenomEra *S. pneumoniae* Assay Kit | CDX-70-01-20, CDX-70-01-40 | No impact |
| GenomEra Norovirus Assay Kit | CDX-100-01-20, CDX-100-01-40 | False positive GI when GII is positive (double positive result) |
| GenomEra Flu A/B + RSV Assay Kit (Note: production is discontinued but the product may have been used during the affected time period) | CDX-110-01-20, CDX-110-01-40 | False positive Flu B when Flu A is positive (double positive result) |
| GenomEra SARS-CoV-2 Assay Kit | CDX-130-01-20, CDX-130-01-20, CDX-130-01-20 | No impact |
| GenomEra SARS-CoV-2, Flu A/B + RSV Assay Kit | CDX-140-01-20, CDX-140-01-40, CDX-140-01-100 | False positive Flu B when SARS-CoV-2 is positive (double positive result) |
| GenomEra SARS-CoV-2 2.0 Assay Kit | CDX-150-01-20, CDX-150-01-40 | No impact |
| GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit | CDX-160-01-20, CDX-160-01-40 | False positive Flu B when SARS-CoV-2 is positive (double positive result) |
| GenomEra HSV 1/2, VZV + EV Assay Kit | CDX-170-01-20, CDX-170-01-40 | False positive HSV-2 when HSV-1 is positive (double positive result) |

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To conclude, the issue does not cause false negative results, but may cause false positive results with some of the GenomEra Assay Kits.

These specified analyzers with the wrong *LeakageTbEu* parameter value have been on the market since 2020/2021 and no complaints of false positive results related to these analyzers have been reported to the manufacturer.

Based on the risk analysis, in any situation caused by this problem, treatment of patients will not be missed, and treatment will not be directed in the wrong direction, nor is there a risk of harmful wrong treatment. See section 2.3.

This is not classified as a possible serious incident according to Regulation (EU) 2017/746. The need for a Field Safety Notice (FSN) and Field Safety Corrective Action (FSCA) is obvious.

2.3. Probability of problem arising

Probability of a false positive result and potential harm to patients:

| **GenomEra Assay Kit** | **Probability** | **Impact on patients** |
|---|---|---|
| GenomEra MRSA/SA AC Assay Kit | Unlikely | Insignificant. Based on review of previous data acquired from *mec*-positive blood culture samples, it is highly unlikely that the Eu result value would falsely exceed the cut-off level even without the Eu signal correction. |
| GenomEra MRSA/SA Multi Swab Assay Kit | Possible | When *mecA*-target is amplified and the signal leak is not corrected, a false positive SA result can be obtained. Thus, the result is interpreted as MRSA positive, i.e., the result is a false positive. However, false positives are a possible phenomenon with the assay even with corrected Eu signal which is stated in the IFU. Moreover, IFU accentuates that the assay kit should not be used alone to diagnose MRSA due to the above-mentioned contingency. Confirmatory tests are always needed. |
| GenomEra Norovirus Assay Kit | Possible | When GII is positive, GI can be falsely reported as positive/borderline.<br>Treatment / isolation procedures are the same in case of GI and GII noroviruses. Thus, double positive result should not lead to any unnecessary treatment / isolation of the patient. |

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| | | |
|---|---|---|
| GenomEra Flu A/B + RSV Assay Kit<br>*(Note: production is discontinued but assay kit may have been used during the affected time period)* | Possible | When Flu A is positive, Flu B can be falsely reported as positive/borderline.<br>Treatment / isolation procedures are the same in case of Flu A and Flu B. Thus, double positive result should not lead to any unnecessary treatment / isolation of the patient. |
| GenomEra SARS-CoV-2, Flu A/B + RSV Assay Kit | Possible | When SARS-CoV-2 is positive, Flu B can be falsely reported as positive/borderline.<br>Treatment is typically symptom based for both viruses (SARS-CoV-2 and Flu B). However, in case of false positive Flu B (double positive), the patient may be treated unnecessarily with oseltamivir (a drug for influenzas), but it is well tolerated, and should not cause any side effects for the patient. |
| GenomEra SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit | Possible | When SARS-CoV-2 is positive, Flu B can be falsely reported as positive/borderline.<br>Treatment is typically symptom based for both viruses (SARS-CoV-2 and Flu B). However, in case of false positive Flu B (double positive), the patient may be treated unnecessarily with oseltamivir (a drug for influenzas), but it is well tolerated, and should not cause any side effects for the patient. |
| GenomEra HSV-1/2, VZV + EV Assay Kit<br>**3.** | Possible | When HSV-1 is positive, HSV-2 can be falsely reported as positive/borderline.<br>Treatment procedures are the same in case of HSV-1 and HSV-2. Thus, double positive result should not lead to any unnecessary treatment of the patient. However, the result may cause confusion (double positives are practically nonexistent) and lead to an unnecessary reanalysis of the sample already taken. |

3. Type of Action to mitigate the risk

3.1. <u>Action To Be Taken by the User</u>

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

☒ On-site device modification/inspection

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☒ Follow patient management recommendations

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

☐ Other ☐ None

Based on the investigations performed and assessment of the available data, Uniogen Oy has decided to perform a corrective action by updating affected instruments on the field.

**Advise on action to be taken by the distributor/user:**

- Please identify whether the GenomEra with specified serial number is in routine use in your laboratory or in your possession. If possible, please provide the raw data to the manufacturer according to the instructions provided for further investigation.
- Please be aware of the possibility of false positive results reported by the specified GenomEra molecular analyzers with certain GenomEra Assay Kits.
- There is no need to quarantine the device since the potential impact on patient safety is insignificant and the device will be corrected according to following advised actions:
    - According to the instructions (*2023-02-22_FSN_005_Corrective action instructions*), please use the software tool to update the incorrect parameters of the GenomEras with specified serial numbers.
    - Please fill in the Distributor/End user reply form and send it back to the manufacturer.

NOTE! If the affected instrument is not in routine use the actions described above may be performed later. In this case we need you to verify that the actions will be conducted prior to reinstalling the instrument.

| | |
|---|---|
| 3.2. By when should the action be completed? | Raise awareness immediately.<br>The specified actions have to be completed by the end of March 2023. |
| 3.3. Particular considerations for: IVD<br>Is follow-up of patients or review of patients' previous results recommended?<br><br>No, manufacturer is not aware of any incorrect results obtained with specified devices. And the possibility of false positive results does not cause missed treatment or wrong harmful treatment of patients. See section 2.3. | |
| 3.4. Is customer Reply Required? | Yes, please fill in the attached forms:<br>2023-02-22_FSN_005_Distributor Reply Form<br>2023-02-22_ FSN_005_End user Reply Form<br>2023-02-22_FSN_005_Corrective action instructions |

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3.5. Action Being Taken by the Manufacturer

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

As instructed above, Action being taken by the user, Uniogen will provide a software tool to correct the parameters. This corrective action shall be performed by the distributor / end user according to the instructions provided by the manufacturer.
After these corrective actions done by customer, Uniogen will review the log file containing the updated parameters of the devices and will verify the integrity of the parameters.

The probability of the event occurring again has already been reduced by means of internal instructions and inspections, so that invalid parameters are detected before the device is released from manufacturer.

| | |
|---|---|
| 3.6. By when should the action be completed? | Action will be completed by the end of April 2023. |

| **4. General Information** | |
|---|---|
| 4.1. FSN Type | New |
| 4.2. Further advice or information already expected in follow-up FSN? * | No |
| 4.3. Manufacturer information | |
| Company Name | Uniogen Oy (SRN: FI-MF-000032341) |
| Address | Tykistökatu 4 , 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 Uniogen Oy. | |
| 4.5. List of attachments/appendices: | 2023-02-22_FSN_005_Distributor Reply Form,<br>2023-02-22_ FSN_005_End user Reply Form,<br>2023-02-22 FSN 005 Corrective action instructions |
| 4.6. Name/Signature | [redacted] |

| **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. |

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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.

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:
Sanna Mattila
Quality and Regulatory Manager

Mobile: +358 40 5239680
vigilance@uniogen.com

22.02.2023

# Reply Form

| 1. Field Safety Notice (FSN) information | |
|---|---|
| FSN Reference number* | 005 |
| FSN Date* | 22/02/2023 |
| Product/ Device name* | GenomEra® CDX |
| Product Code(s) | CDX-10, CDX-10-020 |
| Batch/Serial Number (s) | 20110028, 20120036, 20120038, 20120063, 20120064, 20130076, 20200151, 20200156, 20200161, 20200164, 20200178, 20200192 |

| 2. Distributor Details | |
|---|---|
| Company Name* | |
| Address* | |
| Shipping address if different from above | |
| Contact Name* | |
| Title or Function | |
| Telephone number* | |
| Email* | |

| 3. Return acknowledgement to Sender | |
|---|---|
| Email | vigilance@uniogen.com |
| Deadline for returning the reply form | 31.03.2023 |

| 4. Corrective action information | |
|---|---|
| *Instrument(s) (serial numbers) to be worked on using the provided instructions | |
| *Instrument(s) (serial numbers) **not** worked inside the given time frame. | |
| *If instrument(s) is not worked, check the box to confirm, that it will be done prior to the instrument's next use ☐ | |

| 5. Signature and Date | |
|---|---|
| Print Name | Print name here: |
| Signature | Sign here: |
| Date | |

Mandatory fields are marked with *

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22.02.2023

# Corrective action instructions

## Introduction

Updating Tb-Eu leak parameter does not require any special skills or deeper knowledge about GenomEra CDX System. Updating procedure is straightforward and takes less than 10 minutes to complete. To ensure immediate and smooth customer support during updating process, it is highly recommended to make a Tech Support reservation in advance by sending an email to productsupport@uniogen.com.

This document contains all the needed information for the successful Tb-Eu leak parameter update involving the following GenomEra CDX instruments:

- 20110028
- 20120036
- 20120038
- 20120063
- 20120064
- 20130076
- 20200151
- 20200156
- 20200161
- 20200164
- 20200178
- 20200192

## Tb-Eu leak parameter update

Update procedure is performed with a separate program as follows:

1. Download the program *"GenomEraTbLeakUpdate-APP.exe"* to the root folder of an USB flash drive from the manufacturer's web page.
2. **If several GenomEra instruments are connected to the computer, disconnect all *instrument* USB cables from the computer *except* for the one to be updated.**
3. Make sure you are logged into Windows as *"admin"* with password *"GeCDX#".*
4. Make sure that the **GenomEra instrument is switched off** and **GenomEra CDX software is NOT running**.
5. Connect the USB flash drive to the computer.
6. Open the USB drive root folder and start the program *"GenomEra TbEu update -APP.exe"* by double-clicking the file.
7. Switch on the GenomEra CDX instrument.

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8. Follow the instructions on the console.
9. Send the generated *"log.txt"* file from the USB root folder to the Uniogen support e-mail address productsupport@uniogen.com
10. **Wait for further instructions from Uniogen.**

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# End User Reply Form

| 1. Field Safety Notice (FSN) information | |
|---|---|
| FSN Reference number* | 005 |
| FSN Date* | 22/02/2023 |
| Product/ Device name* | GenomEra® CDX |
| Product Code(s) | CDX-10, CDX-10-020 |
| Batch/Serial Number (s) | 20110028, 20120036, 20120038, 20120063, 20120064, 20130076, 20200151, 20200156, 20200161, 20200164, 20200178, 20200192 |

| 2. End User Details | |
|---|---|
| Laboratory/Health Care Unit Name* | |
| Address* | |
| Shipping address if different from 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* | 31/03/2023 |

| 4. End User | |
|---|---|
| ☐ | *I confirm the receipt, reading, and understanding of the Field Safety Notice |
| ☐ | *I have performed all the actions required by the distributor. |
| Print Name* | End User name here: |
| Signature* | End User sign Here: |
| Date * | |

Mandatory fields are marked with *

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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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# Distributor Reply Form

| 1. Field Safety Notice (FSN) information | |
|---|---|
| FSN Reference number* | 005 |
| FSN Date* | 22/02/2023 |
| Product/ Device name* | GenomEra® CDX |
| Product Code(s) | CDX-10, CDX-10-020 |
| Batch/Serial Number (s) | 20110028, 20120036, 20120038, 20120063, 20120064, 20130076, 20200151, 20200156, 20200161, 20200164, 20200178, 20200192 |

| 2. Distributor Details | |
|---|---|
| Company Name* | |
| Address* | |
| Shipping address if different from above | |
| Contact Name* | |
| Title or Function | |
| Telephone number* | |
| Email* | |

| 3. Return acknowledgement to Sender | |
|---|---|
| Email | vigilance@uniogen.com |
| Deadline for returning the Distributor reply form* | 31.03.2023 |

| 4. Distributors (Tick all that apply) | | |
|---|---|---|
| ☐ | *I confirm the receipt, reading and understanding of the Field Safety Notice. | Distributor to complete or enter: |
| ☐ | *I have identified customers that are using or may have used this device | Distributor to comment: |
| ☐ | *I have informed the identified customers of this FSN | Date of communication per customer: |
| ☐ | *I have performed actions required in the instructions | Date of confirmation per customer: |
| ☐ | *I have received signed End User Reply Forms from affected customers | Date of confirmation per customer: |
| Print Name* | | Distributor print name here: |
| Signature* | | Distributor sign Here: |
| Date * | | |

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Mandatory fields are marked with *

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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