

# HEALTH-CHEM DIAGNOSTICS, LLC

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## ONE STEP DRUGS OF ABUSE TEST STRIP – OPIATE 300®

### NAME AND INTENDED USE

HCD's **One Step Drugs of Abuse Test Strip – Opiate 300®** is a rapid qualitative, competitive binding immunoassay for the determination of Morphine and its metabolites in urine in a convenient one step strip test format. This test is not intended to monitor drug levels, but only to screen urines for the presence of opiates and their metabolites. Both the testing and the results are intended to be used by medical and legal professionals only. The test should not be used without appropriate supervision. HCD's **One Step Drugs of Abuse Test Strip – Opiate 300®** is not intended for Over the Counter (OTC) sale to lay persons.

### INTENDED USE

The HCD's **One Step Drugs of Abuse Test Strip – Opiate 300®** is a rapid qualitative, competitive binding immunoassay for the determination of Morphine and its metabolites in urine. The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectroscopy (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated<sup>6</sup>. Health'Chem's **One Step Drugs of Abuse Test Strip – Opiate 300®** is not intended to monitor drug levels, but only screen urines for the presence of opiates and their metabolites.

### EXPLANATION OF THE TEST

The method employs unique monoclonal antibodies to selectively identify Morphine in test samples with a high degree of sensitivity. Morphine has been a preferred drug for the management of pain in advanced cancer<sup>4</sup>. Large doses of Morphine could develop tolerances and physiological dependency and lead to its abuse. Morphine and its metabolites detected in urine may be present as a result of Heroin, Morphine, Codeine, or poppy seed intake<sup>5</sup>. Immunoassay testing has been developed for the determination of opiates in urine at a concentration of 300 ng/ml set by the National Institute of Drug Abuse<sup>6</sup>.

The HCD's **One Step Drugs of Abuse Test Strip – Opiate 300®** strip (*Opium/Heroin/Morphine*) is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening which does not require instrumentation to arrive at a determination.

### PRINCIPLE OF THE PROCEDURE

HCD's **One Step Drugs of Abuse Test Strip – Opiate 300®** (*Opium/Heroin/Morphine*) consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is higher than the detection level of 300 ng/ml. Unbound dye conjugate binds to the reagent in the negative control zone,

producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area.

A **POSITIVE** specimen produces only one color band in the control area.

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers.
2. Clock or Timer.
3. 13 x 100mm Test Tube.

### WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional medical & legal use only.
3. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.
4. Do not use kit beyond the expiration date imprinted on the outside of the foil pouch.
5. Urine specimens may be infectious. Upon completion of **ALL TESTING** dispose of residual urine in an approved manner. Properly handle and dispose of all used reaction devices in an approved biohazard container.

### STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2°-8°C)(35°-46°F) (**DO NOT FREEZE**) or at room temperature (18°-30°C)(64°-86°F) and will be stable for 12 months.

### SAMPLE COLLECTION AND PREPARATION

Urine (1.0 ml) - the sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2°-8°C)(35°-46°F) and stored up to 48 hours, or frozen (-20°C or colder)(-4°F or colder) prior to assaying. If samples are refrigerated, they should be allowed to come to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

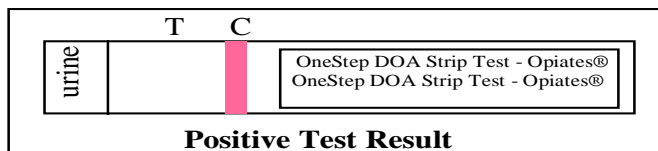
### ASSAY PROCEDURE

1. Remove the **One Step Drugs of Abuse Test Strip – Opiate 300®** from its protective foil wrapper by tearing along the notch.
2. Add 1 ml of urine to be tested to a 13 x 100mm test tube. Holding the strip in a vertical position, place it into the urine and simultaneously start timing. Make sure that only the end with the arrow pointing down is placed in the urine specimen. The urine level should not be higher than the maximum fill line indicated on the strip.
3. Read results after 3 minutes. Test results should not be interpreted after 5 minutes.

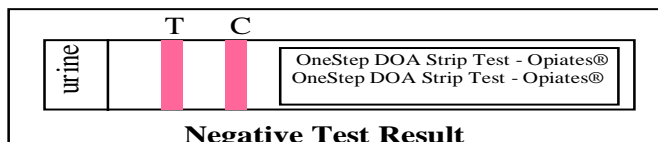
**NOTES:** Refrigerated strips should be allowed to come to room temperature before opening the pouch.

## READING THE TEST RESULTS

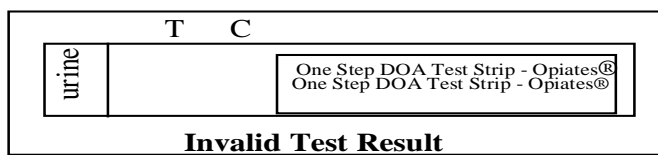
1. **POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the Opiate level is above the detection sensitivity level of 300 ng/ml.



2. **NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the Opiate level is below the detection sensitivity level of 300 ng/ml.



3. **INVALID:** If there are no distinct color bands in both the upper and lower portions of the read area, or no band in the control region (upper portion of the strip), then the test results are invalid. It is recommended that the specimen be retested.



## QUALITY CONTROL

1. Each reaction strip has its own built-in quality control indicator. If after performing the test no line is visible on the strip, you may have placed the strip into the tube incorrectly or the test device may have deteriorated. You will have to repeat the assay using a new **One Step Drugs of Abuse Test Strip - Opiate 300®**. Reread the instructions carefully or call TCPI for assistance (800 482-2907).
2. Good laboratory practice recommends the use of control material to test each product shipment or whenever it is necessary to validate reagent performance and reliability. Commercial controls from BioRad, Utak, and Alltech are available for validation of device functionality. NIDA recommended guidelines for drugs of abuse analyte at levels at least 20% above the NIDA cut off values.

## AFTER TESTING

Urine specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after the completion of all testing including the confirmatory testing. Sample disposal may be controlled by legal chain of custody considerations.

## PERFORMANCE CHARACTERISTICS

**SENSITIVITY:** HCD's **One Step Drugs of Abuse Test Strip - Opiate 300®** (*Opium/Heroin/Morphine*) has been designed for the detection of total Morphine and its metabolites in urine at the detection sensitivity of 300 ng/ml which is suggested for the immunoassay method.

**SPECIFICITY:** HCD's **One Step Drugs of Abuse Test Strip - Opiate 300®** (*Opium/Heroin/Morphine*) test can specifically detect Morphine and its metabolites in urine. There is no interference by the following substances at 10µg/ml concentration in urine:

Table 1 - No Interference at 10µg/ml

Substance	Reaction
Cannabidiol	0
Amphetamine	±
Deoxyephedrine	±
Methamphetamine	+
Deoxyephedrine	0
Phencyclidine	0
Phenobarbital	0

## LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Morphine and its metabolites in human urine only.
2. Although the HCD's **One Step Drugs of Abuse Test Strip - Opiate 300®** (*Opium/Heroin/Morphine*) is very accurate in detecting the urine Morphine level, there is a possibility of false results due to the presence of interfering substances in the urine.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative Morphine level of urine.
4. Adulterants, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

## BIBLIOGRAPHY

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Manufactured in the USA by:

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