PRISCA

PRISCA 5 Report Translation Issue

Our records indicate that your facility may have the following product:

Table 1.   PRISCA 5 Affected Product(s)

Product	Siemens Material Number (SMN)
PRISCA 5 (Software version 5.0.0)	SMN #10470386
PRISCA 5 (Software version 5.0.1)	SMN #10484426
PRISCA 5 (Software versions 5.0.2, 5.1.0, 5.2.0)	SMN #10475998

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the PRISCA software as indicated in Table 1 above and to provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has confirmed a limited report language translation issue, through investigation of a customer complaint. The issue is limited to a specific scenario regarding the Trisomy 13/18 'Double NT A4letter' report when the software is configured in Italian and Estonian languages.

If the calculated risk ratio is less than 1:50 and the risk ratio equals or exceeds the customer configurable preset 'Cutoff' value, then text that appears alongside the risk ratio in the PRISCA 'Double NT A4letter' report is indicated as 'Normal' instead of 'Increased'. All other information in the report is correct. Customers can generate reports for the Trisomy 13/18 Double + NT prenatal scenario that are not impacted by this translation issue such as 'Combined Risk', 'Combined_noGraph', and 'FirstNT_Comment'.

The limited report language translation error does not impact the risk ratio calculation, or any other manner that the risk ratio is presented in the user interface, exported, or transmitted.

Siemens shall be incorporating translation updates in an upcoming software release.

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Risk to Health

- The potential exists that an erroneous "Normal Risk" qualitative result interpretation may confound the differential diagnosis and delay patient counseling and additional testing. This is being mitigated by an accurate risk ratio, which is used in conjunction with other laboratory tests such as the quad screening results of inhibin A, uE3, hCG and AFP, patient demographics and patient history, ultrasound imaging and liquid biopsy testing. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Customers can continue to rely on PRISCA generated risk ratio reporting, graphing, export, and transmission as a supplement to decision making.

- Customers can reference instructions in the PRISCA 5 Operator's Guide and generate reports that are not affected by the issue. Trisomy 13/18 Double + NT prenatal reports that are not impacted by this translation issue are 'Combined Risk', 'Combined_noGraph', and 'FirstNT_Comment'.

Please review this letter with your Medical Director.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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FIELD CORRECTION EFFECTIVENESS CHECK

PRISCA 5 Report Translation Issue

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UFSN PSW20-01.A.OUS dated May 2020 regarding PRISCA 5 Report Translation Issue. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter.   Yes ☐   No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please send a scanned copy of the completed form via email to XXXX@Siemens.healthineers.com.

Or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens Healthineers technical support representative.

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