The Saliva Twist is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody. During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTS**

- Methamphetamine, Benzoylecgonine, Morphine, Δ9-THC, Phencyclidine, Methadone and Oxazepam.

**PRECAUTIONS**

- For medical and other professional in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially biohazardous and handled in the same manner as an infectious agent.
- The used collector and device should be discarded according to local regulations.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. Do not use beyond the expiration date. Do not freeze.

**MATERIALS PROVIDED**

- Test device
- Caps
- Collectors
- Tamper evident tape
- Package insert

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timer
SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit, following the detailed instructions under Directions for Use. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

DIRECTIONS FOR USE

1. Allow the Saliva Drug Test to come to room temperature (15-30 °C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

Bring the pouch to room temperature before opening it. Remove the test and cap from the sealed pouch and use the test as soon as possible. Remove the collector from the sealed pouch and give it to the donor.

2. Instruct the donor to insert the sponge end of the collector into the mouth and actively swirl the inside of the mouth and the top of the tongue. As soon as the sponge softens slightly, the donor should gently press the sponge between the tongue and teeth to ensure complete saturation.

The sponge is saturated when no hard spots can be detected. Collect for a total of 3 minutes before removing the sponge.

3. Remove the collector from the mouth. With the test device on a flat surface, insert the collector into the device by pushing it into the collection chamber and turn the collector clockwise until engaged. Wait 1 minute.

After 1 minute, rotate the collection chamber counterclockwise and set the timer for 9 minutes.

4. Read results at 9 minutes.

5. If positive results are observed, remove the collector by turning it counterclockwise and pulling. Secure the cap over the collection chamber, seal the reservoir with tamper evident tape and send the device to a laboratory for confirmation. The laboratory can access the reservoir by removing the stopper and send the device to a laboratory for confirmation. The test device by pushing it into the collection chamber by turning it counterclockwise until engaged. Wait 1 minute.

6. Remove the collector from the mouth. With the test device on a flat surface, insert the collector into the device by pushing it into the collection chamber and turn the collector clockwise until engaged. Wait 1 minute.

INTERPRETATION OF RESULTS

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

UNDERLYING PRINCIPLES

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

VALID:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line should be adjacent in the test region (Drug/T). This negative result indicates that the drug concentration is above the detectable level.

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

**NOTE:** The shade of color in the test region (Drug/T) will vary, but it should be considered negative whenever there is even a faint colored line.

QUALITY CONTROL

A procedural control is included in the test. A colored 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.

LIMITATIONS

1. The Saliva Twist provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or gas chromatography/tandem mass spectrometry (GC/MS/MS) are preferred confirmatory methods.

2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.

3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A PBS pool was spiked with drugs to target concentrations of 50% cut-off and 25% cut-off and tested with the Saliva Twist.

LITERATURE


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