URGENT FIELD SAFETY NOTICE

Product name: Actim® Partus 1ngeni Date: 9th May 2022

Product name (catalogue number)	**Lot numbers**
Actim Partus 1ngeni (31931RETAL)	2000207

Dear Receiver,

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

Description of the problem

Internal quality control has found that due to an error in the test cassette QR code, the quantitative results will give a false "elevated risk" result for samples that have a phIGFBP-1 concentration below 10 µg/l.

The rootcause of this problem has been found and is currently being addressed.

Actim Partus 1ngeni is intended to help predicting the risk of preterm or imminent delivery. Treatment decisions during pregnancy are based on the entire clinical picture of the patient, and are not based on the test result alone. The risk associated with a false "elevated risk" result could be overtreatment with medication or unnecessary hospitalization or transfer of the patients to a higher level hospital, but would not pose a risk to the expecting mother or unborn baby.

In order to avoid the possible false patient results, **we have decided to withdraw the kit lot affected by this problem** (see above).

For the moment, we are not able provide you with new Actim Partus 1ngeni kits for the Actim® 1ngeni instrument. We recommend you to use the visually interpreted, qualitative Actim® Partus (31931ETAL), instead.

Actim – a part of Medix Biochemica
Headquarters: Klovinpellontie 3, FI-02180 Espoo, Finland
Manufacturing site: Noljakantie 13, FI-80130 Joensuu, Finland
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www.actimtest.com
VAT reg.no. FI29540422

Actions required from receiver

1. Confirm via email that you have received this information.
2. Inform all your Actim Partus 1ngeni customers of this information of withdrawal.
3. Advice your customers to discard the Actim Partus 1ngeni kits that have been withdrawn due to this notification.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 kits to the "Distributor verification form"
5. Assess the number of kits in your storage. Please fill information of all your kits to the "Distributor verification form"
6. Complete "Distributor verification form" and email to Actim support@actimtest.com latest 23rd May 2022.

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.

9th May 2022

Contact reference person:

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