Bio-Rad
Laboratories

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URGENT FIELD SAFETY NOTICE
Genie™ Fast HIV 1/2, 72327-72330

This letter contains important safety information. Please ensure all impacted users in your facility are made aware of this letter and the recommended actions.

For the attention of *laboratory professional users*
Please retain this letter for your records

Date: 2025-10-09
Bio-Rad Reference: FSCA ID-2025-001
Legal Manufacturer:
Bio-Rad SRN FR-MF-000006261
UDI-DI 72327: 03610520015124
UDI-DI 72330: 03610520009598

Dear Valued Customer / Channel Partner,

The purpose of this letter is to inform you of a reduction in the shelf-life of Bio-Rad Genie™ Fast HIV 1/2, Catalog #.72327-72330. A safety issue has been identified that could cause a risk for patients.

Reason for the Field Safety Notice:
Recent monitoring of a control batch has shown that storing Genie™ Fast HIV 1/2 kits at the maximum recommended storage condition (30°C) for more than 15 months may lead to reduced band intensity, particularly in weak positive samples. This reduced band intensity can result in false-negative results when HIV antibody levels are close to the assay's detection limit.
This phenomenon is not observed with kits stored at 2°C to 8°C (minimum recommended storage condition), for which detection remains stable until the end of the product's shelf-life, as indicated in the instruction for use.

Please note that while recent testing only identified the issue in select monitored batches, we have decided to proactively reduce the shelf life for all batches listed below.

Risk to Health:
Continued use of Genie™ Fast HIV 1/2 kits stored at the maximum recommended storage condition (30°C) beyond 15 months may compromise diagnostic accuracy. Users may observe faint or absent test bands in weak positive samples.

As a result, there is a potential risk that low levels of HIV antibodies, especially in samples from recent infections, may not be detected when kits are stored at 30°C for more than 15months. This could result in false-negative results, particularly in cases where antibody concentrations are near the assay's limit of detection.

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Affected Product Identification:

Genie™ Fast HIV 1/2
Rapid immunochromatographic assay for qualitative detection of anti-HIV-1 and anti-HIV-2 antibodies in human venous whole blood, capillary whole blood, serum, or plasma specimens

Please refer to Appendix I for a complete list of impacted products.

Action(s) to be taken by the Customer:
Bio-Rad is requesting that customers affected by this notice take the following action:

- Action 1 (Table 1): Not-Expired Batches on the market

For kits stored at room temperature, Bio-Rad has updated the shelf life to 15 months. This new shelf life supersedes the expiration date currently printed on the product labels. Discontinue the use of Genie™ Fast HIV 1/2 kits once they meet or exceed the newly established 15-month shelf life, replacing the original 18-month expiration on the labels. Update your inventory records accordingly to reflect the revised expiration dates listed in the table below.

Table 1

Code Article	Batch	Labeled Expiration Date (YYYY-MM-DD)	Recommended expiration date (YYYY-MM-DD)
72327	**4L0074**	2026-03-28	2025-12-28
	5C0076	2026-08-17	2026-05-19
72330	**4L0044**	2026-03-28	2025-12-28
	5C0045	2026-08-17	2026-05-19

These actions are long-term and will remain in effect until further notice.

- Action 2 (Table 2): Batches to be released

For batches that will soon be released to the market, a sticker (see below) will be placed on the kit box indicating the revised 15-month expiration date.
Customers are required to strictly adhere to the updated information provided on the sticker.

Note: The expiration dates shown on cassette pouch or the kit box must not be used; only the information on the sticker is valid

Table 2

Code Article	Batch	Labeled Expiration Date (YYYY-MM-DD)	Corrected expiration date on the sticker (YYYY-MM-DD)
72327	**5G0078**	2026-11-27	2026-08-26
72330	**5G0046**		

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Please ensure this notice is passed to all those who need to be aware within your organization or to any organization where the impacted devices have been transferred.

Please complete and return the attached response form as soon as possible to confirm receipt of this important communication.

Resolution by Bio-Rad:
For batches stored at room temperature, Bio-Rad has updated the shelf life of Genie™ Fast HIV 1/2 kits to 15 months.

- For the batches currently on the market, this notification serves as the official labeling update for this issue until further notice (Table 1).
- For the batches to be released (Table 2), a sticker indicating the revised 15-month expiration date will be applied to the kit box to ensure proper shelf-life communication.

The National Competent (Regulatory) Authority has been informed of this Field Safety Notice.

Contact Information:
Please contact Bio-Rad Technical Support if you have any questions regarding this communication.

- Contact information is available on our website at: https://www.bio-rad.com/help-center/contact-information

Bio-Rad would like to assure you that our highest priority is maintaining a high level of safety and quality. We regret any inconvenience caused by this issue.

DocuSigned by:
Elizabeth Platt
174E19908F35446...

Elizabeth Platt
VP, Quality, Regulatory & Clinical Affairs
Bio-Rad Laboratories Inc.

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APPENDIX 1

Product UDI	Catalog Number	Batch/Lot Number(s)	Manufacture/ Distribution Dates	Expiry Date
03610520015124	72327	**4L0074**	2024-09-29	2026-03-28
03610520015124	72327	**5C0076**	2025-02-18	2026-08-17
03610520009598	72330	**4L0044**	2024-09-29	2026-03-28
03610520009598	72330	**5C0045**	2025-02-18	2026-08-17

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FIELD ACTION RESPONSE FORM

Bio-Rad Reference: FSCA ID-2025-001
Bio-Rad Product Segment: ID
Single Registration Number (SRN): FR-MF-000006261

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date	Software Version

CUSTOMER / CHANNEL PARTNER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address:	
Telephone Number / Fax:	
Account Number:	

STATEMENT:

- ☐ No affected product received
- ☐ I am aware of the information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.
- ☐ For completion by Channel Partners: All customers have been informed about this field action and have proceeded according to the instructions issued by Bio-Rad. Number of customers informed: _____

Number of affected products received:		Number of affected products corrected/ destroyed/ returned (as applicable to the Field Action instructions):	
If number of products corrected/ destroyed/ returned is different to the number received, please account for the difference:			

Date:
Customer / Channel Partner Signature (and Stamp if applicable):

Please return this form to: *<enter local details, e.g. return email address>*