

Urgent Field Safety Notice

24 June 2019

Details on Affected Device:

Product Name: Alere DDS[®]2 Test Kits
Product Code: DDS2-403; DDS2-404
LOT Numbers: DOA8090241, DOA8110433, DOA8090264, DOA8090253, DOA8090242
Type of Action: Device Removal

Dear Valued Customer,

This notice contains essential information regarding a Field Safety Corrective Action for specific LOTs of Alere DDS[®]2 Test Kits.

Description

Alere Toxicology Plc is issuing an Urgent Field Safety Notice for Alere DDS[®]2 Test Kits DDS2-403 and DDS2-404, LOTs detailed below. An internal investigation has identified that test performance may deteriorate over time with the potential to produce anomalous results. Continued use of these LOTs (without confirmation testing) could result in false positive reporting of the presence of Cocaine in donor samples.

Note: 5 LOTs of product are implicated in this Field Action. Two have been confirmed as **not** performing to specification (Table 1). The additional 3 LOTs (Table 2) are currently performing to specification however, as there is the potential for future performance issues based on our internal investigation, we have taken the precautionary action to also remove these from the market.

Table 1: LOTs with confirmed performance (false positive) issue.

Product code	LOT
DDS2-403	DOA8090241
DDS2-403	DOA8110433

Table 2: LOTs involved in precautionary action.

Product code	LOT
DDS2-404	DOA8090264
DDS2-404	DOA8090253
DDS2-403	DOA8090242

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. Correct use of the 'Instructions for Use' (IFU) will ensure the correct result is returned by utilising a confirmation step.

The IFU Limitations section details the following requirements:

- Confirm positive results using a more specific alternative chemical 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 products Regulatory Agency (MHRA) has been informed of this Field Safety Corrective Action.

Customer Actions

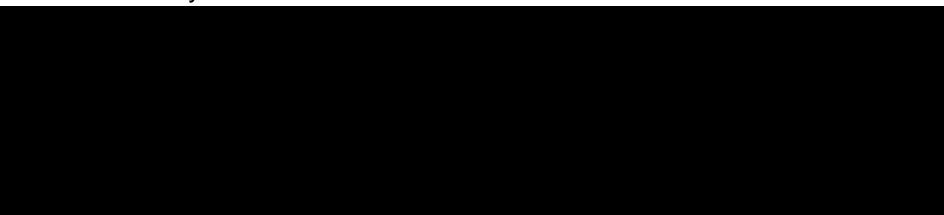
- Provide this notice to all those who need to be aware within your organisation or to any organisation where the potentially affected LOTs have been transferred.
- Check inventory and destroy all stock of implicated LOTs. Record details on verification form.
- Requirement for review of reported test results should be determined by the appropriate technical expert.
- 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 or replacement product, please contact:

Product Support Team, Alere Toxicology Plc, 21 Blacklands Way, Abingdon, Oxfordshire, OX14 1DY, UK
T: +44 (0)1235 443 291, Email: tox.eu.productsupport@alere.com

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

Yours Sincerely



Verification Form

Alere DDS[®]2 Test Kits (DDS2-403 & DDS2-404)

Please complete this form and EMAIL BACK to Alere Toxicology Plc Technical Services at: toxeu.productsupport@alere.com

1. I have read and understood the Urgent Field Safety Notice regarding the Alere DDS[®]2 Test Kits (DDS2-403 and DDS2-404) issued by Alere Toxicology Plc on 24 June 2019.
2. I confirm that all areas where the product could be located have been checked.
3. SELECT ALL STATEMENTS THAT APPLY:

- WE DO NOT USE the products listed.
- The product was redistributed to another team/organization and we have forwarded a copy of this Urgent Field Safety Notice to the appropriate contact.
- We have the affected products and have completed the inventory details below.

We have read and understood the Urgent Field Safety Notice and taken appropriate action.

Local inventory details

Product Code	LOT numbers	Number of test cartridges destroyed

Signature*	Title*
Printed name*	Date*
Telephone*	Email
Company name*	Address*

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

*Denotes MANDATORY field