

# CLIAWAIVED

## Saliva Test

### Instructions

#### INTENDED USE

The Saliva Test is an immunochromatographic assay for rapid, qualitative detection of six drugs and their principal metabolites in human saliva at specified cut-off concentrations. A six-drug combination is composed of the following drugs:

DRUG CLASS		SENSITIVITY
OPIATES/MORPHINE	OPI	30 ng/ml
MARIJUANA	THC	20 ng/ml
COCAINE/BENZOYLECGONINE	COC	30 ng/ml
BENZODIAZEPINE	BZD	50 ng/ml
METHAMPHETAMINE	MET	50 ng/ml
METHADONE	MTD	30 ng/ml

*Note: The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.*

#### SUMMARY AND EXPLANATION OF THE TEST

The Saliva Test is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening human saliva. The method employs unique mixture of monoclonal and polyclonal antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA). There is a growing interest in the use of alternate human sampling other than urine, for the diagnosis of drugs of abuse.

#### PRINCIPLE OF THE TEST

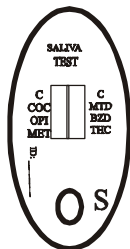
The Saliva Test is a competitive binding immunoassay in which drug and drug metabolites in a saliva sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of five drugs from a single sample. The approximate run time is 10 minutes.

In the assay procedure, the saliva mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen- antibody complex, preventing the development of a rose-pink color band.

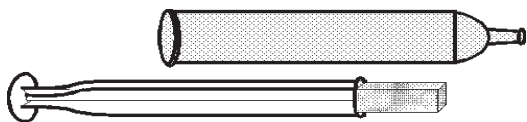
Regardless of the drug levels in the sample, a rose-pink color band is produced in each Control Zone (marked "C") by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.

#### REAGENTS AND MATERIALS PROVIDED

1. Test Devices. Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.



2. Saliva Collection System -Plastic Tube & Saliva Swab.



3. Test Instructions.

#### MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.

#### STORAGE AND STABILITY

Store test kit below 28°C; **do not freeze**. Refer to the expiration date for stability.

#### WARNINGS AND PRECAUTIONS

1. **For forensic use only.**
2. Do not use the test device beyond the expiration date.
3. Saliva specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, do not use the device--the integrity of the device might be compromised.

#### IMPORTANT NOTES:

1. Bring test pouch to room temperature (15°-28°C).
2. Do not break the seal of the pouch until ready to begin testing.
3. The Saliva Collection System is a *one time use only* system. To avoid cross-contamination, use a new Saliva Collection System for each saliva sample.
3. Make sure that there is sufficient saliva in the test (10 drops). Do not spit directly on the device. The Saliva Swab must be used to collect sample in order for the device to function correctly.
4. The result must be interpreted at 10 minutes. Waiting more than 10 minutes may cause the reading to be inaccurate. Discard used test device after interpreting the results to avoid confusion.

#### PATIENT SAMPLING AND TEST PROCEDURE

1. Adulterated saliva could give a false result. **Make sure that there is nothing in the patient's mouth for at least 5 minutes.**

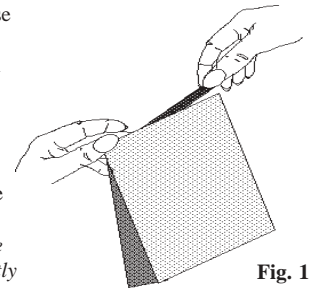


Fig. 1

2. Remove the Saliva Collection System out of the pouch, making sure not to contaminate the device **Fig.1.**

*Note: If it is your protocol to ID the device, write the patient's ID directly on the device*

3. Place foam end of the syringe plunger into the patient's mouth and gently move it for up to 2 minutes to let the sufficient saliva collect in the foam. (NOTE: Have the patient pucker their mouth to get enough oral fluid.) **Fig. 2**

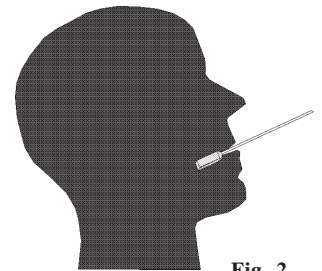


Fig. 2

4. Remove the Saliva Swab out of the patient's mouth and place it inside the syringe tube.

5. Press the syringe plunger to extricate ten (10) drops of the saliva directly onto the sample well of the device. **Fig. 3**

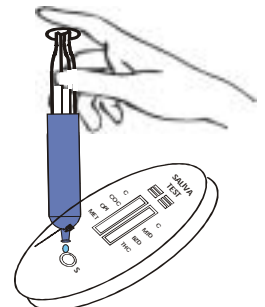
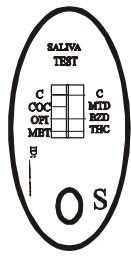


Fig. 3

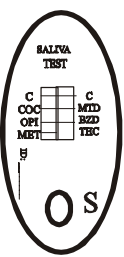
6. Read the results at 10 minutes, using the reader.

## INTERPRETATION OF RESULTS

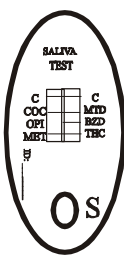
### POSITIVE RESULTS



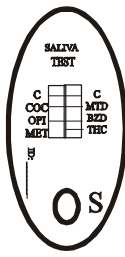
POSITIVE FOR METHADONE



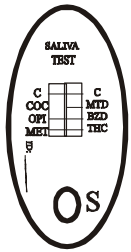
POSITIVE FOR MARIJUANA



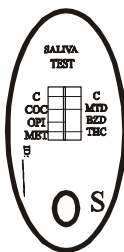
POSITIVE FOR OPIATE



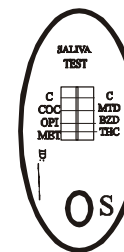
POSITIVE FOR METHAMPHETAMINE



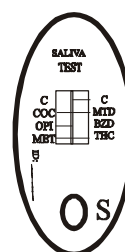
POSITIVE FOR COCAINE



POSITIVE FOR BENZODIAZEPINE



NEGATIVE



INVALID

**Positive:** A rose-pink band is visible in each control zone. No color band appearing in the appropriate test zone indicates a positive result for the corresponding drug of that specific test zone.

**Negative:** A rose-pink band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

**Invalid:** If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

**Note:** There is no meaning attributed to line color intensity or width.

## QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

## BIBLIOGRAPHY

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