URGENT FIELD SAFETY NOTICE

Product name: Actim® Partus Date: September 20th, 2024

Product name (catalogue number)	**Lot numbers**
Actim® Partus (31931ETAC)	2005342

Dear Receiver,

The purpose of this letter is to inform you of a withdrawal of the Actim Partus lot mentioned above.

Description of the problem

Our stability testing has shown that the results of Actim Partus — lot 2005342— do not fulfill the acceptance criteria. A risk for non-specific binding has been identified in this lot. The non-specific binding could cause the appearance of a very faint test line in the result window, indicating a false positive result. True positive results are still obtained from samples with elevated concentrations of phIGFBP-1.

To mitigate the risk of false positive patient results, we have decided to withdraw the kit lot 2005342 from the market. As the lot have fulfilled the specifications at earlier testing time points, there is no need for patient follow-up. The root cause analysis is under investigation.

Actim Partus is intended to help assess the risk of preterm or imminent delivery. Treatment decisions during pregnancy must be based on the entire clinical picture of the patient, and not on a test result alone. A false positive result without taking into account the other clinical findings could mislead the clinical decision-making and may cause a risk for overtreatment of the patient.

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

Actions required from the receiver:

1. Confirm via email that you have received this information.
2. Inform all your customers who have received the Actim Partus lot mentioned above about this withdrawal by providing the Field Safety Notice letter. Please use the separately attached word file as a template.
3. Advise your customers to discard the Actim Partus kits that have been withdrawn due to this notification.
4. Assess the number of kits delivered to your customer. Please inform us about your kits in the form "Distributor verification form".
5. Assess the number of kits in your storage. Please inform us about your kits in the form "Distributor verification form"
6. Fill out the "Distributor verification form" and email it to Actim support@actimtest.com by 20.10.2024 the latest.

Transmission of this Field Safety Notice

This notice needs to be shared with all the stakeholders within your organization who need to be aware of it.

The undersigned confirms that this notice is sent to the appropriate National Competent Authorities.

Please accept our sincere apology for any inconvenience this matter might have caused.

Should you have any questions or concerns, please contact the undersigned.

Yours sincerely,

Tiina Vilkkinen

Head of QA and RA

Contact reference person:

Tiina Vilkkinen
Head of QA and RA
Actim Oy
Klovinpellontie 3, FI-02180 Espoo, Finland
Tel. +358 9 547 68 138
Mobile +358 40 7464744
Email: tiina.vilkkinen@actimtest.com
www.actimtest.com

DISTRIBUTOR VERIFICATION FORM

PRODUCT FIELD SAFETY NOTICE

We acknowledge receipt of the Actim Product Field Safety Notice dated September 20th, 2024 for the below product:

Product name: Actim® Partus
Catalogue number: 31931ETAC
Lot number: 2005342

Yes ☐

Date _____

We have advised our customer to discard the kits that have expired due to this notification.

Yes ☐ No ☐

Date _____

Kit lot	Kits in distributor's storage	Kits in customers' storage

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Actim

Authorised signature:
Date:
Print name:
Title:
Company name:
Address:
City:
State:
Postal code:
Country:
Phone:
Email:

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