For in vitro diagnostic use.

T-Cube® One Step Oral Fluid Drug Test offers qualitative detection of the following drugs and their metabolites in human oral fluid at specific cut-off levels for use in conjunction with immunoassays approved for use with fluids from this source (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Opiate (OPI), Oxycodone (OXY) and Phencyclidine (PCP).

**Intended Use**

T-Cube® One Step Oral Fluid Drug Test is a rapid oral fluid screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human oral fluid at the cut off concentrations for use in employment and insurance testing.

**PRINCIPLE**

T-Cube® One Step Oral Fluid Drug Test is a competitive immunoassay test for the screening of drugs in oral fluid. It is a chromatographic absorbent device in which drug or metabolite is a sample competitor to a limited number of antibody-conjugate binding sites.

When the sample and the collector is immersed in the oral fluid sample, the sample is absorbed into the device by capillary action, mixes with the antibody-conjugate and, diffuses across the permeable membrane. If drug or metabolite is present, a colored band will appear in the corresponding test zone.

**SPECIMEN COLLECTION AND PREPARATION**

1. Avoid placing anything in the mouth 10 minutes prior to testing.
2. Allow the kit and specimen to come to room temperature (65°F -86°F/18°C-30°C) prior to testing. AVOID PLACING ANYTHING IN THE MULTIPACK 15 MINUTES PRIOR TO TESTING.
3. Remove the T-Cube test and the sponge collector from the pouch. If the pouch is punctured or not sealed, do not use the test.
4. Do not use the test if the pouch has been opened more than once.
5. Preferably open the pouch only shortly before collection and testing.
6. Do not read results after 5 minutes.

**TEST PROCEDURE**

Allow the kit and specimen to come to room temperature (65°F-86°F/18°C-30°C) prior to testing. AVOID PLACING ANYTHING IN THE MULTIPACK 15 MINUTES PRIOR TO TESTING.

1. Remove the T-Cube test and the sponge collector from the pouch by tearing the pouch along the notch. Place the test cube upright on a level surface.
2. Put the sponge end of the collector on your tongue or near cheek to collect oral fluid for 5-10 seconds. Discard the used sponge collector. When the last drop of oral fluid has reached the bottom of the test strip, gently close the lid. Keep test cube upright on flat surface and follow Step 3.
3. Discard after first use. The test cannot be used more than once.
4. Do not use the test if the pouch is punctured or not sealed.

**INTERPRETATION OF RESULTS**

**Negative (-)**

A colored band is visible in the Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

**Positive (+)**

A colored band is visible in the Control Region (C), no color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

**Quality Control**

Though there is an internal procedural control line in the test device of Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm test procedures and verify procedural performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same procedural steps should be adopted.

**SPECIMEN COLLECTION AND PREPARATION**

Collect the oral fluid sample using the sponge collector provided. Insert the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 5 minutes of collection. Oral fluid collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

**QUALITY CONTROL**

The following table lists the concentration of compounds (ng/mL) above which T-Cube® One Step Oral Fluid Drug Test identified positive results at the read time of 5 minutes.

**A. Analytical Sensitivity**

Standard drugs were spiked into negative PBS pool to the concentration of 0% Cut-off, -25% Cut-off, -50% Cut-off, -75% Cut-off, -100% Cut-off, and +50% Cut-off. The results were summarized below.

**B. Analytical Specificity**

The following table lists the concentration of compounds (ng/mL) above which T-Cube® One Step Oral Fluid Drug Test identified positive results at the read time of 5 minutes.
A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following components show no cross-reactivity when tested with T-Cube® One Step Oral Fluid Drug Test at a concentration up to 100 µg/mL.

Acetaminophen
Acetaminophenol
Acetaminophenol N-Acetylpamapramide
Acetaminophenol N-Acetylprocainamide
Acetaminophenol Acetophenetidin
Acetaminophenol Loperamide
Acetaminophenol N-Acetylprocainamide
Acetaminophenol Meprobamate
Acetaminophenol Aminopyrine
Acetaminophenol Labetalol
Acetaminophenol Amoxicillin
Acetaminophenol Meperidine
Acetaminophenol Ampicillin
Acetaminophenol Ascorbic Acid
Acetaminophenol Methylphenidate
Acetaminophenol Apomorphine
Acetaminophenol Nalidixic Acid
Acetaminophenol Aspartame
Acetaminophenol Naloxone
Acetaminophenol Atropine
Acetaminophenol Niacinamide
Acetaminophenol Benzphetamine
Acetaminophenol Nifedipine
Acetaminophenol Cholesterol
Acetaminophenol (±) Chlorpheniramine
Acetaminophenol Clonidine
Acetaminophenol Cortisone
Acetaminophenol Dexamethasone
Acetaminophenol Chlordane
Acetaminophenol D,L-Brompheniramine
Acetaminophenol Dioctylsulfosuccinate
Acetaminophenol 1,2-Epoxyethylene
Acetaminophenol Ethyl 4-aminobenzoate
Acetaminophenol Ethylmorphine
Acetaminophenol Ethylmorphine
Acetaminophenol Ethylmorphine
Acetaminophenol Ethylmorphine
Acetaminophenol Ethylmorphine
Acetaminophenol Ethylmorphine

INDEX OF SYMBOLS

- Keep away from sunlight!
- Store between 4°C - 30°C (39°F - 86°F)
- Keep dry
- Do not re-use

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BIBLIOGRAPHY OF SUGGESTED READING

