

# Urine Drug Screen Test

## INTENDED USE

The Multi-Drug InstaStrip Test is an immunochromatographic assay for rapid, qualitative detection of drugs and their principal metabolites in urine at specified cut-off concentrations. A combination is composed from any the following drugs:

DRUG CLASS	SENSITIVITY
PHENCYCLIDINE	25 ng/ml
MARIJUANA	50 ng/ml
COCAINE/BENZOYLECGONINE	300 ng/ml
BARBITURATES	200 ng/ml
BENZODIAZEPINES	300 ng/ml
METHADONE	300 ng/ml
OPIATES/MORPHINE	300 ng/ml
METHAMPHETAMINE	500 ng/ml
AMPHETAMINE	1000 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 Multi-drug InstaStrip Test is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. 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. Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the Multi-drug InstaStrip Test is set as required for the screening immunoassays of these drugs in the reference guidelines set by the National Institute on Drug Abuse (NIDA) and the U.S. Department of Health and Human Services.

## PRINCIPLE OF THE TEST

The Multi-drug InstaStrip Test is a competitive binding immunoassay in which drug and drug metabolites in a urine 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 six drugs from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine 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.



### Optional:

1. Negative Control I. Contains buffered protein solution with sodium azide.
2. PCP Positive Control. Contains PCP at 100 ng/ml in a buffered protein solution with sodium-azide.
3. Marijuana Positive Control. Contains THC at 150 ng/ml in a buffered solution with sodium azide.
4. Opiates Positive Control. Contains MOR at 1000 ng/ml in a buffered protein solution with sodium azide.
5. Cocaine Positive Control. Contains BEG at 1000 ng/ml in a buffered protein solution with sodium azide.
6. Methamphetamine Positive Control. Contains MET at 1500 ng/ml in a buffered protein solution with sodium azide.
7. Amphetamine Positive Control. Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide.

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.
2. Specimen collection containers.

## WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic and professional use only.
2. Do not use the test device beyond the expiration date.
3. Urine 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, the integrity of the device might be compromised.

## STORAGE AND STABILITY

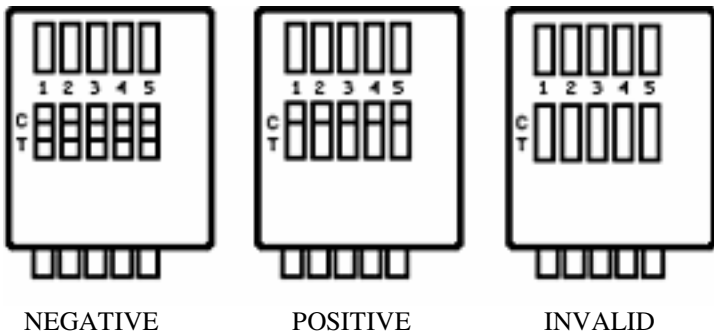
Store test kit below 28°C; do not freeze. Refer to the expiration date for stability.

## TEST PROCEDURE

1. Bring a urine sample and a foil test pouch to room temperature (15°-28°C).
2. Do not break the seal of the pouch until ready to begin testing.
3. Remove a Test Device from the foil pouch.
4. Remove the protective cap and place the revealed strips into the urine sample for 10 seconds. Do not allow the urine level to touch the plastic device.
5. Read the results at 5 minutes.

*Note: The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.*

## INTERPRETATION OF RESULTS



**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.

## LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens can cause erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

## PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The Multi-drug InstaStrip Test detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by the National Institute on Drug Abuse (NIDA) for the immunoassay method.
2. **Specificity.** A study was conducted with the Multi-drug InstaStrip Test to determine the cross-reactivity of drug-related compounds with the test. Substances listed in Table I produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in Table II.
3. **Accuracy:** The accuracy of the Multi-drug Multi-drug InstaStrip Test was first tested in urine samples in-house and subsequently in a clinical trial of urine samples submitted to a NIDA certified

laboratory. In both cases the laboratories used EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The data was combined and the results are summarized as follows:

### PHENCYCLIDINE (PCP)

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
<b>InstaStrip Positive</b>	223	0
<b>InstaStrip Negative</b>	0	290

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

### MARIJUANA (THC)

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
<b>InstaStrip Positive</b>	297	4
<b>InstaStrip Negative</b>	4	259

When compared to EMIT II the relative sensitivity between positive samples was 98.67%. The relative specificity between negative samples was 98.48%. The concordance of the combined data with respect to EMIT II was 98.58%.

### COCAINE (BEG)

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
<b>InstaStrip Positive</b>	194	1
<b>InstaStrip Negative</b>	0	212

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 99.55%. The concordance of the combined data with respect to EMIT II was 99.75%.

### METHAMPHETAMINE (MET)

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
<b>InstaStrip Positive</b>	179	14
<b>InstaStrip Negative</b>	0	262

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 94.9%. The concordance of the combined data with respect to EMIT II was 96.92%.

### OPIATES (OPI)

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
<b>InstaStrip Positive</b>	172	0
<b>InstaStrip Negative</b>	0	190

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

### AMPHETAMINE (AMP)

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
<b>InstaStrip Positive</b>	188	1
<b>InstaStrip Negative</b>	0	340

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 99.7%. The concordance of the combined data with respect to EMIT II was 99.8%.