Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and has been abused via intranasal, sublingual, and injection routes.

The Buprenorphine assay contained within the Swab Cube™ Oral Fluid Drug Screen Device yields a positive result when the Buprenorphine concentration in oral fluid exceeds 10 ng/mL.

**PRINCIPLE**

The Swab Cube™ Oral Fluid Drug Screen Device for AMP/HPP/AMP/COC/THC/BZO/OXY/M/MDM/BAR/BUP is an immunochromatographic assay for the qualitative detection of AMP, HPP, AMP/COC/THC/BZO/OXY/M/MDM, BAR and BUP in oral fluid. The assay employs a monoclonal antibody specific for the drug or its metabolite immobilized on the test strip and a monoclonal antibody specific for the drug or its metabolite conjugated to colloidal gold. A positive test result is obtained when the drug is present in oral fluid and binds with the monoclonal antibody on the test strip. The test does not measure the concentration of the drug.

**PRESERVATION**

The oral fluid specimen should be collected with the provided collection device. The device contains a dextran matrix which binds the drug of abuse and preserves it in the specimen for up to 10 minutes.

**SPECIMEN COLLECTION AND PREPARATION**

To prepare the specimen, proceed as follows:

1. Remove the device from the sealed pouch and use it as soon as possible after opening.
2. Store the test device at room temperature [15°C - 30°C (59°F - 86°F)] prior to testing. Do not place anything in the sample cup. Allow the test device to reach room temperature before use.
3. Andrews 30 mL saliva collection medical grade collection cup.
4. Bring the pH to normal temperature before opening. Remove the test from the sealed pouch and use it as soon as possible after opening.
5. Place the Swab Cube™ Oral Fluid Drug Screen Device into the 30 mL saliva cup. Insert the Swab Cube™ Oral Fluid Drug Screen Device into the saliva cup. Seal the saliva cup and gently chew the sponge for saliva excretion. Soak sponge into saliva for a total of 3 minutes until the salivary fluid specimen is obtained. The test is invalid if the saliva is not saturated. (Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube does not saturate, then the test is invalid.)

**STORAGE AND STABILITY**

The oral fluid specimen should be stored under sealed conditions at room temperature for a period of 24 months.

**MATERIALS**

• Swab Cube™ Oral Fluid Drug Screen Device

**DIRECTIONS FOR USE**

Allow the test device to reach room temperature [15°C-30°C (59°F-86°F)] prior to testing. Do not place anything in the sample cup. Allow the test device to reach room temperature before use.

1. Opening the Swab Cube™ Oral Fluid Drug Screen Device will ensure the test is valid.
2. Remove the test device from the sealed pouch and use it as soon as possible after opening.
3. Andrews 30 mL saliva collection medical grade collection cup.
4. Bring the pH to normal temperature before opening. Remove the test from the sealed pouch and use it as soon as possible after opening.
5. Place the Swab Cube™ Oral Fluid Drug Screen Device into the 30 mL saliva cup. Insert the Swab Cube™ Oral Fluid Drug Screen Device into the saliva cup. Seal the saliva cup and gently chew the sponge for saliva excretion. Soak sponge into saliva for a total of 3 minutes until the salivary fluid specimen is obtained. The test is invalid if the saliva is not saturated. (Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube does not saturate, then the test is invalid.)

**PROCEDURE**

1. Andrews 30 mL saliva collection medical grade collection cup.
2. Place the Swab Cube™ Oral Fluid Drug Screen Device into the 30 mL saliva cup. Insert the Swab Cube™ Oral Fluid Drug Screen Device into the saliva cup. Seal the saliva cup and gently chew the sponge for saliva excretion. Soak sponge into saliva for a total of 3 minutes until the salivary fluid specimen is obtained. The test is invalid if the saliva is not saturated. (Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube does not saturate, then the test is invalid.)

**INTERPRETATION**

A positive test result is obtained when the drug is present in oral fluid and binds with the monoclonal antibody on the test strip. The test does not measure the concentration of the drug.
A new test device. If the problem

VALID: A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

NEGATIVE: Two color lines appear. One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

Two lines appear. * One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates a drug-free specimen. Drug may be present in the specimen below the off level of the assay.

Drug concentration (ng/mL) above which the test will react to a positive result when tested with concentrations up to 100 µg/mL.

INTERFERENCE: A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off level of the assay.

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Swab Cube™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL.


