2.12.2020

URGENT FIELD SAFETY NOTICE

Product name: Actim CRP Date: 2nd December 2020

Product name (catalogue number)	Lot numbers
Actim CRP (31031ETAC)	0044998 and 0045277

Dear Receiver,

The purpose of this letter is to inform you of a recall for product correction for the above products.

Description of the problem

We have observed that in **occasional Actim CRP dipsticks**, the third test line (>80 mg/L) is lighter than specified. This means that the CRP concentrations >80 mg/L can be interpreted as concentrations between 40 and 80 mg/L. This CRP level is already an indication for further testing or treatment and there is not considered to be a risk of health incidence and no extra follow up of patients is needed. To ensure that no false patient results are observed, **we have decided to withdraw the kit lots affected by this problem** (see abowe).

Actions required from receiver

1. Confirm via email that you have received this information.
2. Inform all your customers of this information of withdrawal.
3. Advice your customers to discard the kits that have been withdrawn due to this notification.
4. Asses the number of kits delivered to your customer. Please fill information of all your lots to the "Distributor verification form"
5. Asses the number of kits in your storage. Please fill information of all your lots to the "Distributor verification form"
6. Send sample kit of some of the affected lots for our investigation (if available).
7. Complete "Distributor verification form" and email to Actim actim@actimtest.com latest 15th Dec 2020.

Actim – a part of Medix Biochemica
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Manufacturing site: Noljakantie 13, FI-80130 Joensuu, Finland
actim@actimtest.com
www.actimtest.com
VAT reg.no. FI29540422

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NOTE! The corrective actions are ongoing and the replacing kits might not available immediately.

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 potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersign confirms that this notice has been notified the appropriate National Competent Authorities.

Please accept our sincere apology for all the inconvenience this unfortunate situation brings to you.

If you have any questions or concerns, please do let us know.

Dec 2, 2020 Hanna Kostia

Date and signature

Contact reference person:

Hanna Kostia

Quality System Manager

Actim Oy

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