

Abbott Diagnostics Technologies AS
Kjelsåsveien 161
PO Box 6863 Rodeløkka
NO-0504 Oslo
Norway



Field Safety Notice

Urgent - Immediate Action Required

Date Issued June 6, 2024

Product

Name of Device	1116795 Afinion™ HbA1c (EUR) 1116974 Afinion™ HbA1c (US)
Batch Number	1116974, batch 10222103

Explanation

This letter is to inform you that 20 kits of 1116974, batch 10222103 Afinion HbA1c, US were incorrectly packed inside a larger container box labeled as 1116795 Afinion HbA1c (EUR) that was distributed to Accu Science Ireland Ltd.

Afinion HbA1c SKU number 1116974 is only authorized for commercialization in the United States.

There have been no other reports of shipment boxes with incorrect contents.

Impact on Patient Results or Operator Safety

- In cases where the user used this product; there is no potential health hazard as the two SKUs have the same release specifications. The instructions on how to perform the test are the same for both products.
- In cases where the user did not have other lots available; there is a potential for delayed medical decision/treatment (short term).

Necessary Actions

- Complete and return the “Customer Required Action” Form to provide customer verification.
- If you have forwarded the products listed above to other laboratories, please inform them of this Product Correction and provide a copy of this letter to them.
- Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have questions regarding this information, please contact sm.emnoosl.qa@abbott.com

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Technical Service.

- Confidential -

Page 1 of 2



Customer Required Action

Urgent - Immediate Action Required

Please complete this form, even if you do not have any involved product and Fax to 913-234-4559 or e-mail to CMIFIELDACTION@abbott.com

Customer Verification Form Field Safety Notice

1. We acknowledge receipt of the Abbott Diagnostics Technologies AS notice dated, June 6, 2024.
2. We confirm that all areas where the product could be located have been checked.

3. SELECT ALL STATEMENTS THAT APPLY

The following has been verified:

- We do not have any affected product.
- Affected product was redistributed to another facility. The contact information for that facility is:
_____.
- We have affected product. Please send me a replacement.
- I confirm that I have disposed of this product in accordance with local waste disposal requirements

DATE*:

AUTHORIZED SIGNATURE*:

PRINT NAME*:

TITLE:

DEPARTMENT:

INSTITUTION*:

ADDRESS*:

CITY*:

STATE*:

PHONE*:

POSTAL CODE*:

COUNTRY*:

EMAIL:

***Mandatory Field**

- Confidential -

Page 2 of 2