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Norway

Urgent Field Safety Notice

EN (GB)

Alere Afinion™ 2 Analyzer
FSCA-identifier : CAPA-00001870

Date: March 2018

Dear Customer,

Our records indicate that you have received deliveries of the following affected product:

Product name:	**Alere Afinion™ 2**
Catalogue numbers (REF):	**1116553, 1116556 and 1116557**
Serial Numbers (SN):	**From AF20000001 to AF20002298**
Software (SW) versions:	**20.00, 20.01, 20.04, 20.06 and 21.00** (The SW version is displayed in the start menu at the upper left corner of the screen)

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

Description of the problem:

An error in the software of the Alere Afinion™ 2 Analyzer has been detected. The software error affects the Alere Afinion™ ACR (Albumin/Creatinine Ratio) test only.

The following devices are <u>not</u> affected:

- *The Alere Afinion™ HbA1c, CRP or Lipid Panel results, provided by the Alere Afinion™ 2 Analyzer, are <u>not</u> influenced by this software error.*
- *The software of the Alere Afinion™ AS100 Analyzer model is <u>not</u> affected for any of the tests.*

A temperature correction of the albumin measurements is required for the Alere Afinion™ ACR test. The software defect deactivates this correction, causing a potential hazard of erroneous albumin and ACR results.

The software defect deactivates the temperature correction of the albumin measurements, which is required for the Alere Afinion™ ACR test. The potential hazard is erroneous albumin and ACR results.

The lack of temperature correction will give false low results at analyzer temperatures below 27 °C and false high results above 27 °C. The deviation from correct result is dependent on the actual analyzer temperature which is influenced by the room temperature where the analyzer is placed.

See table on next page for estimated impact on test results due to lack of temperature correction.

Alere Afinion™ 2 Analyzer temperature*	Deviation from correct Albumin and ACR result due to SW error
19	-18 %
20	-16 %
21	-14 %
22	-12 %
23	-9 %
24	-7 %
25	-5 %
26	-2 %
27	0 %
28	2 %
29	5 %
30	7 %
31	9 %
32	12 %
33	14 %
34	16 %
35	18 %
36	21 %
37	23 %

*) Temperature displayed on the analyzer when the lid is closed and no test cartridge is loaded. The analyzer temperature is 1-4°C above the room temperature, and always in the range 19-37°C. The software will not allow the analyzer to begin a diagnostic test if the analyzer temperature is outside of 19-37°C.

Risk to health:

A health hazard evaluation has concluded that the error can potentially lead to missed diagnosis of kidney disease or wrongly diagnosed kidney disease.

ACR is a predictive marker in the early detection of kidney disease and identification of patients at risk for complications of diabetes or hypertension. Because of variability in urinary albumin excretion, two of three specimens collected within a three to six months period should be abnormal before considering a patient to have crossed one of the diagnostic thresholds; microalbuminuria (30 -300 mg/g) or clinical albuminuria (>300 mg/g). Exercise within 24 hours, infection, fever, congestive heart failure, marked hyperglycemia, and marked hypertension may also elevate urinary albumin excretion over baseline values.

Results obtained with Alere Afinion™ ACR should be interpreted with careful consideration to the patient's medical history, clinical examinations and other laboratory results.

Advice on actions to be taken by the USER:

1. Stop running Alere Afinion™ ACR tests on the Alere Afinion™ 2 Analyzer.

2. A USB stick with the new and corrected software 21.02 is enclosed with this letter.
   Record the serial number of your Alere Afinion™ 2 Analyzer(s) and confirm that each device has been successfully upgraded with the new software.

3. Please complete the confirmation form and return this as soon as possible.

4. Please involve the medical doctors responsible for interpretation of the Alere Afinion™ ACR results. Advise on actions to be taken by the medical decision makers are given below.

5. If the Alere Afinion™ 2 Analyzer has been further distributed within or beyond your organization, please ensure that this information, including a USB stick with the new software, is forwarded to the user of the instrument.

Advice on actions to be taken by the MEDICAL DOCTORS:

There are two situations to be considered in the context of risk to the patients:

1) future patient consultations
2) previous patient consultations

For future patient consultations, a software upgrade will rectify the fault and eliminate the risk of erroneous albumin and ACR results using the Alere Afinion™ 2 Analyzer.

For patients previously tested with the Alere Afinion™ ACR on the Alere Afinion™ 2 Analyzer, some patient results may be compromised. Thus, review of previous Alere Afinion™ ACR test results provided by the Alere Afinion™ 2 Analyzer is recommended, and relevant patient follow up should be considered.

PLEASE COMPLETE AND RETURN THIS FORM AS SOON AS POSSIBLE

Send the scanned document in pdf format to e-mail: **FSN.alere@alere.com**
OR: fax the document to: **+353-91-680102**
OR: send the original document by mail to:
Alere International Limited, Parkmore East Business Park, Ballybrit, Galway, Ireland

Confirmation form for the receipt of Field Safety Notice EN (UK)

Alere Afinion™ 2 Analyzer

FSCA-identifier : CAPA-00001870

This response form is to confirm the receipt of the Field Safety Notice regarding the identified software error of Alere Afinion™ 2 Analyzer. If you have any questions or need additional information, please contact your local technical support provider or distributor.

1) I have read and understood this Urgent Field Safety Notice — Yes ☐ No ☐

2) I have informed the medical doctors responsible for clinical interpretation of the Alere Afinion™ ACR test results and patients follow up. — Yes ☐ No ☐

3) I have successfully upgraded the Alere Afinion™ 2 Analyzer(s) in my lab/organization with the new software 21.02.

Alere Afinion™ 2, Serial Number	Upgrade completed
	Yes ☐ No ☐
	Yes ☐ No ☐

4) Has any affected device been transferred to other organizations? Yes ☐ No ☐

If yes to question 4:

5) I have alerted and passed this information including a USB stick for upgrade of the transferred device to the other organization. Yes ☐ No ☐

Name and title of person completing questionnaire:	Signature:
Customer number:	Telephone: E-mail:
Institution:	Department:
Street: Postal code:	City: Country: