Abbott

SoToxa™

ORAL FLUID
TEST KIT

EN INSTRUCTIONS FOR USE

FOR FORENSIC USE ONLY

REF TOX403FUO

INSTRUCTIONS FOR USE

FOR FORENSIC USE ONLY

Important: Please read these instructions for use in full before using the test kit.

KIT CONTENTS

- 25 x SoToxa™ Test Cartridge
- 25 x SoToxa™ Oral Fluid Collection Device
- 1 x Instructions for Use

INTENDED USE

The SoToxa™ Test Kit is intended for the collection and testing of oral fluid in conjunction with the SoToxa™ Mobile Test System for screening for the presence of drugs of abuse and/or their metabolites in oral fluid.

A positive test result should be confirmed by a second test method such as GC-MS (gas chromatography-mass spectrometry) or LC-MS (liquid chromatography-mass spectrometry).

The product is for forensic use only. It is not for home use or for use within a therapeutic, clinical or workplace setting.

PRINCIPLE OF THE TEST

The SoToxa Mobile Test System consists of the SoToxa™ Mobile Analzyer and accessories, which are to be used in conjunction with the SoToxa Test Kit. The test kit consists of the disposable SoToxa™ Test Cartridge, containing test reagents, and the SoToxa™ Oral Fluid Collection Device.

To carry out a test, the test cartridge is first inserted into the analyzer. Oral fluid is then collected using the collection device. Once the sample indicator starts to turn blue, sufficient oral fluid for analysis has been collected. The collection device is then inserted into the test cartridge.

The sample flows by capillary action along the test strip, carrying with it labelled anti-drug antibody. At designated zones on the strip, drug protein conjugate has been applied in bands which are invisible to the human eye. In the absence of a drug in the sample, the anti-drug antibody will bind to the drug protein conjugate to form a line. In the presence of a drug the formation of this complex will be diminished, forming a weaker line. The run time for the test cartridge is indicated by the countdown timer displayed on the analyzer screen.

A procedural control is included in the test cartridge which confirms sufficient sample volume, adequate membrane wicking and correct procedural technique. The absence of a line in the control position will indicate the test results are invalid. This will be detected by the analyzer and reported as a test error.

The analyzer interprets the line intensity on the test strips which is compared with a predetermined threshold derived from concentration curves, to report qualitative results. Upon completion of the test, the results are displayed and can be printed if required. The test cartridge can then be removed.

STORAGE AND STABILITY OF TEST KIT

Store all contents at 59°F to 77°F (15°C to 25°C). Do not freeze.

The reagents in the test kits are stable until the expiration date indicated on the packaging. The test cartridge shelf life is also indicated within the test cartridge barcode, which the analzyer will read on insertion. If the test cartridge is not within expiration date, the analyzer will not proceed with the test and will notify the operator that the test cartridge is expired.

PRECAUTIONS

- The test kit is for forensic use only. It is not for home use or for use within a therapeutic, clinical or workplace setting.
- DO NOT use the test cartridge or oral fluid collection device after the expiration date printed on the pouch label.
- DO NOT open the foil pouch until ready to test.
- DO NOT use the kit if the collection device, test cartridge or their packaging is marked, wet, dirty or damaged.
- DO NOT pull the test cartridge apart.
- DO NOT use the test cartridge if the silica gel pack within the foil pouch is green; the crystals should be yellow.
- DO NOT use the test cartridge if the silica gel pack within the foil pouch is missing or has burst.
- DO NOT use oral fluid collection device if indicator shows blue or has started to turn blue.
- DO NOT ingest the silica gel pack.
- DO NOT leave donor unobserved during sample taking.
- DO NOT use the test cartridge if it has been dropped on the floor after removal from the foil pouch.
- We advise wearing protective gloves throughout the sample collection and testing process, as the specimen is a bodily fluid and should be considered potentially infectious.
- DO NOT allow the donor to chew or suck the collection device.
- DO NOT place the collection device in the mouth after it has been in contact with the sample buffer solution contained within the test cartridge.
- The test cartridge and collection device are designed for single use only and should be discarded in accordance with local or federal regulations.
- Ensure the analyzer is kept horizontal and as still as possible following insertion of the cartridge.
- DO NOT remove the collection device from the test cartridge.
- Only remove the test cartridge at the end of the test, when prompted. When removing the test cartridge, the underside of the cartridge may be hot. Handle the test cartridge by the edges.

Hazard information for the components is as follows:

Test Conjugate Pad: H319: Causes serious eye irritation.

Buffer: Warning: Contains methanol.

H371:
May cause damage to organs.

- Precautionary statement: If exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
- Please note each test cartridge contains 1.3mL of buffer containing methanol.
- Safety Data Sheet (SDS) is available on request.

SAMPLE COLLECTION

- A sample should be obtained using the SoToxa Oral Fluid Collection Device.
- Following oral fluid collection bet practices, we recommend no eating, drinking or smoking 10 minutes prior to sample collection as this reduces the risk of contaminants impacting the test result.
- The donor must collect their own sample.
- If the sample presence indicator within the collection device has not started to turn blue after 5 minutes, then the collection should be ceased. A new collection should be performed with a new collection device after at least a 10 minute waiting period to allow for donor oral fluid to refresh.
- The sample should be processed immediately.

SOTOXA TEST PROCEDURE

A SET UP THE CARTRIDGE

1. Press the **power button** to switch the analzyer on. Wait for the initializing process to complete.
2. Remove a new **test cartridge** from its foil wrapper.
3. Check that the **silica gel pack** is present, intact and is yellow.
   If the silica gel is missing, open or is green, discard the test and start again with a new cartridge.
   Report the problem to Technical Support.
4. When prompted by the analyzer screen, insert the test cartridge.
   The analyzer will check that the cartridge is valid.
   ⚠ Make sure to keep the analyzer **horizontal** and **still** at all times.

B COLLECT THE DONOR SAMPLE

5. Ask the **donor** to unwrap a new **collection device** from the packaging.
   Ensure that they hold the collection device by the plastic stem, and then place it in the mouth.
6. The sample donor must actively swab the collection device around **gums**, **tongue** and **inside the cheek**.
7. Continue swabbing until the sample presence indicator **starts to turn blue**.

C RUN THE TEST

8. Insert the **collection device** into the **test cartridge** (in the analyzer).
   Gently push all the way into the cartridge to the **stop position**.
9. The analyzer will now test the sample. The test time will be displayed on the screen.
   Make sure to keep the analyzer **horizontal** and **still** at all times.
10. The results will be displayed on the analyzer screen. If it has been enabled, a donor questionnaire will begin after pressing 'OK'. If required, the results can be printed.
11. Please ensure that the printer is connected to the analyzer and has been **switched on** before printing.
    To skip this step press 'NO'.
12. The test cartridge and collection device can now be removed from the analyzer.*
    Remove by holding the sides of the test cartridge and pull gently. Do not attempt to pull the collection device or remove from the test cartridge.

    * Take care when removing the test cartridge as the underside of the cartridge may be hot.
    Handle the test cartridge by the side edges.

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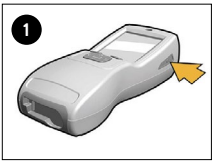
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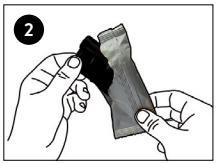
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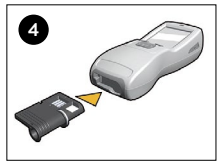
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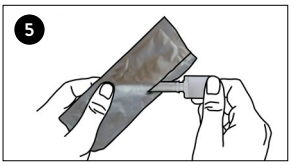
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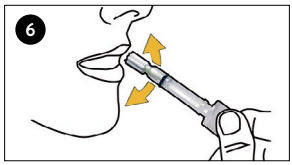
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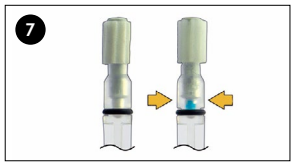
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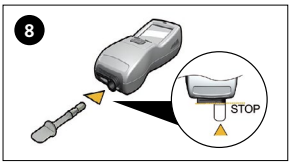
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STOP


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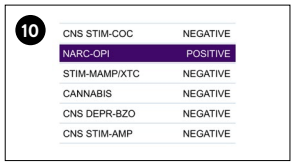
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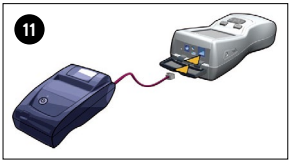
CNS STIM-COC NEGATIVE
NARC-OPI POSITIVE
STIM-MAMP/XTC NEGATIVE
CANNABIS NEGATIVE
CNS DEPR-BZO NEGATIVE
CNS STIM-AMP NEGATIVE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OPERATING CONDITIONS

The operational temperature for running a test is between 41°F to 95°F (5°C to 35°C). Test cartridges must not be at 23°F (-5°C) for more than 10 minutes. Tests must be run in non-condensing humidity levels between 20 to 80%.

CUTOFF LEVELS			
Drug Class	**Abbreviation**	**Target Drug**	**Cutoff (ng/mL)**
Amphetamine	AMP	(S) Amphetamine	50
Benzodiazepines	BZO	Temazepam	20
Cannabis (THC)	THC	Δ^9THC	25
Cocaine metabolite	COC	Benzoylecgonine	30
Methamphetamine	MAMP	(S) Methamphetamine	50
Opiates	OPI	Morphine	40

INTERPRETATION OF RESULTS

Interpretation is carried out by the analzyer, which will display either a negative, positive or invalid result for the drugs which have been tested.

Negative: This indicates that the drug concentration in the oral fluid sample is below the designated cutoff level for that specific drug.

Positive: This indicates that the drug concentration in the oral fluid sample exceeds the designated cutoff level for that specific drug.

Invalid: A result could not be provided for that specific drug.

LIMITATIONS

1. This assay is for forensic use only and provides a preliminary qualitative analytical test result.
2. Confirm positive results using a more specific alternative chemical method; GC-MS or LC-MS is preferred.
3. It is possible that technical or procedural errors, as well as other interfering substances in the oral fluid sample may cause erroneous results.
4. This assay is for the analysis of oral fluid samples only collected by the SoToxa Oral Fluid Collection Device. Testing with other sample types may not give valid results.
5. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in the oral fluid.
6. A negative result may not necessarily indicate drug-free oral fluid. Negative results can be obtained when a drug is present but below the cutoff level of the test.
7. The test does not distinguish between illegal and prescription use.

TECHNICAL SUPPORT

For product technical support and advice, please refer to:
abbott.com/roadside

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Abbott Toxicology Ltd
21 Blacklands Way, Abingdon,
Oxfordshire OX14 1DY, UK
+44 (0)1235 443 291 | toxeu.productsupport@abbott.com | abbott.com/toxicology