Molecular Diagnostics at Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Field Advisory Notice
Molecular Diagnostics at Abbott
Product: Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit
List Number: 04N66-090
Not Lot Specific
Unique Device Identifier (UDI): (01)00884999009578

February 13, 2025

Dear Abbott Customer,

This letter contains important information regarding the Abbott RealTime HIV-1 Qualitative Amplification (AMP) Reagent Kit, List 04N66-090. Please review this information carefully.

Background

HIV-1 polymerase chain reaction (PCR) assays, such as the Abbott RealTime HIV-1 Qualitative assay, are designed to target conserved regions of the HIV-1 genome to achieve highly sensitive and specific detection of HIV-1 RNA. In recent years, multiple gene therapies have been introduced that utilize HIV-1 based lentiviral vectors to deliver therapeutic genes to patients with hereditary or acquired diseases. Due to the use of conserved HIV-1 sequences in these lentiviral vectors, there is the potential for HIV-1 PCR assays to detect HIV-1 target in HIV-negative patients who have received these gene therapies, including those for chimeric antigen receptor (CAR) T-cells or hematopoietic stem cells.

Abbott has confirmed the potential for certain HIV-1 PCR assays, such as the Abbott RealTime HIV-1 Qualitative assay, to detect HIV-1 sequences used in HIV-1 based lentiviral vectors.

Impact

Due to the presence of HIV-1 lentiviral vectors in patients undergoing gene therapies such as CAR T-cell or hematopoietic stem cell-based therapies, there is a potential hazard of the Abbott RealTime HIV-1 Qualitative assay falsely detecting HIV-1 in these patients. The assay is intended to be used as an aid in the diagnosis of HIV-1 infection in pediatric and adult subjects. The assay is not intended to be used as a donor screening test for HIV-1.

Necessary Actions

In the Limitations of the Procedure section of the Instructions for Use for the Abbott RealTime HIV-1 Qualitative assay, Abbott will be adding a statement around the use of the assay for patients receiving gene therapies that utilize HIV-1 based lentiviral vectors which contain the conserved HIV-1 sequences detected by our assays.

Please complete and return the associated Customer Reply Form.

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Review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication, please contact your local Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

2/13/2025

Pamela Yip
Divisional Vice President, Quality Assurance
Molecular Diagnostics at Abbott

Abbott

Customer Reply Form
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Field Advisory Notice FA-AM-FEB2025-304B
Dated February 13, 2025

Dear Abbott Customer,

Please complete the following information below acknowledging receipt of the **Field Advisory Notice FA-AM-FEB2025-304B** and return it to us by Fax or by e-mail, **prior to February 28, 2025** to:

Molecular Diagnostics at Abbott
Attention: AM Field Quality
Fax #: 847-775-6728 or E-mail: AM_FieldQuality@abbott.com

Instructions:
1. Please provide a copy of the accompanying Field Advisory Notice FA-AM-FEB2025-304B to the laboratory manager, supervisor, or health professional responsible for the impacted product.
2. Please complete all sections and return this Customer Reply Form to the above Abbott contact prior to February 28, 2025. If you no longer have the instrument(s)/reagents(s), this form is still required to be completed and returned for the reconciliation of our records.
3. If you have forwarded any impacted product to other laboratories, please inform them of this Field Advisory Notice; provide a copy of the letter and reply form to them; and have them take the necessary actions listed here.

Please record the following information:

Customer Number		Name of Institution	
Address		City	
Country		Postal Code	
Name		Title / Position	
Phone Number		Email Address or Other Contact Information	

Customer Acknowledgement

By completing and signing this document, I confirm that the Field Advisory Notice FA-AM-FEB2025-304B disseminated to all users, understood, and implemented, and that the necessary actions for the customer were completed.

__ Yes, I confirm.

If not, please choose one of the options below:

__ No, I would like to be contacted by an Abbott Representative.
__ Not Applicable. Please explain on the line below (e.g., no longer have the instrument):
_____

_____ _____
Signature Date

_____
Printed Name