Strasbourg, November 21st, 2018

To the directors of health establishments, local correspondents for materiovigilance and reactive vigilance, pharmacists and health managers

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Ref.IS001-18

BATCH RECALL

Specificity problem - TODA AMNIODIAG 5 Strip and Cassette (Ref.1052 et 1050)

To whom it concern,

Our batch traceability indicates that you have received one or more boxes of TODA AMNIODIAG 5 STRIP Lot 1805151S and/or 1807061S or TODA AMNIODIAG 5 CASSETTE Lot 1805151 and/or 1807061 expiring respectively in May 2020 and July 2020. These tests allow the detection iGFBP-1, a sign of premature rupture of fetal membranes.

Description and highlighting of the incident

Following an alert from an health facility, we conducted analytical sensitivity and relative specificity studies to determine if the batches in question had a problem that could lead to false positives. Preliminary results of the relative specificity study indicate that, in rare cases (the exact percentage is not yet known to date), the tests could lead to false positives, results related to a problem of specificity of batches 1805151S, 1807061S, 1805151, 1807061.

Consequences on the results

Some tests carried out with the batches in question may give false positives that may lead to possible hospital care.

Required actions

ANSM has been informed of this communication. We kindly ask you to do the following:

- Upon receipt of this letter, please stop using and quarantine batches 1805151S and 1807061S of the device TODA AMNIODIAG 5 STRIP as well as batches 1805151 and 1807061 of the device TODA AMNIODIAG 5 CASSETTE.
- Return us the acknowledgment of receipt below.

TODA PHARMA, 2 rue du Rhin Napoléon – 67000 Strasbourg (France) - Tel : 03 88 24 28 99 - Fax : 03 88 24 38 64
Website: www.todapharma.com – E-mail : info@todapharma.com
RCS : 498 776 830 -APE : 4646Z - lieu de juridiction : Strasbourg - Siret : 498 776 830 000 24 - Code TVA intra communautaire FR 634 987 768 30

Then :

- Set aside the offending devices while waiting for recovery by our company.
- Tell us the quantity of tests to replace by TODA AMNIODIAG 5 CASSETTE Lot: 1811021 Exp: 2020/07 that we will ship to you as soon as possible.

For any other question, contact the Quality department:
qualite@todapharma.com
Telephone : 03.88.24.28.99
Fax : 03.88.24.38.64

Best regards,
Daniel BERROS, Head pharmacist

ACKNOWLEDGMENT OF RECEIPT OF SECURITY INFORMATION

Form of reception and taking into account

Obligatory answer

TODA AMNIODIAG 5 STRIP tests (Batch 1805151S, 1807061S) and
TODA AMNIODIAG 5 CASSETTE tests (Batch 1805151 et 1807061)

I have read and understood the IS001-18 security information above, as well as the batch recall instructions.

Date : ……...

First and last name : ……

Information on the tests concerned :

Product name	Product reference	Batch number	Quantity in stock to return (**number of unit tests**)
Toda Amniodiag 5 Strip	1052	1805151S	
Toda Amniodiag 5 Cassette	1050	1805151	
Toda Amniodiag 5 Strip	1052	1807061S	
Toda Amniodiag 5 Cassette	1050	1807061	

Supplementary comment :

PLEASE TRANSMIT THIS COMPLETE FORM BY MAIL AT qualite@todapharma.com OR BY FAX AT 03.88.24.38.64 TO THE ATTENTION OF THE QUALITY DEPARTMENT

Custumer name / position :
Telephone :
Email :
Client's signature :