

Urgent Field Safety Notice Afinion™ CRP system

Affected products:

Afinion™ AS100 Analyzer	REF 1115027, 1115173, 1115174, 1115176, 1115172, 1115175, 1115507, 1115419, 1115516
Afinion™ CRP	REF 1115013, 1115014, 1115377
Afinion™ CRP Control	REF 1114993

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Attention: Customers within EU/EEA, Turkey and Switzerland.

FSCA-identifier: MP12/1086

Warning about possible misinterpretation of an information code as a CRP test result and reduced opened vial stability of Afinion™ CRP Control.

1. POTENTIAL MISINTERPRETATION OF INFORMATION CODE

1.1 Description of the problem

Axis-Shield PoC AS, the manufacturer of the Afinion™ CRP system, warns that an information code (error code) which is displayed on the Analyzer screen might potentially be misinterpreted as a high CRP result.

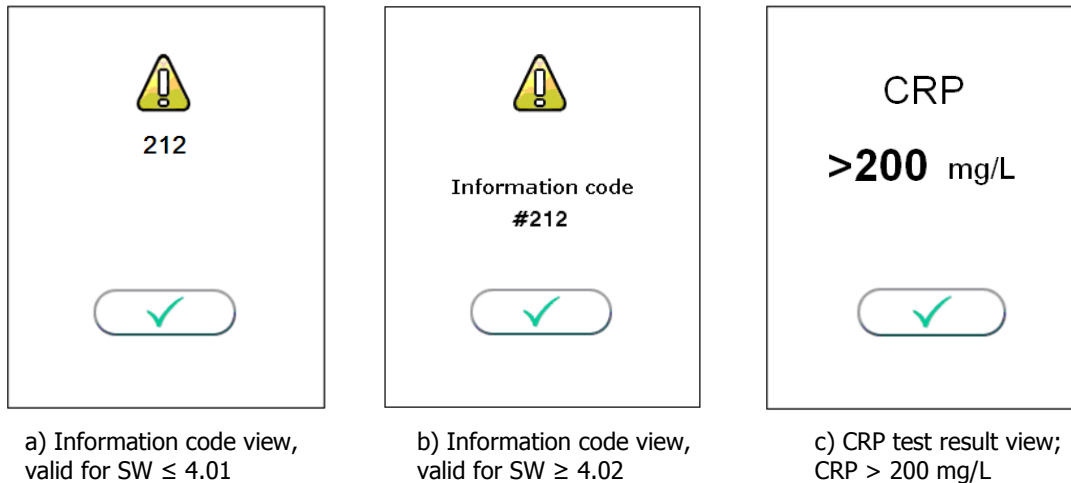
There have been four (4) such reportable incidents since the launch of Afinion™ CRP in 2005 which might have resulted in suboptimal follow-up and treatment of the affected patients.

The analysis of an Afinion™ test cartridge is supervised by the Afinion™ AS100 Analyzer error detection system. In case of a sample or device related error or limitation, an information code is displayed by a 3-digit number (100, 200 or 300 series) along with an alert icon. The possible cause of the information code and the action to take is explained in the Afinion™ AS100 User manual.

1.2 Corrective actions by the manufacturer

To significantly reduce the risk of misinterpreting an information code as an assay result a change in the information code view has been implemented, valid from SW 4.02. The message "Information code" appears in the selected language along with a hash sign (#) and the code number.

Please see the illustration below of the information code view valid for $SW \leq 4.01$ and of the improved information code view valid for $SW \geq 4.02$. In contrast a CRP result > 200 mg/L is illustrated.



1.3 Corrective actions by the user of the Afinion™ CRP system

- 1) Please read the instructions in the Afinion™ AS100 Analyzer User Manual and in the Afinion™ CRP Package Insert to revise how to correctly interpret an information code versus a CRP result.
- 2) The more intuitive information code view, implemented from SW 4.02, will significantly decrease the likelihood of misinterpretation. The Afinion™ Analyzer SW 4.02 is launched by the manufacturer, and the upgrading of the instruments is in progress. You will be contacted by your supplier, if you have not already been contacted, regarding upgrading of your Afinion™ AS100 Analyzer.

2. REDUCED OPENED VIAL STABILITY OF AFINION CRP CONTROL

2.1 Description of the problem

Axis-Shield PoC AS, the manufacturer of the Afinion™ system, warns that the stability of opened vials of Afinion™ CRP Control has been reduced from 8 to 4 weeks. The CRP concentration in frequently opened control vials may increase due to evaporation.

2.2 Corrective actions by the manufacturer

Based on recent in-use stability testing of opened vials, Axis-Shield PoC AS has concluded that the use of an opened vial of Afinion™ CRP Control C I or C II should be limited to 4

weeks. The Afinion™ CRP Control Package Insert has been revised. The new revision number is 1115826 2011-10, packed with lot no. 10156405 and onwards.

2.3 Corrective actions by the user of the Afinion™ CRP system

- 1) Please be aware of the recommended limitation of 4 weeks stability of the opened vials of Afinion™ CRP Control C I or C II.
- 2) Follow the Afinion™ CRP Control recommendations in the Package Insert for handling the controls. See extracts from the Package Insert below:

Opened control vials

- Opened control vials are stable for 4 weeks when stored refrigerated (2-8°C). It is recommended to note the date of opening on the vial label.
- Always store the control vials refrigerated (2-8°C) in an upright position, when not in use.
- The controls can be used directly from the refrigerator without equilibration to room temperature.

Verifying the control results

The measured values should be within the acceptable range stated for the Afinion™ CRP Control C I and Control C II. If the result obtained is outside the acceptable limits, make sure that:

- patient samples are not analysed until control results are within acceptable range.
- the control vial has not passed the expiry date.
- the control vial has not been used for more than 4 weeks.
- the control vial and the CRP test kit have been stored according to recommendations.
- there is no evidence of bacterial or fungal contamination of the control vial.

Correct any procedural error and re-test the control material.

If no procedural errors are detected:

- Re-test the control material using a new control vial.
- Examine the laboratory's quality control record to investigate the frequency of control failures.
- Ensure that there is no trend in out-of-range quality control results.
- Patient results must be declared invalid when controls do not perform as expected. Contact your local supplier for advice before analysing patient samples.

Transmission of this Field Safety Notice

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

Axis-Shield PoC AS confirms that this notice has been notified the appropriate Regulatory Agency in affected member states in EU/EEA, Turkey and Switzerland.

Axis-Shield PoC AS an Alere company

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