Urgent Field Safety Notice
Afinion™ CRP (REF 1115013 and 1115014)

Afinion™ CRP – Intended use

FSCA-identifier NC 013635

Date: 2012-01
Attention: Customers within EU/EEA, Croatia, Turkey and Switzerland.

DESCRIPTION OF THE PROBLEM

Based on recent investigations and customer complaint, Axis-Shield PoC AS has concluded that Afinion™ CRP should not be used with whole blood samples from newborn patients.

UPDATE OF AFINION™ CRP PACKAGE INSERT

The Package Insert will be updated as described below (new text in ***italic/bold***):

Intended use
Afinion™ CRP is an *in vitro* diagnostic test for the quantitative determination of C-reactive protein (CRP) in human whole blood ***except from newborns, in human*** serum and plasma. The measurement of CRP provides information for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Sample material
The following sample materials can be used with the Afinion™ CRP test:

- Capillary blood ~~(from finger prick)~~ ***except from newborns***
- Venous whole blood with anticoagulants (EDTA or heparin) ***except from newborns***
- Serum
- Plasma (EDTA or heparin)
- Afinion™ CRP Control

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 customer/user where the 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.