



Product Correction Notification

Date Issued

October 13, 2025

Product

Product Description	Part Number (PN)	Unique Device Identifier (UDI)
Afinion™ Lipid Panel (EUR)	1116801	07070060014050
Afinion™ Lipid Panel (NOR)	1116802	07070060014074
Afinion™ Lipid Panel (JP)	1116799	07070060014012

Note : This product correction impacts all lots of Afinion™ Lipid Panel that are within expiration date.

Explanation

This letter is to inform you that Abbott has identified that bilirubin, at specific elevated concentrations, can impact the accuracy of Triglyceride (Trig), Total Cholesterol (Chol) and Low-Density Lipoprotein (LDL) Cholesterol analytes when using the Afinion™ Lipid Panel product tested with Alere Afinion™ AS100 Analyzer and Afinion™ 2 analyzer.

Bilirubin concentrations greater than 6 mg/dL (conjugated) and 16 mg/dL (unconjugated) in serum and whole blood may result in a negative bias (or falsely low result) that is greater than 10% impacting the accuracy of the Trig analyte tested on the Afinion™ Lipid Panel product.

Bilirubin concentration of 16 mg/dL in serum and whole blood may result in a negative bias (or falsely low result) that is greater than 10% when tested in samples with Cholesterol concentration at or below 6.2 mmol/L (240 mg/dL) and LDL concentration at or below 4.1 mmol/L (160mg/dL), respectively on the Afinion™ Lipid Panel product.

The accuracy of the High-Density Lipoprotein (HDL) Cholesterol analyte is not impacted by bilirubin at concentrations \leq 20 mg/dL.

The “Interference” section of the current version of Afinion™ Lipid Panel Instructions for Use (IFU) (1117338 Rev. B 2023/09, 1117340 Rev. B 2023/09 and 1117341 Rev. A), states that a bilirubin concentration of 20 mg/dL resulted in less than 10% interference. The Afinion™ Lipid Panel IFU will be updated with the new bilirubin interference information. Until the IFU is updated, all Afinion™ Lipid Panel kits will soon begin to include extra printed materials with this revised information.

**Impact on
Patient Results
or Operator
Safety**

Negative bias (or falsely low results) may be observed for Triglycerides at bilirubin levels of 6 mg/dL (conjugated) and 16 mg/dL (unconjugated) in addition to those observed for Total Cholesterol and LDL Cholesterol at bilirubin levels of 16 mg/dL, respectively.

The negative interference affecting triglycerides, total cholesterol, and LDL cholesterol is minimal and does not have a clinically significant impact. The negative interference may lead to a small underestimation of cardiovascular risk. However, it does not lead to risk misclassification or influence treatment decisions in a way that could cause serious harm to the patient. Bilirubin levels above 1.3 mg/dL are considered elevated. Patients with bilirubin levels at or above 6 mg/dL are presenting with symptoms of jaundice, yellow skin and sclera (eyes). These warrant investigation and medical intervention.

If the clinical presentation of the patient does not require it, no additional testing or look-back are necessary unless deemed appropriate by the health care provider.

**Necessary
Actions**

- Test results from patients with bilirubin levels above 6 mg/dL should be verified using another test method when testing Triglyceride (Trig), Total Cholesterol (Chol) and Low-Density Lipoprotein (LDL) Cholesterol analytes.
- Complete and return the Customer Reply Form.
- If you have forwarded the products listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- 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 your local Technical Service.

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

It is important that your organization takes the actions detailed in the Field Action and confirms that you have received the Field Action.

Your organization's reply is the evidence Abbott needs to monitor the progress of the product actions.

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



Customer Reply

Product Correction Notification –
Acknowledgement form

1. Actions to be taken by Customer:

- We acknowledge receipt of the Abbott Diagnostics Technologies AS Product Correction Notification dated, October 13, 2025.
- We confirm that all areas where the product could be located have been checked.
- 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. We acknowledge that we were made aware of the potential interference presented by bilirubin concentrations greater than 6 mg/dL. This change will be taken into consideration when utilizing the product.

2. Customer Contact details:

DATE*:

AUTHORIZED SIGNATURE*:

PRINT NAME OF CONTACT INDIVIDUAL*:

TITLE:

DEPARTMENT:

INSTITUTION*:

ACCOUNT NUMBER, if known:

ADDRESS*:

CITY*:

STATE*:

PHONE*:

POSTAL CODE*:

COUNTRY*:

EMAIL:

*Mandatory Field

3. Return acknowledgement to sender

Email	<Replace with your distributor/affiliate email address to make it clear to your customers where these replies should be sent >
Fax	<Replace with your distributor/affiliate fax number to make it clear to your customers where these replies should be sent, delete if not needed>
Deadline for returning this form	Please complete and return this form within 10 business days of receipt

- Confidential -

Page 3 of 3