Date: 2025-11-07

Urgent Field Safety Notice
AMNIOQUICK CARD
AMNIOQUICK DUO+
Diluent tube contamination – increased risk of false-negative results

For Attention of

Users of the affected devices, heads of departments using the affected devices, and distributors of the affected devices.

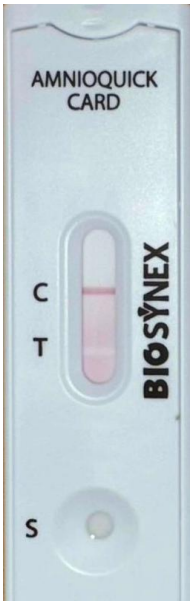
Information on affected devices

Commercial name	Reference	UDI-DI	UDI	Batch number	Expiration date
AMNIOQUICK CARD	1090005	03532678599731	(01)03532678599731 (17)270430 (10)KAC250605	KAC250605	2027-04-30
AMNIOQUICK DUO+	1090004	03532678599724	(01)03532678599724 (17)260630 (10)KAD250106	KAD250106	2026-06-30

These devices are designed to detect rupture of foetal membrane in pregnant women using a vaginal swab sample, in the event of suspected premature rupture of membranes.

Context

Biosynex has received multiple feedback from users indicating difficulties in interpreting the results due to high background noise and the appearance of white ghost (non-colored) bands. Following internal investigations, this issue has been confirmed on certain random diluent tubes.



Reason for the Field Safety Corrective Action

Some diluent tubes included in the kit have been contaminated, which may appear as a color change from colorless to yellowish. This contamination leads to difficulties in the migration of the diluent on the membrane, significantly increases the test's background noise, and causes the appearance of white reactive lines. As a result, there is an increased risk of obtaining a false-negative result with the test, thereby raising the risk of failing to detect a rupture of the fetal membrane in pregnant women.

Actions to be taken by the user

- Immediately stop using the diluent included in the affected device kits.
- Complete and return the attached acknowledgment form no later than **November 19, 2025**. Upon receipt of your duly completed acknowledgment form, Biosynex will replace the diluent tubes.
- Dispose of the diluent tubes and ask for replacement.
- Any negative result in which the test reactive line appears white on a purple background should be considered invalid, as it may correspond to a false-negative result. On the other hand, a negative result without any white "ghost" line shall be considered as negative.
- Please note the following amendment to the Instructions for Use (IFU):
  - The control and test lines must appear colored. Do not interpret a white "ghost" line; consider the result invalid.
  - Do not use a yellow-colored diluent.
- Pending the update of the instructions for use (IFU), a yellow label will be affixed to the kits placed on the market, reminding users of the two precautions mentioned above.
- Please transfer this notice to all personnel who need to be aware within your organization or to any other organization where the potentially affected devices have been distributed.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Actions being taken by Biosynex

Biosynex' investigation is still ongoing to determine the source of the diluent tube contamination.
The affected batches are blocked, and replacement of the defective diluent tubes is underway.
The Instructions for Use (IFU) will be updated in accordance with the information provided above.

Contact details

We apologize for the inconvenience caused. For any request, please contact our Customer Support at +33 3 88 77 57 25 or tech.support@biosynex.com

Attached: Acknowledgment of Receipt Form (Ref. AR_FSN20251103)

Contact details of local representative

Local distributor information to be completed on a case by case basis

The Competent Authority of your country has been informed about this communication to customers.

Acknowledgment of Receipt

Please complete this acknowledgment form and return it to rappel.conso@biosynex.com **before November 19, 2025**.

Acknowledgment of receipt of the urgent safety notice *FSN20251103* regarding the products:

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Full Name:

Email Address:

Company/Institution:

Signature:
(Your signature confirms that you have received and understood this communication)