



**“See Now” Opiate Strip/Cassette Test  
 Urine**  
**For in vitro Diagnosis Use**  
**Product Code: SN 7.9**

**INTRODUCTION**

The “See Now” Opiate (OPI) Test is intended for the qualitative detection of the presence of OPI and its metabolites in urine at or above the cutoff level of 2000 ng/ml. The device is designed for professional use.

This assay provides only a preliminary result.

**SUMMARY OF THE TEST**

Morphine, codeine, and semisynthetic derivatives of morphine belong to the class of drugs called opiates Morphine being a major metabolite of both heroin and codeine<sup>1</sup>, its presence in urine has been used as an indicator of opiate use<sup>2,3</sup>. Both morphine and codeine are naturally occurring alkaloids from opium. Heroin, a semisynthetic derivative (diacetylmorphine) of morphine, is more potent than morphine and is strictly a drug of abuse<sup>4</sup>.

An opiate acts primarily on the opiate receptors to exert its effects on the central nervous system<sup>5</sup>. Opiate and its metabolites may be detected in urine as a result of heroin, morphine, codeine, or poppy seed intake. Immunoassay testing has been developed for the determination of Opiate in urine. The “See Now” Opiate Test device contains mouse monoclonal anti-Morphine antibody colloidal gold conjugate pre-dried on a pad. Morphine-BSA conjugates antigen (on test region) and goat anti mouse IgG (on control region) are coated and immobilized on a reaction membrane.

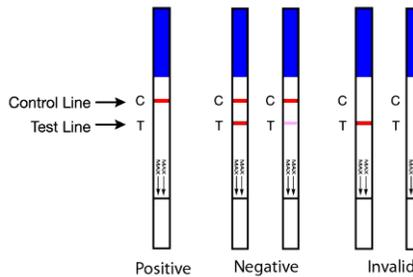
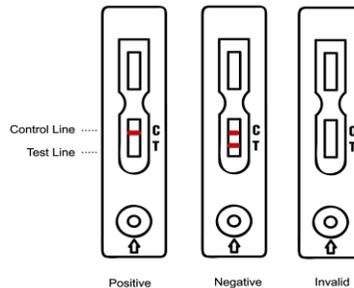
The principal of the “See Now” Opiate Test is a solid phase, competitive inhibition immuno-chromatographic assay, in which a chemically labeled drug (drug conjugate) competes with the drug that may be present in urine, for limited antibody binding sites. When the absorbent pad is soaked with urine, the urine will migrate via capillary action toward the test window where the test reaction occurs. A negative specimen produces two distinct color bands, one in the test zone and one in the control zone; A positive specimen produces only one color band in the control zone.

**SPECIMEN COLLECTION AND STORAGE**

- Urine specimen may be collected at any time in a clean, dry container without preservatives.
- If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing or frozen at -20°C for longer period of time.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.
- Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.

**TEST PROCEDURE**

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 6 drops (0.2 ml) of specimen without air bubbles into the sample well.
- For strip test, immerse the strip into the urine cup and take out the strip after 10 sec. Lay the strip on a flat, clean, dry, non-absorbent surface
- Read the results at 10 minutes. Ensure the background of the test area is white before interpreting the result that



**INTERPRETATION OF RESULTS**

**Positive**

Only one color band appears at the control region. No apparent band at the test region. This indicates that drug presence is above the cutoff concentration.

**Negative**

Two distinct color bands appear at the control and test regions. This indicates that there is no drug in the sample or drug presence is below the cutoff concentration.

**Invalid**

No visible band at the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.

**Note:** A faint line at the test region indicates the drug in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.

**STORAGE AND STABILITY**

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

**PRECAUTION**

- **FOR IN VITRO DIAGNOSTIC USE ONLY.**
- Don't use it after the expiration date.
- The test device should not be reused.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity**

The “See Now” Opiate Test Strips detects Morphine and its metabolites in urine at concentrations equal to or greater than **2000 ng/ml**.

**Specificity**

A study was conducted with The “See Now” Opiate Urinary Test Strips to determine the cross-reactivity of Morphine-related compounds with the test device (Table I).

Table-I Concentration of Morphine-related compounds showing a positive response approximately equivalent to the Morphine cut off set for the test.

Structurally related compounds	ng/ml	Structurally related compounds	ng/ml
Morphine	2000	Hydromorphone	5000
Morphine-3-β-D-Glucuronide	2000	Heroin	5000
Codeine	2000	Oxycodone	10000
6-monoacetylmorphine	5000	Levorphanol	20000
Ethylmorphine	5000	Naloxone	20000
Nalorphine	10000	Thebaine	50000
Hydrocodone	10000	Norcodeine	20000

**Accuracy**

Accuracy of the “See Now” Opiate Urinary Test Device has been evaluated. A total of 80 clinic samples tested (40 negative and 40 positive), The two assays gave an overall of 95%.

**Reproducibility**

The precision was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable inter lot variation when testing both positive and negative samples across three different lots of devices.

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## “See Now” Opiate (OPI) Cassette Test In human oral fluid specimens

For in vitro Diagnosis Use

Product Code: SN 7.9.S

### INTRODUCTION

The “See Now” Opiate (OPI) cassette test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of opiate metabolites in human oral fluid specimens (saliva).

This assay provides only a preliminary analytical test result

### SUMMARY OF THE TEST

Opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the saliva of a person who has taken only heroin. The body also changes codeine to morphine. Thus the presence of morphine (or the metabolite, morphine glucuronide) in the saliva often indicates heroin, morphine and/or codeine use.

The “See Now” OPI cassette test 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 conjugate 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

### MATERIALS PROVIDED

1. The “See Now” OPI cassette test.
2. Instruction for use.

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or clock.
2. Oral fluid collection swabs
3. Oral fluid collection tube.

### SPECIMEN COLLECTION AND STORAGE

The test device should be stored at 4 to 30°C and will be effective until the expiration date stated on the package. The product is humidity -sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

**Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.**

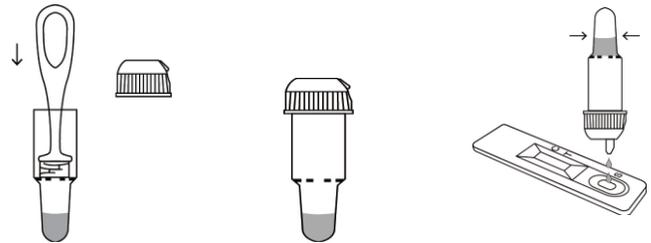
1. Remove the oral fluid collection swab from the sealed pouch and **insert the sponge end of the oral fluid collection swab into the mouth**. Actively swab the inside of the mouth and tongue to **collect oral fluid for a total of 3 minutes** until the sponge becomes fully saturated. Gentle pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
2. Remove the oral fluid collection swab from the mouth.
3. Place the saturated swab into the collection chamber and press the sponge firmly down on the plastic strainer to release as much liquid as possible.
4. Tightly shut the outer cap of the collection tube.

### TEST PROCEDURE

**Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.**

1. Remove the test card from sealed pouch and use it within one hour.
2. Flip open the dropper tip of the collection tube.
3. Invert the collection tube and transfer 2 drops of oral fluid (approximately 80  $\mu$ L ) into the specimen well (S) of the test card. Avoid ping air bubbles in the specimen well.
4. Read results at 10 minutes.

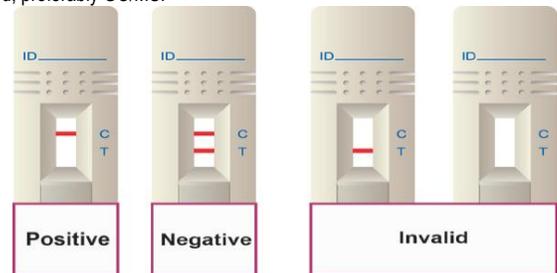
**Note: Do not interpret the results after 20 minutes..**



Specimen Collection Step 3 Specimen Collection Step 4 Procedure Step 3

### INTERPRETATION OF RESULTS

The “See Now” OPI cassette test is a qualitative assay. It identifies the drug in human saliva at its cut-off concentration or higher. The concentration of the drug can not be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.



#### Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug and their metabolites in the specimen, it only indicates the level of tested drug and their metabolites in the specimen is less than cut-off level.

#### Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug and their metabolites in the specimen is above the cut-off level.

#### Invalid:

If there is no colored band in control line zone of any strip, the test result is invalid. Retest the sample with a new device.

**Note: A borderline( $\pm$ ) in test line zone should be considered negative result.**

### LIMITATION OF PROCEDURE

1. The “See Now” OPI cassette test 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) is 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.

### PRECAUTION

#### FOR IN VITRO DIAGNOSTIC USE ONLY

- Don't use it after the expiration date.
- The test device should not be reused.
- Do not use after the expiration date shown on the pouch.
- Saliva is not classified as biological hazard unless derived from a dental procedure.

### PERFORMANCE CHARACTERISTICS

#### A. Sensitivity

The cut-off concentration (sensitivity level) of the “See Now” OPI cassette test is determined to be: **40 ng/ml**.

#### B. Precision

The results of 30 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.

#### C. Specificity

The “See Now” OPI saliva cassette test relative specificity it is 99%..