



Abbott Toxicology Limited
21 Blacklands Way
Abingdon Business Park
Abingdon, Oxford
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Product Notification

PRODUCT NAME: SoToxa™ Oral Fluid Test Kit
PRODUCT CODE: TOX403FWO
LOT NUMBERS: DOA3042002

Date: 11 December 2023

Dear Valued Customer,

Abbott Toxicology Ltd is issuing a Product Notification for various LOTS of **SoToxa Oral Fluid Test Kit (TOX403FWO)**. An internal investigation has identified that Cannabis (THC) test performance may deteriorate over time with the potential to produce false positive THC results at a rate greater than that detailed in the performance specification claim.

The following LOTS are impacted by this notification

PRODUCT CODE	LOT	EXPIRY
TOX403FWO	DOA3042002	30/11/2024

Please note that no impact to the other analytes on the drug panels has been identified and therefore results for the following are not affected: Cocaine (COC); Opiates (OPI); Methamphetamine (MAMP); Amphetamine (AMP) and Benzodiazepines (BZO).



POTENTIAL IMPACT

The SoToxa Oral Fluid Test Kit is intended to be used in conjunction with the SoToxa Oral Fluid Mobile Analyser, to screen for the presence of Drugs of Abuse and/or their metabolites in oral fluid.

A false positive screening result may lead to an inappropriate donor decision in situations where the instructions for use (IFU) is not followed and laboratory confirmation of SoToxa THC positive results is not completed.

When confirmation analysis is completed as per the IFU then the risks associated with this issue are low.

The IFU Limitations sections details the following requirements:

TOX403FWO

This assay is for professional (forensic) use only and provides a preliminary analytical test result

Confirm positive results using a more specific alternative chemical method; GC-MS or LC-MS is preferred.

CUSTOMER ACTIONS

- Provide this notice to all those who need to be aware within your organisation or to any organisation where these LOTs have been transferred or used.
- Follow the instructions for use (IFU) to perform laboratory confirmation when a SoToxa THC positive result is obtained.
- Requirement for review of previously reported test results should be determined by the appropriate technical expert.
- Complete and email the enclosed Verification Form within 10 days of your receipt of this Notice to field.safety.notifications@abbott.com.

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

field.safety.notifications@abbott.com

Please be assured that this issue has been investigated thoroughly and corrective actions have been implemented to prevent recurrence in the future. We appreciate your urgent attention to this matter and apologise for any inconvenience this may have caused.



Sincerely,

A handwritten signature in black ink, appearing to read 'M. Rogers'.

Martyn Rogers
Director of Quality Assurance and Regulatory Affairs



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VERIFICATION FORM

SoToxa™ Oral Fluid Test Kit (TOX403FWO)

Please complete this form and **email back** to Abbott at:
field.safety.notifications@abbott.com

I have read and understood the Product Notice regarding the SoToxa (TOX403FWO) issued by Abbott Toxicology Ltd on 11 December 2023.

SIGNATURE*	TITLE*
PRINTED NAME*	DATE*
TELEPHONE*	EMAIL*
COMPANY NAME*	ADDRESS*

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