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

Product Field Safety Notice

Urgent

Date Issued

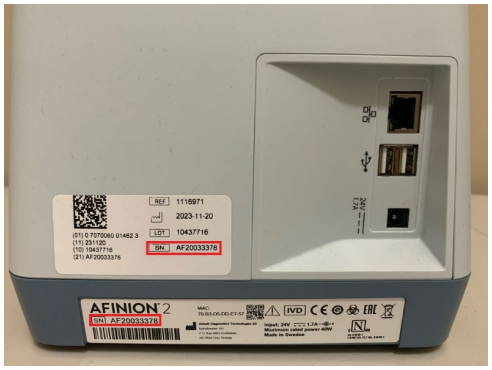
May 22, 2024

Product

Product Description	Part Number(s)	UDI	Serial number(s)
Afinion™ 2 , IN	1116772	7070060014432	Series AF20052000 to AF20060000
Afinion™ 2 , JP	1116774	7070060014456	
Afinion™ 2 , NOR	1116777	7070060014487	
Afinion™ 2 , NOR	1116778	7070060014494	
Afinion™ 2	1116770	7070060014418	
Afinion™ 2	1116771	7070060014425	
Afinion™ 2 , IN	1117030	7070060015118	

Explanation

This letter is to inform you that Abbott has identified an issue related to cracks developing in an internal component (pump housing) of the Afinion™ 2 instrument within a subset of serial numbers. Specifically, the serial numbers AF20052000 - AF20060000 which can be found on the back of the analyze:



If the problem occurs, the user will experience frequent information codes. Specifically:

- Information codes 214 or 215 when running Afinion™ HbA1c, Afinion™ ACR or Afinion™ Lipid Panel
- Information Code 302 when running Afinion CRP assays.

Impact on Patient Results or Operator Safety

No results would be obtained, and in turn, there would be a potential delay of treatment. Upon assessment, there is no health hazard associated with this issue and therefore no identifiable or potential adverse health consequence associated with the use of, or exposure to the instrument. There is no impact to patient management. Failsafe mechanisms are built into the instrument to

Quality record references: FCA-00000294

prevent erroneous results.

Necessary Actions

- Please complete and return the “Customer Required Action” form accompanying this letter. If your instrument is impacted by the above combination of serial numbers and information code(s), a replacement will be processed.
- If you have forwarded the products listed above to other laboratories, please inform them of this product action and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

If you have experienced any patient or user injury associated with this field action, please immediately report the event to Technical Service.

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

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

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Customer Reply

Field safety notice – Acknowledgement form

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

1. We acknowledge receipt of the Abbott Diagnostics Technologies AS notice dated, May 22, 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 instruments. No further action needed.
- ☐ Affected instruments were redistributed to another facility. The contact information for that facility is: _____.
- ☐ We have instruments within the serial number range indicated in the letter, but I HAVE NOT exeprienced the information codes outlined. No further action needed.
- ☐ We have affected instruments within the serial number range indicated in the letter, AND have experienced the information code(s) noted. An instrument replacement will be processed. Serial Number(s) impacted are as follows:

Serial Number(s):_____

Information Code(s) Experienced:_____

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**

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