

## DRUGCHECK® 5 TEST CUP

NO STEP - ONSITE®

Catalog # 60500

Instructions

### INTENDED USE

The DRUGCHECK® 5 Test Cup is an immunochromatographic assay for rapid qualitative detection of five drugs and their principal metabolites in urine at specified cutoff concentrations. This five drug combination is composed from the following drugs:

MARIJUANA (THC)	50 ng/ml
COCAINE (BENZOYLECGONINE)	300 ng/ml
AMPHETAMINE	1000 ng/ml
METHAMPHETAMINE	1000 ng/ml
OPIATES	2000 ng/ml

*Note: The test provides only preliminary test 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 DRUGCHECK® 5 Test Cup uses an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need for instrumentation. The method employs a unique mixture of 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 economic 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) and the U.S. Department of Health and Human Services.

### PRINCIPLE OF THE TEST

The DRUGCHECK® 5 Test Cup is a competitive binding immunoassay in which drugs 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 five drugs from a single urine 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 and preventing the development of a rose-pink color band in the Test Zone.

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

### MATERIALS PROVIDED

1. Test Devices containing dye-conjugated antibody and immobilized antigen in a protein matrix with sodium azide.
2. Test Instructions.

*Note: You may need to provide a clock or timing device to accurately determine when to read the test.*

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic and professional use only.
2. Do not use the test device beyond the expiration date.
3. Use a new device for each urine test to avoid cross contamination of urine samples. The DRUGCHECK® 5 Test Cup cannot be reused.
4. Urine specimens may be infectious; properly handle and dispose of all urine and urine reaction devices in a biohazard container.
5. Visually inspect the foil package to ensure it has not been compromised before beginning the test. If the package does not reach you intact, the integrity of the test cup may be compromised.

### STORAGE AND STABILITY

Store test kit below 28°C (83°F); do not freeze. If stored at 2°-8°C (36°F-46°F), allow the test kit to reach room temperature (15°-28°C; 59°-83°F) before performing the test. The Test Cup will be stable until the expiration date as printed on the foil package.

### SPECIMEN COLLECTION AND PREPARATION

Fresh urine specimens should be collected directly into the cup and do not require any special handling or pre-treatment. The DRUGCHECK® 5 Test Cup employs a thermal strip to validate the urine collection. This device should be checked immediately after collection.

**Note:** Urine specimens can be transferred from a urine collection container into the DRUGCHECK® 5 Test Cup, if necessary.

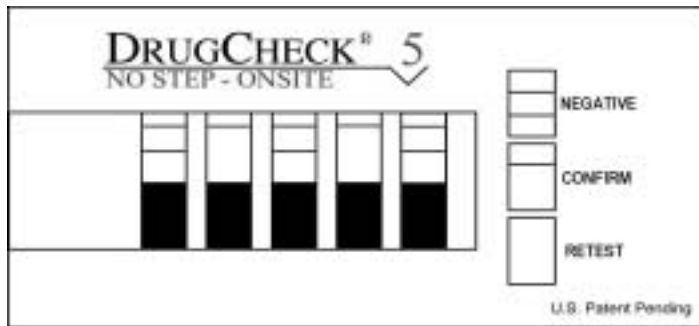
### TEST PROCEDURE

*Do not break the seal of the protective pouch until ready to begin testing.*

1. Tear open the foil pouch and remove the test cup.
2. Issue the device to the individual to be tested.
3. Have them urinate directly into the DRUGCHECK® 5 Test Cup. Ensure the specimen is above the minimum level line on the test label.
4. The cup must be returned immediately to the collection site. Remove tear-off label and read the results at five minutes post collection.

**NOTE:** In order to prevent any incorrect results, the test results should **not be interpreted after 8 minutes.**

### INTERPRETATION OF RESULTS



**Each of the tests is read individually and independently of one another.**

**Confirm:** A rose-pink color band is visible in each Control Zone. No color band whatsoever appears in the appropriate Test Zone, indicating a preliminary positive result for the corresponding drug of that specific Test Zone. Send this urine specimen to a certified laboratory for confirmation.

**Negative:** A rose-pink color band is visible in each Control Zone and in 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.

**Retest:** If a color band is not visible in the Control Zone, the test is invalid. Another test should be run to re-evaluate the specimen. Each strip in the DRUGCHECK® 5 Test Cup is read and functions independently. An invalid result on one test strip does not invalidate other results derived from the same device.

**Note:** *There is no meaning attributed to line color intensity or width. Any evidence of a line should be considered a line.*

### QUALITY CONTROL

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

### 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 in detecting the urine drug levels (accuracy is a function of the specific strip) there is the possibility false results will occur due to the presence of interfering substances in the urine and/or factors beyond the control of the manufacturer, e.g. technical or procedure errors associated with the testing.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels or level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents can cause erroneous test results when added to urine specimens regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

### PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** The DRUGCHECK® 5 Test Cup 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 U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method.

2. **Precision:** The DRUGCHECK® 5 Test Cup produced a 100% precision level when tested with drug standards at 50% above and 50% below cutoff concentration levels.

The precision was determined by replicate assays with kits from three different production lots. The resultant data indicated 100% precision for the duplicates within each lot and no appreciable interlot variation when testing both positive and negative spiked samples across three (3) different lots of devices.

3. **Accuracy:** In addition to in-house performance testing, where there were no inappropriate reactions and there was no interaction between any of the strips, clinical trials of at least 101 clinical specimens were conducted. During these trials, the clinical specimens were evaluated using the DRUGCHECK® 5 Test Cup, the Applied Biotech, Inc. SureStep™ drug screen, and GC/MS.

The individual results from the study are as follows:

### 3.1 Marijuana (THC)

	<u>Surestep Positive</u>	<u>Surestep Negative</u>
DRUGCHECK® Positive	83	0
DRUGCHECK® Negative	0	47

When compared to SureStep™ the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to SureStep™ was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	83	0
DRUGCHECK® Negative	0	47

When compared with GC/MS, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to GC/MS was 100%.

### 3.2 Cocaine (COC)

	<u>SureStep Positive</u>	<u>SureStep Negative</u>
DRUGCHECK® Positive	96	0
DRUGCHECK® Negative	0	35

When compared to SureStep™ the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to SureStep™ was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	96	0
DRUGCHECK® Negative	0	35

When compared with GC/MS, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to GC/MS was 100%.

### 3.3 Opiates (OPI)

	<u>SureStep Positive</u>	<u>SureStep Negative</u>
DRUGCHECK® Positive	55	0
DRUGCHECK® Negative	2	58

When compared to SureStep™ the relative sensitivity between positive samples was 96.49%. The relative specificity between negative samples was 100%. The accuracy with respect to SureStep™ was 98.26%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	56	1
DRUGCHECK® Negative	0	58

When compared with GC/MS, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 98.28%. The accuracy with respect to GC/MS was 99.13%.

### 3.4 Amphetamine (AMP)

	<u>SureStep Positive</u>	<u>SureStep Negative</u>
DRUGCHECK® Positive	49	0
DRUGCHECK® Negative	0	58

When compared to SureStep™ the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to SureStep™ was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	49	0
DRUGCHECK® Negative	0	58

When compared with GC/MS, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to GC/MS was 100%.

### 3.5 Methamphetamine (MET)

	<u>SureStep Positive</u>	<u>SureStep Negative</u>
DRUGCHECK® Positive	54	0
DRUGCHECK® Negative	0	47

When compared to SureStep™ the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to SureStep™ was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DRUGCHECK® Positive	54	0
DRUGCHECK® Negative	0	47

When compared with GC/MS, the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The accuracy with respect to GC/MS was 100%.

*There were no inappropriate reactions or cross-reactivity between strips noted in any of the data collected.*

4. **Specificity:** A study was conducted with the DRUGCHECK® 5 Test Cup to determine the cross-reactivity of drug-related compounds with the test. Substances listed in Table 1 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 2.

**Table 1: Concentrations of drug-related compounds showing positive response approximately equivalent to the cutoff set for the test:**

The following Opiate-related substances yield a positive result for Opiates:

Morphine	2,000 ng/ml	Oxycodone	70,000 ng/ml
Codeine	2,000 ng/ml	Hydrocodone	10,000 ng/ml
Opiate	2,000 ng/ml	Hydromorphone	2,500 ng/ml
Ethyl Morphine	2,000 ng/ml		

The following MET-related substances yield positive results for Methamphetamine:

d-Methamphetamine	1,000 ng/ml	(+/-)-Ephedrine	50,000 ng/ml
d-Amphetamine	50,000 ng/ml	b-Phenylethylamine	50,000 ng/ml
Chloroquine	50,000 ng/ml	Procaine	10,000 ng/ml
l-Methamphetamine (l-Deoxyephedrine)	25,000 ng/ml	Ranitidine	50,000 ng/ml
3,4-methylenedioxyamphetamine (MDMA)	2,000 ng/ml		

The following Marijuana-related substances yield positive results for Marijuana:

11-Nor-Δ-8-THC-9-COOH	50 ng/ml	Δ-9-THC	10,000 ng/ml
11-Non-Δ-9-THC-9-COOH	50 ng/ml	Cannabinol	100,000 ng/ml
Δ-8-THC	7,500 ng/ml	11-hydroxy-Δ-9-THC	2,500 ng/ml

The following Amphetamine-related substances yield positive results for Amphetamines:

d-Amphetamine	1,000 ng/ml
l-Amphetamine	100,000 ng/ml
(±)3,4-Methylenedioxyamphetamine (MDA)	5,000 ng/ml

The following Cocaine-related substances yield positive results for Cocaine:

Benzoylcegonine	300 ng/ml
Cocaine	300 ng/ml
Ecgonine	>100,000 ng/ml
Ecgonine Methyl Ester	>100,000 ng/ml

**Table 2: Compounds tested and found not to cross-react with the test at a 1 mg/ml concentration in urine:**

Compounds which produce no reaction

Acetaminophen	Creatine	Lidocaine
Acetone	Dextromethorphan	N-Methyl-Ephedrine
Albumin	4-Dimethylaminoantipyrine	(+)-Naproxine
Amitriptyline	Dopamine	Penicillin-G
Ampicillin	(-)-Ephedrine	Pheniramine
Aspartame	Erythromycin	Phenothiazine
Aspirin	Ethanol	L-Phenylethylamine
Atropine	Furosemide	Quindine
Benzocaine	Guaiacol Glyceryl Ether	Sulindac
Bilirubin	Hemoglobin	Tyramine
Caffeine	Impramine	Vitamin C
Chlorpheniramine	Isoproterenol	

### BIBLIOGRAPHY

- Baselt, R.C., Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed., Biomedical Publ., Davis, CA, p. 488 (1982).
- Cody, J.T., Schwarzhoff, R., J. Anal. Toxicol., 17: 2630 (1993).
- Urine Testing for Drugs of Abuse, NIDA Research Monograph 73, (1986).
- Dasguspta, A., Saldana, S., Kinnaman, G., Smith, M., Johansen, K., Clin. Chem., 39(1): 104-108 (1993).
- Department of Health and Human Services, Fed. Regist., 53(69):19970-11989 (1988), (1989).
- FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshitij Mohan, 7/ 21/1987.