Abbott Rapid Dx International Ltd
Parkmore E Business Park
Ballybrit, Galway
Ireland, H91 VK7E

Urgent Field Safety Notice (FCA-00000338)

Immediate Action Required

Date Issued

Monday, October 7, 2024

Product

Product Description	Catalog Number	Lot Number
ACTIM® Partus Test	31931ETAL	2005341

Explanation

Abbott Rapid Diagnostics International Limited (RDIL), has received a field safety notification (FSN) from ACTIM Oy, the manufacturer of ACTIM® Partus Test, informing us of a withdrawal of the ACTIM® Partus lot mentioned above, and require RDIL (distributor for the ACTIM® Partus Test) to inform our Distributors and/or Customers of this FSN.

The stability testing has shown that the results of ACTIM Partus — lot 2005341— 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.

Impact on Donor/Patient Results

As per the information from ACTIM Oy, to mitigate the risk of false positive patient results, they have decided to withdraw the kit lot 2005341 from the market. ACTIM Oy, has indicated that as the lot has fulfilled the specifications at earlier testing time points, there is no need for patient follow-up. However, we would recommend that you follow your local protocol regarding the need for review of previously reported patient results. Please seek consultation from your medical advisors where applicable. The root cause analysis is under investigation by ACTIM Oy.

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.

Necessary Actions to be Taken by Distributor / Customer

Please follow the necessary actions below:

If....	Then...
You are currently using or have inventory of impacted lot 2005341.	Discontinue use of and discard any remaining inventory of lot 2005341.

- Determine the quantity of ACTIM® Partus Test (31931ETAL) kits in storage and discard kits for only Lot Number 2005341, in accordance with your quality management systems, and relevant in-country regulatory requirements as applicable.
- If you have forwarded any of the affected kits from the above-mentioned lot to another customer, please provide them with a copy of this communication.
- Follow your local protocol regarding the need for review of previously reported patient results. Please seek consultation from your medical advisors where applicable.
- Please complete the form attached in Appendix I of this document per instructions provided.
- **As a Customer of Abbott, please send the acknowledgement and/or any queries to the Abbott FSN Mailbox (field.safety.notifications@abbott.com)**

Contact Information

If you or any of the health care providers you serve have questions regarding this information, please contact your local area Abbott Customer Service.

Sincerely,

Signed by:
Lovina Nnadi
Signer Name: Lovina Nnadi
Signing Reason: I approve this document
Signing Time: October 7, 2024 | 7:55:22 AM CDT
29B8C933CEFE4F46BFA66DC5D53EF586

Name
Designation
Abbott Rapid Dx International Ltd

Appendix I

Urgent Field Safety Notice Reply Form

I hereby acknowledge that I have received, read, and understood the included Urgent Field Safety Notice for ***ACTIM® Partus Test (31931ETAL) – lot number 2005341*** kits.

☐ We have taken the necessary actions as directed by this Field Safety Notice and have informed all customers that have received the impacted lot ***2005341*** of ***ACTIM® Partus Test (31931ETAL)*** kits.

☐ We acknowledge that this document may be presented to regulatory or administrative bodies globally according to mandatory legislation.

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

Date _____ Name (Printed) _____ Signature _____

Title _____ Department _____

Institution & Address _____

Post/Zip Code _____ City _____

Telephone _____ FAX _____ E-mail _____

Return e-mail to **field.safety.notifications@abbott.com**