

FIELD SAFETY NOTICE

Affected Product Information	Name: VitroStainer 42
	Cat. Number: VIT-VS42
	Description and Intended Use: For in vitro diagnostic use. Instrument designed for the automatic staining of histological sections from formalin-fixed, paraffin-embedded (FFPE) tissue samples. The instrument is intended for use in clinical-pathological and physiological settings that require biomarker analysis. This platform is designed to be operated by qualified professionals trained in immunohistochemistry (IHC) techniques in histopathology laboratories.
Notice ID	#1491153212
Date	12/02/2025
Recipients	Customers and Distributors who have some equipment installed

Dear Customer/Distributor,
We need to inform you about a field safety notice due to a potential malfunction in the product.

DESCRIPTION OF THE DETECTED ISSUE

In some cases, the instrument may complete a full cycle without detecting that one or more reagents do not have sufficient volume for the programmed techniques.

POTENTIAL RISKS ASSOCIATED WITH THE AFFECTED PRODUCT

If the incident occurs, there may be a missing reagent for one of the slides and the tissue analysed will not stain properly. There is a possibility that this risk may become apparent, but it should be detected by the user through internal control in the case itself or through the use of external positive controls as recommended by international standards and good practice guides of the main scientific societies in the field of histopathology. Due to this low probability of the incident occurring, this notification is made to the client, but without notification to the Health Authority as it is not considered a safety alert.

CORRECTIVE ACTIONS IMPLEMENTED

To address this issue, Vitro S.A. has identified all possible causes and has taken the following actions:

1. Replaced reagent vials with a new version V2 designed to minimize the risk of leakage during transport. All reagents are now shipped in these updated vials.
2. Released a new instrument software version (from V1.00.71.07 onwards), which includes a fix for potential rack detection issues during the cycle to ensure the volume deduction is accurate
3. Designed a new reagent rack V2 that corrects the detection errors present in rack V1, ensures software detection of the rack even in case of incorrect placement, which could cause the software to fail in tracking the volumes consumed from the vial..
4. Increased the filling volume in the vials to ensure the required safety volume. This change has been implemented since January 23, 2025.
5. Increased the dead volume recognized by the software for each vial type. This change is included in a new instrument software version (from 1.00.79.4 onwards).

6. Reduce the temperature of the cold plate where the reagents are placed during the cycle to minimize possible evaporation

Vitro S.A. is currently working to install this updated software version and replace reagent racks in all installed equipment as soon as possible.

Additionally, a Liquid-Level Detection (LLD) system will be available for all equipment (Expected to be released by 30th April).

ACTIONS TO BE TAKEN BY THE END USER

1. Verify at the end of each cycle that all tissues are stained properly by checking that the internal or external positive controls included in each slide are correct. Ensure that none of the vials are empty at the end of a cycle; at least the dead volume should remain inside the vials
2. Do not swap reagent vials between different instruments.
3. Store vials that are not being used in a cycle with the lid closed at the temperature indicated by the manufacturer on the label. Do not use the instrument to store unused reagents.
4. Ensure that reagent vials are stored closed and in an upright position with minimal risk of tipping over.
5. Running cycles during weekends is not recommended.
6. Forward this communication to all relevant personnel within your organization where the affected product has been distributed.

By following all these recommendations, users can ensure the optimal performance of the instrument and reagents, thereby guaranteeing the safety and reliability of patient diagnoses.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR

1. Forward this communication to all relevant customers and ensure that they acknowledge the information provided.
2. In collaboration with Vitro S.A., implement all corrective actions outlined in this notice within your customer base to ensure the proper functioning and safety of the affected equipment.
3. Ensure that reagent vials are stored closed and in an upright position with minimal risk of tipping over.

Vitro S.A. is committed to providing high-quality, safe, and effective products. We sincerely apologize for any inconvenience this issue may have caused and appreciate your attention and cooperation.

For any additional information, please feel free to contact us at regulatory@vitro.bio

Yours faithfully,



Alberto Roncero
Quality and Regulatory Affairs Director
VITRO S.A



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FIELD SAFETY NOTICE ACKNOWLEDGMENT FORM

We kindly ask you to complete and return this form within **10 days** of receipt via email to regulatory@vitro.bio.

☐ I have read, understood, and implemented the necessary actions included in the Field Safety Notice with reference **#1491153212** regarding the following product:

Product Name	Reference
VitroStainer 42	VIT-VS42

*DATE :

*NAME :

*POSITION :

*COMPANY/SERVICE :

*ADDRESS :

*CITY :

*POSTAL CODE :

*COUNTRY :

*PHONE :

*EMAIL :

*SIGNATURE :

NOTES:

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Fields marked with an asterisk () are required.*