

# NexScreen Cup™

## Instructions

### INTENDED USE

The NexScreen Cup™ is an immunochromatographic assay for rapid qualitative detection of drugs of abuse and their principal metabolites in urine at specified cutoff concentrations listed below:

ABBREVIATION	TARGET ANALYTE	CUT-OFF (ng/mL)
AMP	Amphetamine	1,000
BAR	Barbiturates	300
BZO	Benzodiazepines	300
COC	Cocaine	300
THC	Marijuana	50
MDMA	Ecstasy	500
MET	Methamphetamine	1,000
MTD	Methadone	300
OPI	Opiates / Morphine	300
OPI	Opiates / Morphine	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Tricyclic Antidepressants	1,000

This assay is intended for professional use. It is not for over the counter sale.

*Note: This assay provides only preliminary analytical test results. A more specific alternative method must be used in order to obtain confirmed analytical results. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when preliminary results indicated positive.*

### SUMMARY AND EXPLANATION OF THE TEST

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.

The NexScreen Cup™ uses a fast, qualitative, visually read competitive immunoassay method for screening without the need for instrumentation. The method employs a mixture of antibodies and antigens to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, drug half-life, and the drug user's age, weight, activity, and diet.

### PRINCIPLE OF THE TEST

The NexScreen Cup™ is a competitive 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 up to ten drugs from a single urine sample. The test results can be read at 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 colored line 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 colored line in the Test Zone.

Regardless of the drug levels in the sample, a colored line is produced in each Control Zone by a parallel immunochemical reaction. The presence of this colored line in the control region serves as 1) verification that sufficient volume is added and 2) that proper flow is obtained.

### MATERIALS PROVIDED

- 25 Test cups with strips containing dye-conjugated antibody and immobilized antigen in a protein matrix with sodium azide.
- Test Instructions.

### MATERIALS NEEDED BUT NOT PROVIDED

- Timing device (i.e., timer, clock, watch, etc.)

### WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For professional use only.
- Do not use the test device beyond the expiration date.
- Use a new device for each urine test to avoid cross contamination of urine samples. The NexScreen Cup™ cannot be reused.
- Urine specimens may be infectious; properly handle and dispose of all urine and urine reaction devices in a biohazard container.
- 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 comprised.

### STORAGE AND STABILITY

Store test kit below 30°C (86°F); do not freeze. If stored at 2°-8°C (36°F-46°F), allow the test kit to reach room temperature 15°-30°C (59°-86°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 with a minimum of 30ml volume and do not require any special handling or pre-treatment. The NexScreen 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 NexScreen Cup™ if necessary.

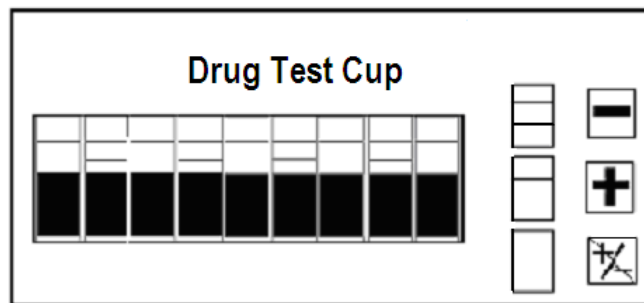
### TEST PROCEDURE

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

- Tear open the foil pouch and remove the test cup.
- Issue the device to the individual to be tested.
- Have them urinate directly into the NexScreen Cup™. Ensure the specimen is above the minimum level line on the test label.
- The cup must be returned immediately to the collector. Authorized personnel at collection sites to 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 5 minutes.

### INTERPRETATION OF RESULTS



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

**Positive:** A colored line is visible in each Control Zone. No color line appears in the 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 colored line is visible in each Control Zone and in the 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 colored line 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 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 the line color intensity or width. Any evidence of a line should be considered a line.

### QUALITY CONTROL

User should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. Control specimens are available from commercial sources. Use the same assay procedure as with a urine specimen.

**LIMITATIONS OF THE TEST**

1. This product is designed for the detection of drugs of abuse and their metabolites in human urine only.
2. There is the possibility that 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 NexScreen 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. **Accuracy:** NexScreen Cup™ test strips were evaluated using urine specimens from clinical laboratories where the samples were analyzed by GC/MS. In addition, tests were also compared with other commercially available products. The results are listed below:

**3.01 AMPHETAMINE**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	47	0
NexScreen Cup™ Negative	0	79

When compared to predicate kit, the agreement for positive samples was 100% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	45	2
NexScreen Cup™ Negative	1	78

When compared with GC/MS, the agreement for positive samples was 97.8% and for negative samples was 97.5%. With respect to GC/MS, the agreement for all samples was 97.6%.

**3.02 BARBITURATES**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	56	0
NexScreen Cup™ Negative	0	60

When compared to predicate kit, the agreement for positive samples was 100% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	54	2
NexScreen Cup™ Negative	2	58

When compared with GC/MS, the agreement for positive samples was 96.4% and for negative samples was 96.7%. With respect to GC/MS, the agreement for all samples was 96.6%.

**3.03 BENZODIAZEPINES**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	42	0
NexScreen Cup™ Negative	1	79

When compared to predicate kit, the agreement for positive samples was 97.7% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 99.2%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	40	2
NexScreen Cup™ Negative	1	79

When compared with GC/MS, the agreement for positive samples was 97.6% and for negative samples was 97.5%. With respect to GC/MS, the agreement for all samples was 97.5%.

**3.04 COCAINE**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	53	0
NexScreen Cup™ Negative	2	85

When compared to predicate kit, the agreement for positive samples was 96.4% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 98.6%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	49	4
NexScreen Cup™ Negative	3	84

When compared with GC/MS, the agreement for positive samples was 94.2% and for negative samples was 95.5%. With respect to GC/MS, the agreement for all samples was 95%.

**3.05 MARIJUANA**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	62	0
NexScreen Cup™ Negative	0	76

When compared to predicate kit, the agreement for positive samples was 100% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	60	2
NexScreen Cup™ Negative	3	73

When compared with GC/MS, the agreement for positive samples was 95.2% and for negative samples was 97.3%. With respect to GC/MS, the agreement for all samples was 96.4%.

**3.06 MDMA**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	50	0
NexScreen Cup™ Negative	2	65

When compared to predicate kit, the agreement for positive samples was 96.2% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 98.3%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	48	2
NexScreen Cup™ Negative	3	64

When compared with GC/MS, the agreement for positive samples was 94.1% and for negative samples was 97%. With respect to GC/MS, the agreement for all samples was 95.7%.

**3.07 METHAMPHETAMINE**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	50	0
NexScreen Cup™ Negative	2	78

When compared to predicate kit, the agreement for positive samples was 96.2% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 98.5%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	48	2
NexScreen Cup™ Negative	3	77

When compared with GC/MS, the agreement for positive samples was 94.1% and for negative samples was 97.5%. With respect to GC/MS, the agreement for all samples was 96.2%.

**3.08 METHADONE**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	55	0
NexScreen Cup™ Negative	0	66

When compared to predicate kit, the agreement for positive samples was 100% and for negative samples was 100%. With respect to predicate kit, the agreement for all samples was 100%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	52	3
NexScreen Cup™ Negative	2	64

When compared with GC/MS, the agreement for positive samples was 96.3% and for negative samples was 95.5%. With respect to GC/MS, the agreement for all samples was 95.9%.

**3.09 OPIATES 300**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	69	1
NexScreen Cup™ Negative	1	70

When compared to predicate kit, the agreement for positive samples was 98.6% and for negative samples was 98.6%. With respect to predicate kit, the agreement for all samples was 98.6%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	68	2
NexScreen Cup™ Negative	2	69

When compared with GC/MS, the agreement for positive samples was 97.1% and for negative samples was 97.2%. With respect to GC/MS, the agreement for all samples was 97.2%.

**3.10 OPIATES 2000**

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	65	1
NexScreen Cup™ Negative	0	73

When compared to predicate kit, the agreement for positive samples was 100% and for negative samples was 98.6%. With respect to predicate kit, the agreement for all samples was 99.3%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	64	2
NexScreen Cup™ Negative	2	71

When compared with GC/MS, the agreement for positive samples was 97% and for negative samples was 97.3%. With respect to GC/MS, the agreement for all samples was 97.1%.

### 3.11 OXYCODONE

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	52	1
NexScreen Cup™ Negative	2	59

When compared to predicate kit, the agreement for positive samples was 96.3% and for negative samples was 98.3%. With respect to predicate kit, the agreement for all samples was 97.4%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	51	2
NexScreen Cup™ Negative	2	59

When compared with GC/MS, the agreement for positive samples was 96.2% and for negative samples was 96.7%. With respect to GC/MS, the agreement for all samples was 96.5%.

### 3.12 PHENCYCLIDINE

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	59	1
NexScreen Cup™ Negative	0	78

When compared to predicate kit, the agreement for positive samples was 100% and for negative samples was 98.7%. With respect to predicate kit, the agreement for all samples was 99.3%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	55	5
NexScreen Cup™ Negative	3	75

When compared with GC/MS, the agreement for positive samples was 94.8% and for negative samples was 93.8%. With respect to GC/MS, the agreement for all samples was 94.2%.

### 3.13 PROPOXYPHENE

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	81	2
NexScreen Cup™ Negative	4	68

When compared to predicate kit, the agreement for positive samples was 95.3% and for negative samples was 97.1%. With respect to predicate kit, the agreement for all samples was 96.1%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	81	2
NexScreen Cup™ Negative	3	69

When compared with GC/MS, the agreement for positive samples was 96.4% and for negative samples was 97.2%. With respect to GC/MS, the agreement for all samples was 96.8%.

### 3.14 TRICYCLIC ANTIDEPRESSANTS

	<u>Predicate Kit Positive</u>	<u>Predicate Kit Negative</u>
NexScreen Cup™ Positive	56	1
NexScreen Cup™ Negative	0	61

When compared to predicate kit, the agreement for positive samples was 100% and for negative samples was 98.4%. With respect to predicate kit, the agreement for all samples was 99.2%.

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
NexScreen Cup™ Positive	55	2
NexScreen Cup™ Negative	3	58

When compared with GC/MS, the agreement for positive samples was 94.8% and for negative samples was 96.7%. With respect to GC/MS, the agreement for all samples was 95.8%.

4. Specificity: The specificity of NexScreen Cup™ products were tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine.

**Table 1:** The following structurally related compounds produce positive results when tested at levels greater than the concentrations (ng/ml) listed below:

The following Amphetamine-related substances yield positive results for

#### Amphetamines:

d-Amphetamine	1,000
l-Amphetamine	10,000
3,4 methylenedioxyamphetamine(MDA)	4,500
p-Methoxyamphetamine(PMA)	1,500
Methylenedioxyethylamphetamine(MDEA)	>100,000
Methylenedioxymethamphetamine(MDMA)	>100,000

The following Barbiturate-related substances yield positive results for

#### Barbiturates:

Secobarbital	300
Alphenal	400
Amobarbital	2,000
Aprobarbital	300
Barbital	300
Butobarbital	300
Butalbital	3,000
Pentobarbital	400
Phenobarbital	300

The following Benzodiazepine-related substances yield positive results for

#### Benzodiazepines:

Oxazepam	300
Alprazolam	400
Bromazepam	2,000
Chlordiazepoxide	8,000
Clobazam	400
Clonazepam	5,000
Diazepam	2,000
Estazolam	20,000
Flunitrazepam	1,000
Lorazepam	4,000
Lometazepam	5,000
Nitrazepam	200
Nordiazepam	500
Temazepam	200
Triazolam	8,000

The following Cocaine-related substances yield positive results for

#### Cocaine:

Benzoylgonine	300
Cocaine	50,000
Egonine	>100,000
Egonine Methyl Ester	>100,000

The following Marijuana-related substances yield positive results for

#### Marijuana:

11-Nor-Δ-9-THC-9-COOH	50
Δ-9-THC	10,000
Cannabidiol	100,000
Δ-8-THC	7,000
11-hydroxy-Δ-9-THC	2,000
Cannabinol	100,000

The following MDMA-related substances yield positive results for

#### MDMA:

3,4 methylenedioxy-methamphetamine(MDMA)	500
d-Methamphetamine	250
d-amphetamine	10,000
l-Methamphetamine	500
Methylenedioxyethylamphetamine(MDEA)	500
3,4 methylenedioxyamphetamine(MDA)	>100,000
p-Methoxyamphetamine(PMA)	>100,000

The following Methamphetamine-related substances yield positive results for

#### Methamphetamine:

d-Methamphetamine	1,000
d-amphetamine	40,000
l-Methamphetamine	20,000
Methylenedioxyethylamphetamine(MDEA)	2,000
Methylenedioxy-methamphetamine(MDMA)	2,000
3,4 methylenedioxyamphetamine(MDA)	>100,000
p-Methoxyamphetamine(PMA)	>100,000

The following Methadone-related substances yield positive results for

#### Methadone:

Methadone	300
(±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium(EDDP)	50,000
2-Ethyl-5-methyl-3,3-diphenylpyrrolidine (EMDP)	50,000

The following Opiates 300-related substances yield positive results for

#### Opiates 300:

Morphine	300
6-Acetylmorphine	300
Codeine	300
Ethyl morphine	2,000
Hydromorphone	3,000
Hydrocodone	3,000

The following Opiates 2000-related substances yield positive results for

#### Opiates 2000:

Morphine	2,000
6-Acetylmorphine	2,000
Codeine	2,000
Ethyl morphine	25,000
Hydromorphone	30,000

The following Oxycodone-related substances yield positive results for

#### Oxycodone:

Oxycodone	100
Oxymorphone	80,000

The following PCP-related substances yield positive results for

#### Phencyclidine:

Phencyclidine (PCP)	25
Thienylcyclohexylpiperidine (TCP)	3,000

The following Propoxyphene-related substances yield positive results for

#### Propoxyphene:

Propoxyphene	300
Norpropoxyphene	20,000

The following TCA-related substances yield positive results for **TCA**:

Nortriptyline	1,000
Amitriptyline	1,000
Desipramine	800
Imipramine	1,000
Nordoxeplene	1,500
Cyclobenzaprine	3,000
Clomipramine	10,000
Doxepine	5,000
Protriptyline	3,000
Perphenazine	50,000
Promazine	30,000
Trimipramine	5,000

**Table 2:** The following compounds were found not to cross-react when tested at concentrations of 100 ug/ml:

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

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