URGENT FIELD SAFETY NOTICE

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

Product name (catalogue number)	**Lot numbers**
Actim Partus 1ngeni (31931RETAL)	0046027

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

Our long-term stability testing has shown that the quantitative results of Actim Partus 1ngeni do not fulfill the acceptance criteria. Due to the increased system variation, the result level of Actim Partus 1ngeni test is too low. This means the result may be reported as false "low risk", although the phIGFBP-1 concentration is approximately 10 µg/l. The decrease in result level is moderate, and concentrations at 30 µg/l and higher, are reported correctly as "elevated risk". Thus, patients with clearly elevated phIGFBP-1 concentrations showing the highest risk, are still being identified.

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. Thus, even a false "low risk" test result due to moderate decrease of the result level near the cut-off of the test is not considered to be a risk of health incidence and there is no need for an additional follow-up of the patients that have been tested.

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
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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 Advice your customers to discard the Actim Partus 1ngeni kits that have been withdrawn due to this notification.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. Asses 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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