Alere Toxicology Plc
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Abingdon Business Park
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office +44 (0)1235 861 483
fax +44 (0)1235 835 607

17th September 2018

Urgent Field Safety Notice

Details on affected device:

Product Name: Alere DDS®2 Test Kits
Product Code: DDS2-403, DDS2-404, DDS2-407 and DDS2-412
LOT Numbers: All
Type of Action: Label Correction

Dear Valued Customer,

This notice contains essential information regarding a change to cross-reactivity values detailed in the Instructions for Use provided with Alere DDS®2 Test Kits (DDS2-403, DDS2-404, DDS2-407 and DDS2-412).

Description

Alere Toxicology Plc is issuing an Urgent Field Safety Notice for Alere DDS®2 Test Kits (DDS2-403, DDS2-404, DDS2-407 and DDS2-412). An internal investigation has confirmed that cross-reactivity data for the Amphetamine (AMP) and Methamphetamine (MAMP) assays detailed in the Instructions for Use (IFU), is incorrect or required further clarification.

Changes are detailed in the tables below. Note: Methamphetamine and Amphetamine can be found in two stereoisomers and therefore data has been amended to individually detail the cross-reactivity for the two forms of these drugs.

1. S form (Meth) amphetamine (Dextro (meth) amphetamine).
2. R form (Meth) amphetamine (Levo (meth) amphetamine).

AMPHETAMINE	**Lowest concentration cross-reactivity on AMP assay observed (ng/mL)**	
Crossreagente	**Current IFU**	**Amended IFU**
Methamphetamine	No cross-reactivity at 100.000	S Methamphetamine: **100,000** R Methamphetamine: **100,000**
Amphetamine	50	S Amphetamine: **50** R Amphetamine: **5,000**
MDMA	100,000	**10,000**

METHAMPHETAMINE	**Lowest concentration cross-reactivity on MAMP assay observed (ng/mL)**	
Crossreagente	**Current IFU**	**Amended IFU**
Methamphetamine	50	S Methamphetamine: **50** R Methamphetamine: **1,000**
Amphetamine	No cross-reactivity at 100,000	S Amphetamine: **6,000** R Amphetamine: **50,000**
MDA	100,000	**10,000**
Ranitidine	100,000	**5,000**

Continued reference to the IFU cross-reactivity data in the current IFU (without confirmation testing) could result in false positive reporting of the presence of Amphetamine or Methamphetamine in donor samples.

Note 1: All DDS®2 test kits continue to perform according to specification and can be used as normal. There are no changes to cut off values detailed in the IFU.

Note 2: We are also taking the opportunity to remove MDEA and LAAM from the cross-reactivity table as these drugs are no longer prevalent in routine sample analysis.

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Risk to health

The Alere DDS®2 Test Kit is intended to be used in conjunction with the Alere DDS®2 mobile Analyser, to screen for the presence of Drugs of Abuse and/or their metabolites in oral fluid. In workplace or law enforcement applications a false positive result may lead to inappropriate actions being enacted against the donor. In Drug Treatment applications a false positive result may lead to the donor treatment pathway being incorrectly assessed or delayed. This scenario can only occur when the following two conditions both exist.

1. Donor has taken either prescribed or non-prescribed/illicit version of cross reacting drug in sufficient quantity to cause a cross reaction in the assay.
2. Organisation performing the testing does not follow IFU and does not confirm positive results with an appropriate confirmatory method.

The IFU Limitations section details the following requirements:

- Confirm positive results using a more specific alternative method; GCMS or LCMS is preferred.
- These results should not be used in isolation to change patient treatment or make a clinical decision.

For the reasons given above we consider the risk to health to be low.

The Medicines and Healthcare Regulatory Agency (MHRA) has been informed of this Field Safety Corrective Action.

Customer actions

- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- Requirement for review of reported test results should be determined by the appropriate technical expert.
- Please check your records for the Alere DDS®2 test Kit IFU (Ref: APOC0200 Ed.6b). Destroy this IFU and replace with IFU Ref: APOC0200 Ed.7a. Available at: www.aleretoxicology.co.uk/en/home/products-services/drug-testing/products/dds2.html/#tab3.
- Please complete and mail the enclosed Verification Form within 10 days to confirm your receipt of this Notice.

Should you have any questions about the information contained in this notification, please contact:

Product Support Team, Alere Toxicology Plc, 21 Blacklands Way, Abingdon Business Park, Abingdon OX14 1DY, UK
+44 (0)1235 443 291 | toxeu.productsupport@alere.com

We appreciate your urgent attention to this matter and apologise for any inconvenience this may have caused.

Yours sincerely,

Martyn Rogers
Head of Quality Assurance and Regulatory Affairs, Alere Toxicology Plc

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Verification Form

Alere DDS®2 Test Kit (DDS2-403, DDS2-404, DDS2-407 and DDS2-412)

Please complete this form and EMAIL BACK to Alere Toxicology Plc Product Support.

1. I have read and understood the Urgent Field Safety Notice regarding the Alere DDS®2 Test Kits (DDS2-403, DDS2-404, DDS2-407 and DDS2-412) issued by Alere Toxicology Plc on 17th September 2018.
2. I confirm that all areas where the IFU could be located have been checked.
3. SELECT ALL STATEMENTS THAT APPLY:

☐ WE DO NOT USE the products listed.

☐ Product is redistributed to another team/organisation; we forwarded a copy of this Urgent Field Safety Notice to that team.

☐ We have the affected products/IFU. We have read and understood the Urgent Field Safety Notice and amended our records.

PERSONAL INFORMATION (*DENOTES MANDATORY FIELD)	
Printed name*:	Title*:
Signature*:	Date*: ☐☐/☐☐/☐☐☐☐
Telephone*:	Address*:
Email:	
Company name*:	

Please complete and return this form within 10 business days of receipt.

Email: toxeu.productsupport@alere.com | Send