

**IMPORTANT PRODUCT
INFORMATION
NEW LAV BLOT II, 72252****Important information on NEW LAV BLOT II e-IFU regarding corrected figure of the R4 positive control profile.****For the attention of professional users in a laboratory.
Please retain this letter for your records****Date:** 27 NOV 2024**Bio-Rad Reference:** FA ID 2024-007

Dear Valued Customer / Channel Partner,

The purpose of this letter is to advise you that Bio-Rad has released an updated version of NEW LAV BLOT II eIFU.

Reason for the Action:

Incorrect positive control example image was included. See below for details.

Affected Product Identification:

NEW LAV BLOT II

e-IFU available since August 2024 in downloads.bio-rad.com: e-IFU code number
0001355 - 2022/01**Action(s) to be taken by the Customer:**

Bio-Rad is requesting that customers affected by this notice take the following action:

- Discard local printed versions of e-IFU code numbers 0001355 version 2022/01
- Replace it with the new e-IFU code number 0001355 version 2024/11. This new version can be downloaded from the “[Downloads.bio-rad.com](https://downloads.bio-rad.com)” website as indicated on the box label.



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

Resolution by Bio-Rad:

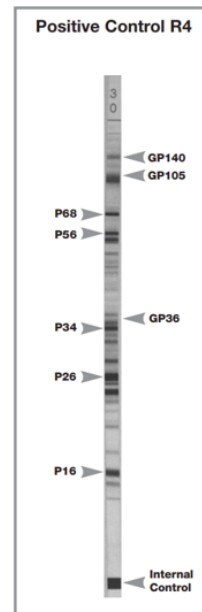
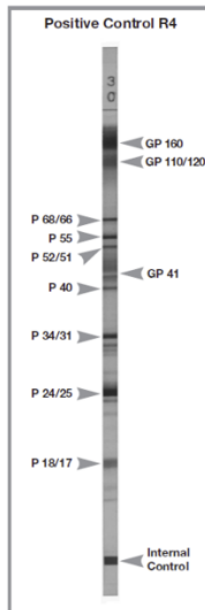
Description of the error and correction:

e-IFU 0001355 - 2022/01 (IVDR), released 2024 August: incorrect

e-IFU 0001355 - 2024/11, corrected version -
2024 November

Positive control R4 example profile

Caution: precise bands may differ in reality.
Do not use this picture for final interpretation. Use the
positive control strip to identify the patient antibodies and
check that the internal control band is present on each strip.



In the correct bands pattern, P16 band and HIV-2 markers as GP140 and GP36 are indicated. The error is detectable when trying to compare the true bands pattern obtained for internal R4 positive control anti-HIV 2 after processing. No patient results can be interpreted.

Contact Information:

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

- [<Bio-Rad support numbers / email>](#)

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.

Laetitia Cartier, Quality Assurance Manager

Signé par :
Laetitia Cartier

Nom du signataire : Laetitia Cartier
Motif de la signature : J'approuve ce document
Heure de signature : 28-nov.-2024 | 8:39:12 AM PST
1AAD7BEBF92F4466A8B14F1219D818BC