

PRISCA

Follow-up: PRISCA 5 Report Translation Issue – Added Romanian Configuration

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

Siemens Healthcare Diagnostics Inc. is issuing a revision to Urgent Field Safety Notice PSW 20-01.B.OUS to inform customers of an additional configuration impacted by a report translation issue.

Siemens's investigation completion has confirmed that the PRISCA 5 Report Translation Issue impacts software configured in the Romanian language in PRISCA reports for Trisomy 21 and Trisomy 18 + NT specific scenarios.

If the calculated Trisomy 21 risk ratio is less than the customer configurable preset 'Cutoff' value, then the text that appears alongside the risk ratio in the PRISCA report is 'Increased' instead of 'Low' risk. The issue is specific to 1st and 2nd trimester reports that do not include the Nuchal Translucency (NT) measurement.

All other information in the report is correct. Customers can generate PRISCA reports for the 2nd trimester Trisomy 21 that are not impacted by this translation issue such as 'Second_Comment' and 'Quadruple_Comment'.

If the calculated Trisomy 18 + NT (with Nuchal Translucency) risk ratio is equal or greater than the customer configurable preset 'Cutoff' value and less than 1:50, and the patient is in the 2nd Trimester of pregnancy, then the text that appears alongside the risk ratio in the 'Triple NT', 'Triple NT A4letter', 'Triple NT signed', TripleNT_noGraph and "Quadruple NT default" reports is 'Low' instead of 'Increased' risk.

All other information in the report is correct. Customers can generate PRISCA reports for the 2nd trimester Trisomy 18 + NT that are not impacted by the issue such as 'SecondNT_Comment' and 'QuadrupleNT_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.

Risk to Health

The potential exists that an erroneous "Low" or "Increased" Risk qualitative result interpretation may confound the differential diagnosis and delay patient counseling and additional testing or lead to follow-up investigation. 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 21 prenatal reports that are not impacted by this translation issue are 'Second_Comment' and 'Quadruple_Comment'. Trisomy 18 + NT prenatal reports that are not impacted by this translation issue are 'SecondNT_Comment' and 'QuadrupleNT_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

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UFSN PSW20-01.C.OUS dated August 2021 regarding Follow-up: PRISCA 5 Report Translation Issue – Added Romanian Configuration. 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.

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|--|------------------------------|-----------------------------|
| 1. I have read and understood the UFSN instructions provided in this letter. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. I have PRISCA 5 configured in the Romanian language. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Name of person completing questionnaire:	
Title:	
Institution:	Software Serial Number (Required):
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.