

## Bio-Rad Laboratories

Clinical Diagnostics Group 9500 Jeronimo Road Irvine, California 92618-2017 Tel: (949) 598-1200 www.bio-rad.com/qualitycontrol

## Important Product Quality Notice Notice of Correction

Bio-Rad Laboratories
VIROTROL HIV-1 Ag
Catalog Number 00108A
Lot Number 114150

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.

Cc Chairman Medical Board and relevant Head of Departments

Date August 17, 2018

To Clinical Laboratory Supervisor, Manager or Director

**Product** VIROTROL HIV-1 Ag

Lot Number 114150

Catalog Number 00108A

Issue VIROTROL HIV-1 Ag is intended for use as an unassayed reactive quality

control with in vitro assay procedures for determination of antigens to

Human Immunodeficiency Virus Type 1 (HIV-1).

We have recently confirmed non-reactive results when using VIROTROL HIV-1 Ag, Lot #114150 with some commercially available assay test kits. Due to this issue, we recommend that you immediately discontinue use of

this product lot.

**Actions Required** 

- Discard all remaining inventory of VIROTROL HIV-1 Ag, Lot #114150 that you have at your location in accordance with the requirements of your local waste management authorities.
- Please contact Bio-Rad Laboratories Customer Service at 1-800-2-BIO-RAD (1-800-224-6723) or your local Bio-Rad Laboratories Sales Office to make arrangements to alter any pending orders or shipments.
- Please have the appropriate laboratory personnel complete the enclosed acknowledgment form to document that you have received this correction notice and are aware of this product quality notification. Please send the completed form back via email to QSD\_FAR@bio-rad.com or by fax to 949-598-1557 (Attention: Regulatory Affairs).
- Contact Bio-Rad Laboratories Technical Support Department in USA at 1-800-854-6737 or by email at qsd.techservice@bio-rad.com if you have technical questions regarding this notice.



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