Agilent Technologies, Inc.
5301 Stevens Creek Boulevard
Santa Clara, California 95051

www.agilent.com

June 6th, 2022
Reference number: CAPA00415

Urgent Field Safety Notice for AriaDx
Field Action Notice for AriaMx

Dear Valued Customer,

The purpose of this notification is to inform you that we have initiated a Field Safety Corrective Action (FSCA) for the *AriaDx Real-Time PCR System* (CE-IVD; Agilent Part Number: K8930AA) and Field Corrective Action (FCA) for the *AriaMx Real-Time PCR System* (RUO; Agilent Part Number: G8830A, G8831A) related to a potential data "mismatch" when operating in an unstable network environment. Please review the information provided carefully.

Description of the issue

Agilent has been made aware of one incident for the AriaDx Real-Time PCR System where the raw fluorescence data from instrument A was placed into instrument B's experiment file, while instrument B's experiment file headers and sample names remained as expected (i.e. the sample names and data are mismatched). Investigations have shown that this data "mismatch" is *caused by an unstable network environment* and can occur on both AriaDx and AriaMx Real-Time PCR Systems.

To ensure the integrity of your data, please carefully review this notice and consult with your IT department to verify your IP assignment processes for your AriaDx and/or AriaMx Real-Time PCR Systems as well as your network reliability. If you think that you may be affected after reviewing the section below, please carefully read the section "Actions to be taken by the user" that provides information about mitigation steps.

Potential risk to patients for AriaDx Real-Time PCR System

If undetected in a diagnostic setting, the return of fluorescence data mismatched to sample headers in a run file could lead to a false negative or false positive result with potential consequence on clinical management decisions.

Potential risk for AriaMx Real-Time PCR System

If undetected, the return of fluorescence data mismatched to sample headers in a run file can lead to incorrect data sets and negatively impact interpretation of the datasets.

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You are NOT impacted if any of the three conditions below apply:

- You only own one AriaDx or AriaMx Real-Time PCR instrument, or only one Aria Real-Time PCR instrument is connected to your network; or
- Each System is directly connected via LAN cable (peer-to-peer) to the PC running the AriaDx or AriaMx software; or
- You do not use the AriaDx or AriaMx software to monitor runs in progress to completion.

Actions to be taken by the user

Our records indicate that your laboratory has purchased at least one instrument. Within 7 calendar days, please take the following actions:

1. Confirm that you have received this information by completing and returning the enclosed Return Form to: outreach@response.agilent.com

2. If you believe you could be affected, you may continue to use your instrument by taking the following actions:
   - Do not use the AriaDx or AriaMx Software feature that allows to monitor runs in progress to completion.
   - Verify your instrument IP address is not of the specific form 169.254.x.y, which is an indication of an unstable network configuration (automatic private IP addressing).
   - Verify that a unique IP address has been assigned to each instrument using DHCP (recommended) or by manually configuring the IP address(es) for each instrument.
   - Connect instruments directly to the network or via a router. Avoid using a network switch.
   - Verify the indicators of network performance listed below with your IT administrator:
     - A stable connection between the instrument and the network/software
     - No loss of connection to a previously connected instrument
     - No difficulty in connecting to an Aria instrument (e.g. connectivity timeouts, etc.)
     - Any other indicators that your laboratory may have for unstable networks

3. Agilent also recommends you consult with your IT department and verify your protocols/procedures for IP address assignment and network performance.

4. If you believe that your instruments have been operating in an unstable network environment, please follow your internal laboratory procedures to evaluate the impact.

Further Actions by Agilent

Agilent will be providing a software and firmware version update as soon as possible to address the impact of unstable network conditions. You will be notified separately. The update will be available on our Agilent.com website. When informed by Agilent of the availability of new firmware and software, you should upgrade to the new firmware and software version via the Aria Instruments and Software Download website.

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Contact your local country contact if you have any questions regarding this notice, or if you would like assistance with completing the Return Form.

Transmission of this notice

We kindly ask you to inform those who need to be aware of this notification within your organization or any other organization to which the affected or potentially affected product(s) have been transferred. Please ensure that your organization maintains awareness of this notice and the recommended steps until the corrective actions have been completed.

PLEASE NOTE: No other Agilent devices are impacted by this notice.

AriaDx and AriaMx System Information

AriaDx:

The AriaDx Real-Time PCR instrument is a fully integrated quantitative PCR amplification, detection, and data analysis system for nucleic acids samples. The instrument is to be used only by operators trained in laboratory techniques and procedures. The customer is responsible for validation of assays and compliance with regulatory requirements that pertain to their procedures and uses of the instrument.

Each laboratory must validate their own assays for use on the AriaDx Real-Time PCR System. Assays must include controls designed to detect inconsistencies in instrument performance due to, for example, changes in optical performance or thermal block uniformity. The AriaDx Real-Time PCR Instrument is not available in all jurisdictions.

AriaMx:

The AriaMx Real-Time PCR system is a fully integrated qPCR solution for amplification, detection, and data analysis. It is intended For Research Use Only. Not for use in diagnostic procedures.

Reporting to authorities:

Please be aware that the relevant National Competent Authorities have been advised of this safety notice. Thank you for your attention to this matter. We apologize for any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Sincerely,

xxx
Diagnostics and Genomics Group
Agilent Technologies, Inc.