

KCUR 920065



**INTENDED USE**

The QuikScreen® 9 is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. This drug combination is composed of the following drugs:

| DRUG CLASS               | SENSITIVITY |
|--------------------------|-------------|
| AMPHETAMINE              | 1000 ng/ml  |
| BARBITURATES             | 200 ng/ml   |
| BENZODIAZEPINES          | 300 ng/ml   |
| COCAINE/BENZOYLECAGONINE | 300 ng/ml   |
| MARIJUANA                | 50 ng/ml    |
| METHADONE                | 300 ng/ml   |
| METHAMPHETAMINE          | 1000 ng/ml  |
| OPIATES/MORPHINE         | 2000 ng/ml  |
| PHENCYCLIDINE            | 25 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 QuikScreen® 9 is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs 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 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 QuikScreen® 9 is set as required for the screening immunoassays of these drugs in the reference guidelines set by 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 QuikScreen® 9 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 any of the drug combinations 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 (top bands) 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. **REF 60900**
2. Test Instructions  
Optional:
3. Negative Control I  
Contains buffered protein solution with sodium azide. **REF 4010N**
4. Amphetamine Positive  
Control Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide. **REF 11120-BP**
5. Barbiturates Positive Control  
Contains BAR at 1000 ng/ml in a buffered protein solution with sodium azide. **REF 18040P**
6. Benzodiazepines Positive Control  
Contains BZD at 1000 ng/ml in a buffered protein solution with sodium azide. **REF 18020P**
7. Cocaine Positive Control  
Contains BEG at 1000 ng/ml in a buffered protein solution with sodium azide. **REF 12000-BP**
8. Marijuana Positive Control  
Contains THC at 150 ng/ml in a buffered solution with sodium azide. **REF 13020P**
9. Methadone Positive Control  
Contains MAD at 1000 ng/ml in a buffered protein solution with sodium azide. **REF 19020P**
10. Methamphetaminic Positive  
Control Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. **REF 11320-BP**
11. Opiates Positive Control  
Opiates Positive Control Contains MOR at 5000 ng/ml in a buffered protein solution with sodium azide. **REF 11220-BP**
12. PCP Positive Control  
Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. **REF 14020P**

**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. If stored at 2°-8°C, allow the test kit to reach room temperature (15°-28°C) before performing the test. Refer to the expiration date for stability.

**SPECIMEN COLLECTION AND PREPARATION**

Fresh urine specimens should be collected directly into the cup. The QuikScreen® 9 device employs a thermal strip which should be checked immediately after collection to validate urine specimen. SAMHSA regulations specify that any temperature below 90.5°F must be considered adulterated. No additives or preservatives are required. *Note: Urine specimens can be transferred from a urine collection container into the cup QuikScreen® 9 test cup, if necessary.*

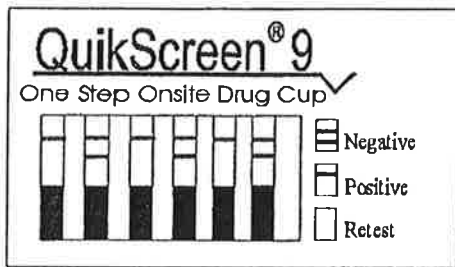
**TEST PROCEDURE**

1. Do not break the seal of the pouch until ready to begin testing.
2. Remove the Test Cup from the foil pouch.

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Eff. Date: 02-18-05

- Collect urine specimen directly into the Test Cup. Insure that the sample amount meets the minimum level as indicated on the side of the Test Cup.
- 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

**Confirm:** A rose-pink band is visible in each control zone (top band). No color band appearing in the appropriate test zone (bottom band) indicates a preliminary positive result for the corresponding drug of that specific test zone. Send urine specimen to a certified laboratory for confirmation.

**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.

**Retest:** 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

- This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
- 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.
- The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
- 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

- Sensitivity.** The QuikScreen<sup>®</sup> 9 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.
- Specificity.** A study was conducted with the QuikScreen<sup>®</sup> 9 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.

**Table I:** Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

The following Amphetamine-related substances yield positive results for Amphetamine at 1000 ng/ml cut-off:

|                         |                 |   |                  |
|-------------------------|-----------------|---|------------------|
| d-Amphetamine           | 1000 ng/ml      |   |                  |
| l-Amphetamine           | 50,000 ng/ml    | β-phenylethylamine                      | 100,000 ng/ml    |
| d,l-Amphetamine         | 1,250 ng/ml     | tyramine                                | 120,000 ng/ml    |
| Deoxyephedrine          | 1,000,000 ng/ml | (±) 3,4-Methylenedioxyamphetamine (MDA) | 500 ng/ml        |
| Phentermine             | 50,000 ng/ml    | Pseudoephedrine                         | 5,000,000 ng/ml  |
| (±) Phenypropionolamine | 50,000 ng/ml    | Ephedrine                               | 10,000,000 ng/ml |

The following Barbiturates-related substances yield positive results for Barbiturates at 200ng/ml cut-off:

|                                    |           |               |           |
|------------------------------------|-----------|---------------|-----------|
| Amobarbital                        | 200 ng/ml | Penobarbital  | 200 ng/ml |
| Barbital                           | 200 ng/ml | Phenobarbital | 200 ng/ml |
| Bromacripiline                     | 200 ng/ml | Secobarbital  | 200 ng/ml |
| Bivaharbital                       | 200 ng/ml | Zivast        | 200 ng/ml |
| Clonazepam (sodium dodecylsulfate) | 260 ng/ml |               |           |

The following Benzodiazepine-related substances yield positive results for Benzodiazepines at 300 ng/ml cut-off:

|                                |            |                            |             |
|--------------------------------|------------|----------------------------|-------------|
| Alprazolam                     | 62.5 ng/ml | 1-N-Hydroxyethylflurazepam | 130 ng/ml   |
| Bromazepam                     | 250 ng/ml  | α-Hydroxytriazolam         | 200 ng/ml   |
| Chlordiazepoxide               | 950 ng/ml  | Ketazolam                  | 210 ng/ml   |
| Clonazepam                     | 2500 ng/ml | Lorazepam                  | 200 ng/ml   |
| Clonazepam                     | 500 ng/ml  | Lormetazepam               | 230 ng/ml   |
| Chlorthalidone                 | 50 ng/ml   | Metazepam                  | 1,000 ng/ml |
| Chlorthalidone                 | 460 ng/ml  | Midazolam                  | 130 ng/ml   |
| Doxepin (Chemically not a BZD) | 200 ng/ml  | Nitrazepam                 | 200 ng/ml   |
| Demoxepam                      | 600 ng/ml  | Norchloridiazepoxide       | 770 ng/ml   |
| n-Desethylflurazepam           | 300 ng/ml  | Nordiazepam                | 200 ng/ml   |
| Desmethyldiazepam              | 50 ng/ml   | Oxazepam                   | 200 ng/ml   |
| Diazepam                       | 50 ng/ml   | Praxepam                   | 100 ng/ml   |
| Flunitrazepam                  | 250 ng/ml  | Temazepam                  | 200 ng/ml   |
| Flurazepam                     | 100 ng/ml  | Triazolam                  | 200 ng/ml   |
| Halazepam                      | 160 ng/ml  |                            |             |
| α-Hydroxypropionolam           | 200 ng/ml  |                            |             |

The following Cocaine-related substances yield positive results for Cocaine

at 300 ng/ml Cut-Off Level

|                |             |
|----------------|-------------|
| Benzylecgonine | 300 ng/ml   |
| Cocaine        | 300 ng/ml   |
| Isaxoprine     | 2,500 ng/ml |

The following Marijuana-related substances yield positive results for Marijuana at 50 ng/ml cut-off:

|                                   |          |
|-----------------------------------|----------|
| 11-Nor-Δ <sup>9</sup> -THC-9-COOH | 50 ng/ml |
| 11-Nor-Δ <sup>9</sup> -THC-9-COOH | 50 ng/ml |
| Δ <sup>9</sup> -THC               | 1 μg/ml  |
| Δ <sup>8</sup> -THC               | 4 μg/ml  |
| Cannabidiol                       | 10 μg/ml |
| 11-Hydroxy-Δ <sup>9</sup> -THC    | 10 μg/ml |

The following Methadone-related substances yield positive results for Methadone at 300 ng/ml Cut-Off Level:

|                  |              |
|------------------|--------------|
| Methadone        | 300 ng/ml    |
| Doxylamine       | 50,000 ng/ml |
| Dextromethorphan | 10,000 ng/ml |
| Diphenhydramine  | 10,000 ng/ml |
| EDDP             | 500 ng/ml    |

The following Methamphetamine-related substances yield positive results for Methamphetamine at 1000 ng/ml Cut-Off Level:

|   |                  |
|---|------------------|
| (±) 3,4-Methylenedioxyamphetamine (MDMA, Ecstasy) | 1,250 ng/ml      |
| d-Amphetamine                                     | 50,000 ng/ml     |
| (±) 3,4-Methylenedioxyamphetamine (MDA)           | 250,000 ng/ml    |
| (±) Methamphetamine                               | 1,000 ng/ml      |
| d, l-Amphetamine                                  | 500,000 ng/ml    |
| Deoxyephedrine                                    | 1,000 ng/ml      |
| Ephedrine   | 10,000,000 ng/ml |
| Phenylpropionolamine                              | 10,000,000 ng/ml |
| Pseudoephedrine                                   | 2,500 ng/ml      |

The following Opium-related substances yield a positive result for Opium at 2000 ng/ml Cut-Off Level:

|                            |                 |
|----------------------------|-----------------|
| Morphine                   | 2,000 ng/ml     |
| Morphine-3-β-D-Glucuronide | 2,000 ng/ml     |
| Codine                     | 2,000 ng/ml     |
| Heroin                     | 2,000 ng/ml     |
| Norendine                  | 20,000 ng/ml    |
| Hydrocodone                | 5,000 ng/ml     |
| Hydromorphone              | 2,000 ng/ml     |
| Oxycodone                  | 100,000 ng/ml   |
| Lorazepamol                | 6,000 ng/ml     |
| Naloxone                   | 10,000 ng/ml    |
| Thebaine                   | 15,000 ng/ml    |
| Imipramine                 | 500,000 ng/ml   |
| Atropine                   | 1,000,000 ng/ml |
| Meperidine                 | 1,000,000 ng/ml |
| Ranitidine                 | 1,000,000 ng/ml |

The following Phencyclidine (PCP)-related substances yield positive results for PCP at 25 ng/ml Cut-Off:

|                                      |              |  |           |
|--------------------------------------|--------------|--|-----------|
| n-Acetylprocainamide                 | 10,000 ug/ml | Phencyclidine                            | 25 ug/ml  |
| Cocaine                              | 5,000 ug/ml  | 1-(4-Hydroxyphenyl) phenylcyclohexane    | 550 ug/ml |
| p-Hydroxymethamphetamine             | 50,000 ug/ml | 1-(1-Phenylcyclohexyl) pyrrolidine       | 200 ug/ml |
| Thebaine                             | 10,000 ug/ml | 4-Phenyl-1-piperidino cyclohexanol       | 60 ug/ml  |
| 1-(1-Phenylcyclohexyl) morphine      | 600 ug/ml    | 1-[1-(2-Thienyl)-cyclohexyl] piperidine  | 30 ug/ml  |
| N,N-Diethyl-1-phenyl-cyclohexylamine | 2.0 ug/ml    | 1-[1-(2-Thienyl)-cyclohexyl] pyrrolidine | 600 ug/ml |
| 1-[1-(2-Thienyl)cyclohexyl]morphine  | 200 ug/ml    |  |           |

Table II: Compounds tested and found not to cross-react with the test at a specified concentration amount in urine.

The following compounds do not cross-react with (1000 ng/ml cut-off) Amphetamine at a 100 ug/ml concentration in urine:

|                              |                                    |                                    |
|------------------------------|------------------------------------|------------------------------------|
| Acetaminophen                | 5,5-Diphenylhydantoin              | Morphine Sulfate                   |
| Acetylsalicylic Acid         | Doxylamine                         | Oxazepam                           |
| Amikacin                     | Ecgonine HCl                       | Oxycodone                          |
| Amiripipiline                | Ecgonine Methyl Ester              | Penicillin G                       |
| Ampicillin, Sodium Salt      | Glucose                            | Pentobarbital                      |
| Articrenol                   | Histamine                          | d-Propoxyphene                     |
| Aspartame                    | Hydrochlorothiazide                | 1-Propanol                         |
| Atropine                     | Hydrocodone                        | Phencyclidine HCl                  |
| Benzoic Acid                 | Hydromorphone                      | 1-Phenylephrine                    |
| Benzoylcegonine              | Indomethacin                       | Quinine                            |
| Caffeine                     | Ketoprofen                         | Ranitidine                         |
| (1) Chlorpheniramine Maleate | Levorphanol                        | Sodium Salicylate                  |
| (2) Chlorpheniramine Maleate | $\Delta^9$ -THC                    | Tetracycline                       |
| Chlorpromazine HCl           | (-)-11-Nor- $\Delta^9$ -THC-9-COOH | Tetrahydrozoline                   |
| Cimetidine                   | Meperidine                         | Theophylline                       |
| Cocaine                      | Methylphenidate                    | Thioridazine                       |
| Dextromethorphan HBr         | Methadone                          | Trifluoperazine                    |
| Diazepam                     | Methaqualone                       | Morphine-3- $\beta$ -D-Glucuronide |
|                              |                                    | Tryptophan                         |

The following compounds do not cross-react with (200 ng/ml cut-off) Barbiturates at a 100 ug/ml concentration in urine:

|                      |                                    |                     |
|----------------------|------------------------------------|---------------------|
| Acetaminophen        | 5,5-Diphenylhydantoin              | Morphine Sulfate    |
| Acetylsalicylic Acid | Doxylamine                         | Oxazepam            |
| Amikacin             | Ecgonine HCl                       | Oxycodone           |
| Amiripipiline        | Ecgonine Methyl Ester              | Penicillin G        |
| Ampicillin           | Glucose                            | Pentobarbital       |
| Articrenol           | Histamine                          | Phendimetrazine     |
| Aspartame            | Hydrochlorothiazide                | Phentermine         |
| Atropine Sulfate     | Hydrocodone                        | 1-Phenylephrine     |
| Benzoic Acid         | Hydromorphone                      | Phenylpropanolamine |
| Benzoylcegonine HCl  | Indomethacin                       | Prednisone          |
| Caffeine             | Ketoprofen                         | Quinine             |
| Chlorpheniramine     | Levorphanol                        | Ranitidine          |
| Chlorpromazine HCl   | $\Delta^9$ -THC                    | Sodium Salicylate   |
| Cimetidine           | 11-Nor- $\Delta^9$ -THC-9-COOH     | Tetracycline        |
| Cocaine              | Meperidine                         | Tetrahydrozoline    |
| Deoxyephedrine       | Methylphenidate                    | Theophylline        |
| Dextromethorphan     | Methadone                          | Thioridazine        |
| Diazepam             | Methaqualone                       | Trifluoperazine     |
| Diethylpropion       | Morphine-3- $\beta$ -D-Glucuronide | Tryptophan          |

The following compounds do not cross-react with (300 ng/ml cut-off) Benzodiazepines at a 100 ug/ml concentration in urine:

|                       |                                    |                     |
|-----------------------|------------------------------------|---------------------|
| Acetaminophen         | Doxylamine                         | Oxycodone           |
| Acetylsalicylic Acid  | Ecgonine HCl                       | Phendimetrazine     |
| Amikacin              | Ecgonine Methyl Ester              | Penicillin G        |
| Amiripipiline         | Glucose                            | Pentobarbital       |
| Ampicillin            | Histamine                          | Phencyclidine       |
| Articrenol            | Hydrochlorothiazide                | Phenobarbital       |
| Aspartame             | Hydrocodone                        | Phentermine         |
| Atropine Sulfate      | Hydromorphone                      | Phenylpropanolamine |
| Benzoic Acid          | Indomethacin                       | 1-Phenylephrine     |
| Benzoylcegonine HCl   | Ketoprofen                         | d-Propoxyphene      |
| Caffeine              | Levorphanol                        | 1-Propanol          |
| Chlorpheniramine      | $\Delta^9$ -THC                    | Ranitidine          |
| Chlorpromazine HCl    | (-)-11-Nor- $\Delta^9$ -THC-9-COOH | Sodium Salicylate   |
| Cimetidine            | Meperidine                         | Tetracycline        |
| Cocaine               | Methylphenidate                    | Tetrahydrozoline    |
| Deoxyephedrine        | Methadone                          | Theophylline        |
| Dextromethorphan      | Methaqualone                       | Thioridazine        |
| Diethylpropion        | Morphine-3- $\beta$ -D-Glucuronide | Trifluoperazine     |
| 5,5-Diphenylhydantoin | Morphine Sulfate                   | Tryptophan          |

The following compounds do not cross-react with (300 ng/ml cut-off) Cocaine at a 100 ug/ml concentration in urine:

|                      |                                    |                     |
|----------------------|------------------------------------|---------------------|
| Acetaminophen        | Ecgonine HCl                       | Phendimetrazine     |
| Acetylsalicylic Acid | Ecgonine Methyl Ester              | Penicillin G        |
| Amikacin             | Glucose                            | Pentobarbital       |
| Amiripipiline        | Histamine                          | d-Propoxyphene      |
| Ampicillin           | Hydrochlorothiazide                | 1-Propanol          |
| Articrenol           | Hydrocodone                        | Phencyclidine       |
| Aspartame            | Hydromorphone                      | Phenobarbital       |
| Atropine Sulfate     | Indomethacin                       | Phentermine         |
| Benzoic Acid         | Ketoprofen                         | Phenylpropanolamine |
| Caffeine             | Levorphanol                        | 1-Phenylephrine     |
| Chlorpheniramine     | $\Delta^9$ -THC                    | Quinine             |
| Chlorpromazine HCl   | 11-Nor- $\Delta^9$ -THC-9-COOH     | Ranitidine          |
| Cimetidine           | Meperidine                         | Sodium Salicylate   |
| Cocaine              | Methylphenidate                    | Tetracycline        |
| Deoxyephedrine       | Methadone                          | Tetrahydrozoline    |
| Dextromethorphan     | Methaqualone                       | Theophylline        |
| Diazepam             | Morphine-3- $\beta$ -D-Glucuronide | Thioridazine        |
| Diethylpropion       | Morphine Sulfate                   | Trifluoperazine     |
|                      | Oxazepam                           | Tryptophan          |
|                      | Oxycodone                          |                     |

The following compounds do not cross-react with (50 ng/ml cut-off) Marijuana at a 100 ug/ml concentration in urine:

|                      |                                    |                            |
|----------------------|------------------------------------|----------------------------|
| Acetaminophen        | Digitoxin                          | Meperidine                 |
| Acetamidophenol      | Digoxin                            | Methadone                  |
| Acetylsalicylic Acid | Ecgonine HCl                       | Methaqualone               |
| Amikacin             | Ecgonine Methyl Ester              | Naloxone                   |
| Ampicillin           | Ephedrine                          | Necnycin                   |
| d,l-Amphetamine      | Epinephrine                        | Niacinamide                |
| Amiripipiline        | Genisic Acid                       | Oxazepam                   |
| Articrenol           | Glucose                            | Perphenazine               |
| Aspartame            | Guaiacal                           | Penicillin G               |
| Atropine Sulfate     | Glycerol Ether                     | Phencyclidine              |
| Benzoic Acid         | Histamine                          | Phenobarbital              |
| Benzoylcegonine      | Hydrochlorothiazide                | $\alpha$ -Phenylethylamine |
| Caffeine             | Hydrocodone                        | Phenylpropanolamine        |
| Camphor              | Hydromorphone                      | Pramethazine               |
| Chloroquine          | Homatropine                        | Pseudoephedrine            |
| Chlorpheniramine     | Imipramine                         | Ranitidine                 |
| Chlorpromazine HCl   | Isoproterenol                      | Salicylic Acid             |
| Cocaine HCl          | Ketamine                           | Secobarbital               |
| Cocaine              | Lidocaine                          | Tetracycline               |
| Cimetidine           | Methylphenidate                    | Tetrahydrozoline           |
| Cortisone            | Morphine                           | Theophylline               |
| Deoxyephedrine       | Morphine-3- $\beta$ -D-Glucuronide | Thioridazine               |
| Dextromethorphan     | Morphine Sulfate                   | Trifluoperazine            |
| Diazepam             | d-Methamphetamine                  | Tryptophan                 |

The following compounds do not cross-react with (300 ng/ml cut-off) Methadone at a 100 ug/ml concentration in urine:

|                       |                                    |                     |
|-----------------------|------------------------------------|---------------------|
| Acetaminophen         | Ecgonine HCl                       | Phendimetrazine     |
| Acetylsalicylic Acid  | Ecgonine Methyl Ester              | Penicillin G        |
| Amikacin              | Glucose                            | Pentobarbital       |
| Amiripipiline         | Histamine                          | d-Propoxyphene      |
| Ampicillin            | Hydrochlorothiazide                | 1-Propanol          |
| Articrenol            | Hydrocodone                        | Phencyclidine       |
| Aspartame             | Hydromorphone                      | Phenobarbital       |
| Atropine Sulfate      | Indomethacin                       | Phentermine         |
| Benzoic Acid          | Ketoprofen                         | Phenylpropanolamine |
| Benzoylcegonine HCl   | Levorphanol                        | 1-Phenylephrine     |
| Caffeine              | $\Delta^9$ -THC                    | Quinine             |
| Chlorpheniramine      | 11-Nor- $\Delta^9$ -THC-9-COOH     | Ranitidine          |
| Chlorpromazine HCl    | Meperidine                         | Sodium Salicylate   |
| Cimetidine            | Methylphenidate                    | Tryptophan          |
| Cocaine               | Methaqualone                       | Tetracycline        |
| Deoxyephedrine        | Morphine-3- $\beta$ -D-Glucuronide | Tetrahydrozoline    |
| Diazepam              | Morphine Sulfate                   | Theophylline        |
| Diethylpropion        | Oxazepam                           | Thioridazine        |
| 5,5-Diphenylhydantoin | Oxycodone                          | Trifluoperazine     |

The following compounds do not cross-react with (1000 ng/ml cut-off) Methamphetamine at a 100 ug/ml concentration in urine:

|                                    |                                    |                   |
|------------------------------------|------------------------------------|-------------------|
| Acetaminophen                      | 5,5-Diphenylhydantoin              | Oxazepam          |
| Acetylsalicylic Acid               | Doxylamine                         | Oxycodone         |
| Amikacin                           | Ecgonine HCl                       | Phendimetrazine   |
| Amiripipiline                      | Ecgonine Methyl Ester              | Penicillin G      |
| Ampicillin, Sodium Salt            | Glucose                            | Pentobarbital     |
| Articrenol                         | Histamine                          | d-Propoxyphene    |
| Aspartame                          | Hydrochlorothiazide                | 1-Propanol        |
| Atropine Sulfate                   | Hydrocodone                        | Phencyclidine HCl |
| Benzoic Acid                       | Hydromorphone                      | Phenobarbital     |
| Benzoylcegonine HCl                | Indomethacin                       | 1-Phenylephrine   |
| Caffeine                           | Ketoprofen                         | Quinine           |
| (+) Chlorpheniramine, Maleate-Salt | Levorphanol                        | Ranitidine        |
| (-) Chlorpromazine HCl             | $\Delta^9$ -THC                    | Sodium Salicylate |
| Cimetidine                         | 11-Nor- $\Delta^9$ -THC-9-COOH     | Tryptophan        |
| Cocaine                            | Meperidine                         | Tetracycline      |
| Deoxyephedrine                     | Methylphenidate                    | Tetrahydrozoline  |
| Dextromethorphan HBr               | Methadone                          | Theophylline      |
| Diazepam                           | Methaqualone                       | Thioridazine      |
|                                    | Morphine-3- $\beta$ -D-Glucuronide | Trifluoperazine   |
| Diethylpropion                     | Morphine Sulfate                   |                   |

The following compounds do not cross-react with (2000 ng/ml cut-off) Opiates at a 100 µg/ml concentration in urine:

|                             |                              |                            |
|-----------------------------|------------------------------|----------------------------|
| <i>Acetaminophen</i>        | <i>5,5-Diphenylhydantoin</i> | <i>Pentobarbital</i>       |
| <i>Acetylsalicylic Acid</i> | <i>Doxylamine</i>            | <i>d-Propoxyphene</i>      |
| <i>Amikacin</i>             | <i>Egonine HCl</i>           | <i>l-Propanol</i>          |
| <i>Amitriptyline</i>        | <i>Egonine Methyl Ester</i>  | <i>Phencyclidine</i>       |
| <i>Ampicillin</i>           | <i>Glucose</i>               | <i>Phenobarbital</i>       |
| <i>Arterenal</i>            | <i>Histamine</i>             | <i>Phentermine</i>         |
| <i>Asparicame</i>           | <i>Hydrochlorothiazide</i>   | <i>Phenylpropanolamine</i> |
| <i>Benzoic Acid</i>         | <i>Indomethacin</i>          | <i>l-Phenylephrine</i>     |
| <i>Benzoylcegonine HCl</i>  | <i>Ketoprofen</i>            | <i>Quinine</i>             |
| <i>Caffeine</i>             | <i>Δ-THC</i>                 | <i>Sodium Salicylate</i>   |
| <i>Chlorpheniramine</i>     | <i>11-Nor-Δ-THC-9-COOH</i>   | <i>Tetracycline</i>        |
| <i>Chlorpromazine HCl</i>   | <i>Methylphenidate</i>       | <i>Tetrahydrozoline</i>    |
| <i>Cimetidine</i>           | <i>Methadone</i>             | <i>Theophylline</i>        |
| <i>Deoxyephedrine</i>       | <i>Methaqualone</i>          | <i>Thiuridazine</i>        |
| <i>Dextromethorphan</i>     | <i>Oxazepam</i>              | <i>Trifluoperazine</i>     |
| <i>Diazepam</i>             | <i>Phendimetrazine</i>       | <i>Tryptophan</i>          |
| <i>Diethylpropion</i>       | <i>Penicillin G</i>          |                            |

The following compounds do not cross-react with (25 ng/ml cut-off) Phencyclidine at a 100 µg/ml concentration:

|                              |                                   |                            |
|------------------------------|-----------------------------------|----------------------------|
| <i>Acetaminophen</i>         | <i>Doxylamine</i>                 | <i>Oxazepam</i>            |
| <i>Acetylsalicylic Acid</i>  | <i>Egonine HCl</i>                | <i>Oxycodone</i>           |
| <i>Amikacin</i>              | <i>Egonine Methyl Ester</i>       | <i>Phendimetrazine</i>     |
| <i>Amitriptyline</i>         | <i>Glucose</i>                    | <i>Penicillin G</i>        |
| <i>Ampicillin</i>            | <i>Histamine</i>                  | <i>d-Propoxyphene</i>      |
| <i>Arterenal</i>             | <i>Hydrocodone</i>                | <i>l-Propanol</i>          |
| <i>Asparicame</i>            | <i>Hydromorphone</i>              | <i>Phenobarbital</i>       |
| <i>Atropine Sulfate</i>      | <i>Hydrochlorothiazide</i>        | <i>Phentermine</i>         |
| <i>Benzoic Acid</i>          | <i>Indomethacin</i>               | <i>Phenylpropanolamine</i> |
| <i>Benzoylcegonine HCl</i>   | <i>Ketoprofen</i>                 | <i>l-Phenylephrine</i>     |
| <i>Caffeine</i>              | <i>Levorphanol</i>                | <i>Quinine</i>             |
| <i>Chlorpheniramine</i>      | <i>Δ-THC</i>                      | <i>Ranitidine</i>          |
| <i>Chlorpromazine HCl</i>    | <i>11-Nor-Δ-THC-9-COOH</i>        | <i>Sodium Salicylate</i>   |
| <i>Cimetidine</i>            | <i>Meperidine</i>                 | <i>Tryptophan</i>          |
| <i>Deoxyephedrine</i>        | <i>Methylphenidate</i>            | <i>Tetracycline</i>        |
| <i>Dextromethorphan</i>      | <i>Methadone</i>                  | <i>Tetrahydrozoline</i>    |
| <i>Diazepam</i>              | <i>Methaqualone</i>               | <i>Theophylline</i>        |
| <i>Diethylpropion</i>        | <i>Morphine-3-β-D-Glucuronide</i> | <i>Thiuridazine</i>        |
| <i>5,5-Diphenylhydantoin</i> | <i>Morphine Sulfate</i>           | <i>Trifluoperazine</i>     |

3. Accuracy: The accuracy of the QuikScreen® 9 Test was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. The laboratory used EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The results are summarized as follows:

### 3.1 AMPHETAMINE (AMP) 1000ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 205                          | 0                            |
| QuikScreen® Negative | 0                            | 237                          |

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%.

### 3.2 BARBITURATE (BAR) 200ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 23                           | 0                            |
| QuikScreen® Negative | 0                            | 542                          |

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%.

### 3.3 BENZODIAZEPINE (BZD) 300ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 33                           | 1                            |
| QuikScreen® Negative | 2                            | 529                          |

When compared to EMIT II the relative sensitivity between positive samples was 94.29%. The relative specificity between negative samples was 99.81%. The concordance of the combined data with respect to EMIT II was 97.47%.

### 3.4 COCAINE (BEG) 300 ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 165                          | 2                            |
| QuikScreen® Negative | 0                            | 151                          |

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 98.69%. The concordance of the combined data with respect to EMIT II was 99.37%.

### 3.5 MARIJUANA (THC) 50 ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 52                           | 0                            |
| QuikScreen® Negative | 0                            | 513                          |

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%.

### 3.6 METHADONE (MAD) 300ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 161                          | 0                            |
| QuikScreen® Negative | 5                            | 704                          |

When compared to EMIT II the relative sensitivity between positive samples was 96.99%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 99.43%.

Note: The above data for Methadone reflects the results of in-house urine sample testing.

### 3.7 METHAMPHETAMINE (MET) 1000 ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 162                          | 0                            |
| QuikScreen® Negative | 8                            | 237                          |

When compared to EMIT II the relative sensitivity between positive samples was 95.29%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 98.03%.

### 3.8 OPIATES (OPI) 2000 ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 195                          | 0                            |
| QuikScreen® Negative | 0                            | 500                          |

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%.

### 3.9 PHENCYCLIDINE (PCP) 25ng/ml Cut-Off Level

|                      | <u>Syva EMIT II Positive</u> | <u>Syva EMIT II Negative</u> |
|----------------------|------------------------------|------------------------------|
| QuikScreen® Positive | 14                           | 0                            |
| QuikScreen® Negative | 0                            | 551                          |

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%.

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 =Order Number, Catalog Number


 =In-Vitro Diagnostic Device

 =Use only once.

 =Read instructions carefully before use.

 =LOT Number, Batch Number

 =Use Before Expiration Date

 = Ce Mark