EURO DIAGNOSTICA

Urgent Field Safety Notice

Commercial name of the affected product: DIASTAT ANA ELISA kit lot no TS 2076
FSCA-identifier: 2017-02-15
Field Safety Corrective Action/ Recall: destruction of IVD kit

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Date: 2017-02-15

Details of affected in vitro diagnostic product:

Product name: DIASTAT ANA ELISA
Product code: FANA 200
Lot No: TS 2076

Description of the problem:

The reason for this field safety notice is that the affected kit lot TS 2076 of DIASTAT ANA ELISA is at risk of malfunctioning due to an unstable conjugate. Testing of retained material at Euro Diagnostica with a sample panel from healthy donors showed that there was an increased risk for equivocal sample results with the ANA lot TS 2076. Investigation suggests that the lgG conjugate is unstable over time. The shelf-life of the product cannot be guaranteed. There is a risk that users get false positive test results. This may not cause a safety risk to patients, but is a product malfunction. However, based on product information to customers, there is a risk that treatment may be started based on a false positive result, which could be critica! for patient health and safety.

Based on the above information it has been decided that ANA200 lot TS2076 is to be recalled to avoid risk to patient health and safety.

Advice on action to be taken by the user:

Confirmation form to be sent back to the manufacturer (destruction of IVO kit).

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected In vitro diagnostic product lot has been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

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… On behalf of
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