



IMPORTANT FIELD NOTICE

Attn.: Laboratory Manager

December 18, 2023

Reference: PI000000210

Subject: K5849AA - Alissa Interpret, The ACMG (American College of Medical Genetics and Genomics) classification scheme does not result in the correct classification on Alissa Interpret

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified an issue in the software responsible for ACMG classification scheme whereby variants are classified incorrectly.

INTENDED USE

K5849AA

Alissa Interpret software is intended for variant storage, visualization, and annotation using public, commercial and customer internal data sources. It allows end users to set up pipelines to perform or automate the triage and classification of genetic variants. It provides features for recording variant assessments and the drafting of variant analysis reports. The integration capabilities allow for the automated exchange of variant and report information with external software systems.

Alissa Interpret software is intended to be used by trained lab professionals, clinical geneticists and molecular pathologists as a decision-support software platform for the analysis and interpretation of genetic variants identified in human samples in the context of clinical information recorded for a sample.

Use of the product is subject to certain limitations.

The clinical interpretation of a variant and the content of reports generated in Alissa Interpret are the sole responsibility of the end users. Agilent Technologies makes no warranties with respect to any clinical assessments expressed in reports created in Alissa Interpret.

DESCRIPTION OF THE ISSUES

1. The ACMG (American College of Medical Genetics and Genomics) classification scheme implemented in Alissa Interpret does not result in the variant of uncertain significance (VOUS) classification when the Benign and Pathogenic variants are contradictory. The criteria for all variants are not being checked and the software stops too early when assigning a classification.
2. ACMG classification scheme implemented in Alissa Interpret does not result in the correct classification when the user-specific strength criteria are updated. It could incorrectly pick any classification.

TABLE 1. AFFECTED PRODUCTS AND VERSION NUMBERS

	Product Name	Part Number	Software Version Numbers
1	Alissa Interpret	K5849AA	v5.3.7 and v5.4.3

PROBABILITY OF RISK

According to ACMG guidelines, variant interpretation should be conducted by a board-certified clinical molecular geneticist (or molecular genetic pathologist or the equivalent), with the evidence supporting variant classification documented in clinical reports. As such, results provided by Alissa Interpret undergo expert review and interpretation, taking into account the totality of the evidence, prior to any decisions related to variant classification. Therefore, the probability of risk is deemed improbable.



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ACTIONS TO BE TAKEN BY THE CUSTOMER

1. Examine and confirm your software version for the Alissa Interpret and your data where the affected software versions were used.
2. An update to the software is being worked on and is scheduled to be released on 21DEC2023. Our marketing team will reach out once it is available. We recommend that you update your software as soon as possible to resolve this error.
3. Please acknowledge that you have received, read, and understood the Field Notice by completing then signing the enclosed Acknowledgement Form and returning it to fieldactions@agilent.com.

Contact your local sales representative if you have any questions regarding this notification.

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 product(s) have been transferred. Please ensure that your organization maintains awareness of this notice.

PLEASE NOTE: No other Agilent devices are involved in this Field 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 customer satisfaction.

Sincerely,

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