Urgent Field Safety Notice

SBN-RDS-PathologyLab-2026-002

Specimen, image label, and whole slide image discrepancy in navify® Digital Pathology v2.5

RDS/PathologyLab
Version 1

Product Name	**navify®** Digital Pathology (on-prem) v2.5 **navify®** Digital Pathology (Cloud) v2.5
Product Description	**navify®** Digital Pathology (on-prem) v2.5 **navify®** Digital Pathology (Cloud) v2.5
GMMI / Part No **Device Identifier**	**navify®** Digital Pathology (on-prem) v2.5 GMMI: 10092343001 UDI: 761333602095AQ **navify®** Digital Pathology (Cloud) v2.5 GMMI: 09453733001 UDI: 761333602095AQ Roche Digital Pathology Dx - US Only
Production Identifier **(Lot No./Serial No.)**	Not applicable
SW Version	2.5.0, 2.5.0.1, 2.5.0.2, and 2.5.1
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Two complaints have been received for **navify®** Digital Pathology (nDP) Image Management System, alleging an image/metadata discrepancy in the Viewer window.

An internal investigation identified that the issue involves misalignment of specimen names, block names, and image labels with their corresponding Whole Slide Images (WSI) when specific specimen naming conventions are used. This discrepancy occurs exclusively within a subset of individual patient cases; there is no evidence of the discrepancy between different patients or different cases.

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The issue is triggered by a discrepancy in sorting logic for naming convention in nDP, where the software sorts metadata labels and WSIs using separate methods that can generate the issue only when **both** of the following preconditions are met:

1. **Multiple Specimens:** The case contains more than one specimen.
2. **Mixed Specimen Naming Convention:** Specimen names within the case mix purely numeric values (e.g., "100", "300") with alphanumeric or "leading zero" values (e.g., "060BR", "060", "3-1").

When both preconditions are met, WSIs shift positions relative to their cognate metadata. The severity of the shift depends on the number of blocks and slides per specimen. There are no reports of patient harm linked to this issue.

Note: ***In the United States, navify® Digital Pathology software is a component of the Roche Digital Pathology Dx device cleared by the US FDA for Whole Slide Imaging purposes.***

Internal investigation identified the root cause. The issue was introduced in **navify® Digital Pathology (nDP) version 2.5**, and sustained in versions 2.5.0.1, 2.5.0.2, and 2.5.1 when new sorting logic was applied to specimen labels but was not applied to the corresponding whole slide images in the Viewer window. While specimen, block, and image labels follow strict alphabetical ordering, whole slide images are sorted inconsistently due to differences in how the user interface sorts numeric versus text-based names. The main contributing factor is the customer's naming convention for specimens. The software itself does not currently provide any error flag/message for this issue.

The probability of the software defect leading to adverse health consequences is remote because the software defect is only triggered in cases with multiple specimens and by a non-standard specimen naming convention condition: the mixing of purely numeric values with alphanumeric or "leading zero" formats within a single patient's case. Standard pathology accessioning practices prevent this by assigning unique, consistent alphanumeric structures (e.g., SP302-**A**, SP302-**B**) to all specimens from a patient. There are also some mitigations that make it possible for a pathologist to identify the anomaly to catch the issue, such as actively zooming in to view correct synchronized data in the case bar, noticing visual discrepancies with adjacent ancillary data (like thumbnails or algorithm results), spotting blank "orphaned" slide labels, or reconciling findings with external laboratory systems and final printed reports.

However, despite this remote probability, the potential consequences are severe if the error goes undetected. Evaluating a mislabeled slide could lead to a delayed or incorrect diagnosis (such as misidentifying a tumor margin), which may dictate inappropriate medical or surgical interventions, or cause permanent damage to a body structure if irreversible surgery is performed on healthy tissue.

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Actions taken by Roche Diagnostics

To restrict the spread of the issue to the customers who have not yet updated to the impacted software version and to any new customers, the software version 2.5.0 is no longer available via the Software Distribution Service (SDS).

A Corrective and Preventive Action (CAPA) investigation has been initiated, and the new Software patch nDP v2.5.2 will provide the fix for this issue. This patch will be a mandatory update for all customers. The patch will be pushed by Roche for all Cloud customers, and Roche Field Service Engineers (FSE) will install the patch for all On-Prem customers.

Updates regarding the commercial availability of the patch v2.5.2 for Cloud and On-Premise customers will be provided in a follow-up version of this notification.

In order to reduce the risk of this issue impacting patient care, impacted customers will be asked to perform a retrospective review of all cases that meet the two preconditions mentioned above and were processed since the installation of software versions 2.5.0, 2.5.0.1, 2.5.0.2, and 2.5.1.

Actions to be taken by the customer/user

To ensure data integrity and mitigate the risk of metadata misalignment until software patch **nDP v2.5.2** is applied, all impacted customers must be instructed to implement the following containment measures:

- **Adopt modified naming conventions & Verification Protocols**: impacted customers must adopt modified naming conventions for specimens and adhere to manual verification and active zooming protocols during clinical analysis.
- **Conduct Retrospective Case Reviews and Reconciliation**: Pathologists must reconcile all viewer data against external records (LIS, surgical notes), and retrospective reviews must be conducted for all cases processed since the installation of software versions 2.5.0 through 2.5.1
- **Maintain On-Site Visibility of Instructions**: Post a copy of the "Instructions for Impacted Customers" provided in the attachment in a prominent location visible to all system operators; these must remain posted until the final software update is installed.
- For detailed instructions on impacted customer actions, refer to the ***- "Attachment 1 to SBN-RDS-PathologyLab-2026-002: Instructions for Impacted Customers"***

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Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals, then one or more of the following statements may be included:

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).>

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com