

Bio-Rad Laboratories

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Important Product Information Notice of Correction

Bio-Rad Laboratories VIROTROL HIV-2 Catalog Number 00105B Lot Number 114730

This Notice is intended for the end-users of this product.

If you are not the end-user, please forward this Notice to the appropriate laboratory personnel.

Date September 4, 2019

To Clinical Laboratory Supervisor, Manager or Director

Cc Chairman Medical Board and relevant Head of Departments

From Bio-Rad Laboratories QSD Regulatory Affairs

Product VIROTROL HIV-2

Lot Number 114730

Expiration date Nov. 30, 2019

Catalog No. 00105B

Issue VIROTROL HIV-2 is intended for use as an unassayed reactive control

with in vitro assay procedures for determination of antibodies to Human

Immunodeficiency Virus Type 2 (HIV-2).

We have recently confirmed non-reactive results when using VIROTROL HIV-2, Lot #114730 on Ortho VITROS HIV 1+2 assays. Due to this issue, we recommend that you immediately discontinue use of this product lot.

Actions Required

- Discard all remaining inventory of VIROTROL HIV-2, Lot #114730 that you have at your location in accordance with the requirements of your local waste management authorities.
- Please contact Bio-Rad Laboratories Technical Support Department in USA at 1-800-854-6737 or your local Bio-Rad Laboratories Sales Office to make arrangements for any credit requests or to alter any pending orders or shipments.
- Have the appropriate laboratory personnel complete the enclosed acknowledgment form to document that you have received this notice and are aware of this product quality notification. Please send the completed form back via email to <u>gsd.techservice@bio-rad.com</u> or send it via fax to 949-598-1531 (Attention: Technical Support).
- Contact Bio-Rad Laboratories Technical Support Department in USA at 1-800-854-6737 or by email at <u>qsd.techservice@bio-rad.com</u> if you have technical questions regarding this notice

We appreciate your patience and apologize for any inconvenience this may have caused.