



Product Field Safety Notice (FSN)

Date Issued February 4, 2026
Date Letter Sent February 4, 2026

Product Product Description: **Afinion™ HbA1c**
Part number: **1116795**
Basic-UDI: **7070060HBA000136**

| Cartridge Lot number | Kit Lot number | Expiration Month |
|----------------------|----------------|------------------|
| 10233220 | 10233287 | May 27 |
| 10233356 | 10233364 | May 27 |
| 10233432 | 10233471 | May 27 |
| 10233528 | 10233566 | May 27 |
| 10233678 | 10233691 | Jun. 27 |
| 10233705 | 10233857 | Jun. 27 |
| 10233788 | 10233932 | Jun. 27 |
| 10233935 | 10233936 | Jun. 27 |
| 10233994 | 10234034 | Jun. 27 |
| 10234088 | 10234093 | Jul. 27 |
| 10234123 | 10234180 | Jul. 27 |

Product Description: **Afinion™ HbA1c (ID)**
Part number: **1116795**

| Cartridge Lot number | Kit Lot number | REF Kit lot number | Exp. Date |
|----------------------|----------------|--------------------|-----------|
| 10233994 | 10234369 | 10234034 | Jun. 27 |

Product Description: **Afinion™ HbA1c**
Part number: **1117196**
Basic-UDI: **7070060HBA000136**

| Cartridge Lot number | Kit Lot number | Expiration Month |
|----------------------|----------------|------------------|
| 10233576 | 10233663 | May 27 |
| 10234312 | 10234316 | Aug. 27 |

Explanation

This Field Safety Notice is not related to a product safety issue.

Abbott is committed to providing high-quality products and ensuring patient safety. We are writing to inform you of an issue identified with certain Afinion™ HbA1c cartridges that may result in Information Code 215 being displayed on the Afinion™ instrument during testing.

A subset of Afinion™ HbA1c cartridges may exhibit precipitation in the reconstitution reagent in position 3d of the test cartridge. The precipitation may trigger Information Code 215 on the Afinion™ instrument. The expected appearance of an Afinion™ HbA1c cartridge is shown in Image #1. An example of how a cartridge containing precipitation in position 3d may appear is shown in Image #2.

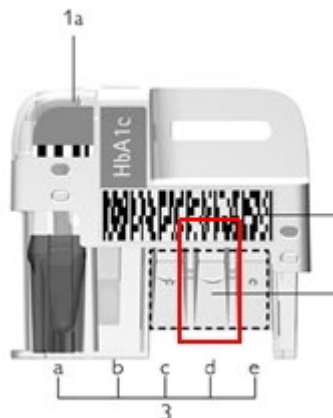


Image #1

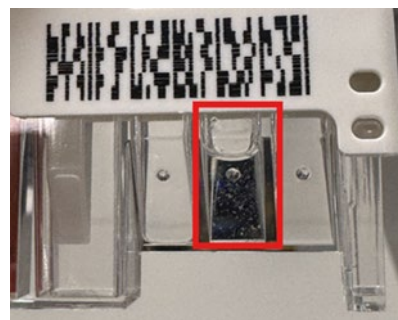


Image #2

The presence of precipitation does not affect the accuracy of test results. The analyzer has built-in fail-safe mechanisms that prevent the reporting of erroneous results. When the instrument detects a condition that could compromise the test, an Information Code (e.g. 215) will be displayed on the Afinion™ instrument instead of providing a result.

A thorough investigation of this issue has been conducted, the manufacturing root cause has been identified, and corrective actions have been implemented to prevent recurrence in future production.

Impact on Patient Results

If an information code is not triggered, the reported result remains accurate and there is no impact on patient results.

Necessary Actions

- Please complete and return the “Customer Reply Form” accompanying this letter.
- You may continue to use the product.
- If you experience repeated information codes 215 with any of the impacted lots listed in the “Product” section, you will receive your replacement upon receipt of the completed form.
- If you experience repeated information codes 215 on any lot not listed in the “Product” section of this letter, please contact your regional Technical Services team for troubleshooting.
- If you have forwarded the products listed in the “Product” section to other laboratories, please inform them of this product action and provide them with a copy of this letter.
- Please retain this letter for your laboratory records.

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Contact Information

It is important that your organization takes the actions outlined in the FSN and confirms that you have received the Field Safety Notice.

Your organization's reply provides Abbott with the evidence needed to monitor the effectiveness of the product actions.

If you have any questions regarding this FSN, please contact Abbott Technical Service. See contact details below:

| Country | Phone No. | Email |
|--|--|--|
| Botswana, Cameroon, Jordan, Kenya, Mali, Mozambique, Namibia, Rwanda, South Africa, Uganda | +27 10 500 9700 Option 3 +27 10 017 6500 Option 2 | ARCIS.TechSupport@abbott.com |
| Bahrain, Bosnia-Herzegovina, Croatia, Cyprus, Czechia, Greece, Iceland, Lithuania, Netherlands, Poland, Portugal, Qatar, Romania, Saudi Arabia, Slovenia, United Arab Emirates (UAE) | +44 161 483 9032 | EME.TechSupport@abbott.com |
| Ireland, United Kingdom (UK) | +44 161 483 5884, Option 3 | EME.TechSupport@abbott.com |
| Peru, Uruguay | +576019142746 | LA.TechSupport@abbott.com |
| Australia, New Zealand, Cambodia, Hong Kong | +61 7 3363 7711 | AP.Techsupport@abbott.com |
| Austria | +43 800 298042 Option 3 | TechnicalService.DA@abbott.com |
| Belgium | +33 172 10 00 80 Option 3 & +49 221 271430 Option 3 | techsupport.france@abbott.com TechnicalService.DA@abbott.com |
| Canada | +1 800 818 8335 Option 2 | Ottawa.Technical.Services@abbott.com |
| China | +86-400-198 402 | AP.Techsupport@abbott.com |
| Colombia | 01 8000423877 +576019142746 | ts.colombia@abbott.com |
| France | +33 172 10 00 80 Option 3 | techsupport.france@abbott.com |
| Germany | +49 221 271430 Option 3 | TechnicalService.DA@abbott.com |
| India | | AP.Techsupport@abbott.com |
| Indonesia | 000800-040 2921 | AP.Techsupport@abbott.com |
| Italy | +39 02 2774131 Option 5 | EMETechSupportIT@abbott.com |
| Malaysia | 1800-819416 | AP.Techsupport@abbott.com |
| Mexico | +528008721618 +525595473015 | LA.TechSupport@abbott.com |
| Philippines | +632 77189122 | AP.Techsupport@abbott.com |
| South Korea | 00798-14-2064396 | AP.Techsupport@abbott.com |
| Spain | +34 936 008 008 | EMETechSupportES@abbott.com |
| Switzerland | +41 (0)44 782 60 70 Option 1 French, Option 2 Italian, Option 3 German, then Press 2 for Technical Services | techsupport.france@abbott.com TechnicalService.DA@abbott.com EMETechSupportIT@abbott.com |
| Taiwan | 00801-128036 | AP.Techsupport@abbott.com |

Rapid DIAGNOSTICS

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Customer Reply Form

Field safety notice – Acknowledgement form

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

Afinion™ HbA1c, Part Number 1116795; Afinion™ HbA1c, Part Number 1117196

This response form is to confirm receipt of this notification and to request replacement product, if eligible.

Customer Details

Account / Customer Number _____

Healthcare Organization Name* _____

Distributor Name, if applicable _____

Street* _____

City* _____

Zip Code* _____

Contact Name* _____

Department/Unit _____

Title or function _____

Telephone number* _____

E-mail* _____

Shipping Address if different from above _____

*Mandatory Fields

Customer Action Undertaken

1. We acknowledge receipt of this Abbott Field Safety Notice dated 4 February 2026, related to Afinion™ HbA1c.
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 cartridges. No further action needed.
- Affected cartridges were redistributed to another facility. The contact information for that facility is: _____
- We have cartridges within the lot number range indicated in the “Product” section of the FSN, but we HAVE NOT observed the information codes outlined in the Field Safety Notice. No further action needed.
- We have affected cartridges within the lot number range indicated in the “Product” section of the FSN , AND have observed the noted information code.

In the form on the next page, indicate the lot number(s) in use when the information code was observed. Indicate the number of kits that are impacted and require replacement. A product replacement will be processed based on the number of kits reported as impacted.

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Customer Reply Form

Field safety notice – Acknowledgement form

Request for Replacement Product

Afinion™ HbA1c, Part Number 1116795; Afinion™ HbA1c, Part Number 1117196

This response form is to confirm receipt of this notification and to request replacement product, if eligible.

1 kit equals 15 cartridges

| Product Name | Part Number | Cartridge Lot number* | Kit Lot number* | Requested replacement Qty |
|----------------|-------------|-----------------------|-----------------|---------------------------|
| Afinion™ HbA1c | 1116795 | | | kits |
| | | | | kits |
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| | | | | kits |
| | | | | kits |
| | | | | kits |
| | | | | kits |

*If additional space is needed, please complete another form.

1 kit equals 15 cartridges

| Product Name | Part Number | Cartridge Lot number* | Kit Lot number* | Requested replacement Qty |
|----------------|-------------|-----------------------|-----------------|---------------------------|
| Afinion™ HbA1c | 1117196 | | | kits |
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| | | | | kits |
| | | | | kits |
| | | | | kits |
| | | | | kits |
| | | | | kits |

*If additional space is needed, please complete another form.

Printed Name

Signature and Date

Return acknowledgement to sender. Email: CMIFieldAction@abbott.com

Please complete and return this form within **10 business days** of receipt.

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