

QuikScreen® Test

REF 60001

Instructions



INTENDED USE

The QuikScreen® Test is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. This test is an in vitro diagnostic medical device for healthcare professional use only. A drug combination is composed from any of the following drugs:

DRUG CLASS	SENSITIVITY
AMPHETAMINE	500 ng/ml
AMPHETAMINE	1000 ng/ml
BARBITURATES	200 ng/ml
BENZODIAZEPINE	200 ng/ml
BENZODIAZEPINE	300 ng/ml
COCAINE/BENZOYLECGONINE	150 ng/ml
COCAINE/BENZOYLECGONINE	300 ng/ml
METHAMPHETAMINE	500 ng/ml
METHAMPHETAMINE	1000 ng/ml
OPIATES/MORPHINE	300 ng/ml
OPIATES/MORPHINE	2000 ng/ml
PHENCYCLIDINE	25 ng/ml
MARIJUANA	50 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® 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 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 (SAMHSA). Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the QuikScreen® Test is set as required for the screening immunoassays of these drugs in the reference guidelines set by SAMHSA and the U.S. Department of Health and Human Services.

PRINCIPLE OF THE TEST

The QuikScreen® 12 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 (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. REF PI-60001
 2. Test Instructions. REF PI-60001
- Optional:**
3. Negative Control I. Contains buffered protein solution with sodium azide. REF 4010N
 4. Amphetamine Positive Control. Contains AMP at 1500 ng/ml or 3000 ng/ml in a buffered protein solution with sodium azide. REF 11120P
 5. Barbiturate Positive Control. Contains BAR at 1000 ng/ml in a buffered solution with sodium azide. REF 18020P
 6. Benzodiazepine Positive Control. Contains BZD at 1000 ng/ml in a buffered solution with sodium azide. REF 18020P
 7. Cocaine Positive Control. Contains COC at 1000 ng/ml in a buffered protein solution with sodium azide. REF 12000P
 8. Methamphetamine Positive Control. Contains MET at 1500 ng/ml or 3000 ng/ml in a buffered protein solution with sodium azide. REF 11320P
 9. Opiates Positive Control. Contains OPI at 1000 ng/ml or 5000 ng/ml in a buffered protein solution with sodium azide. REF 11220P
 10. Phencyclidine Positive Control. Contains PCP at 100 ng/ml in a buffered solution with sodium azide. REF 14020P
 11. Marijuana Positive Control. Contains THC at 150 ng/ml in a buffered solution with sodium azide. REF 13020P

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® Test 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® 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.
3. 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.
4. 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.

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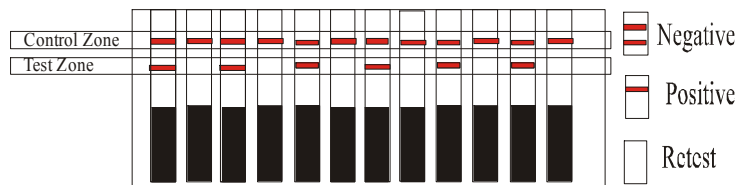
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INTERPRETATION OF RESULTS

(Number of strips will vary depending on test)

QuikScreen® Test

One Step Onsite Drug Cup



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. 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.

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 QuikScreen® 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 SAMHSA and the U.S. Department of Health and Human Services for the immunoassay method.
2. **Specificity.** A study was conducted with the QuikScreen® 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**.

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 a positive result for Amphetamine at 500 ng/ml Cut-Off level:

d-Amphetamine	500 ng/ml
l-Amphetamine	25,000 ng/ml
d,l-Amphetamine	600 ng/ml
(±)3,4-Methylenedioxyamphetamine-HCl (MDA)	600 ng/ml
(±)3,4-Methylenedioxyethylamphetamine-HCl (MDEA)	100,000 ng/ml
β-Phenylethylamine	1,000 ng/ml
(±)Phenylpropanolamine	100,000 ng/ml
Tyramine	12,500 ng/ml

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

d-Amphetamine	1000 ng/ml
l-Amphetamine	25,000 ng/ml
d,l-Amphetamine	10,000 ng/ml
β-Phenylethylamine	180,000 ng/ml
Tyramin	100,000 ng/ml
(±) 3,4-Methylenedioxyamphetamine-HCl (MDA)	1200 ng/ml

The following Barbiturate-related substances yield a positive result for Barbiturates at 200 ng/ml Cut-Off Level:

Secobarbital	200 ng/ml
Pentobarbital	800 ng/ml
Amobarbital	1600 ng/ml
Butobarbital	2000 ng/ml
Barbital	3500 ng/ml
Phenobarbital	3500 ng/ml

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

Alpha hydroxyvaltriazolam	200 ng/ml	Lorazepam	250 ng/ml
Alprazolam	40 ng/ml	Lormetazepam	250 ng/ml
Bromazepam	50 ng/ml	Medazepam	1000 ng/ml
Clobazam	150 ng/ml	Nitrazepam	125 ng/ml
Chlorazepate	100 ng/ml	Nordiazepam	200 ng/ml
Clonazepam	500 ng/ml	Oxazepam	200 ng/ml
Diazepam	150 ng/ml	Prazepam	750 ng/ml
Desmethyldiazepam	50 ng/ml	Temazepam	75 ng/ml
Flunitrazepam	150 ng/ml	Triazolam	50 ng/ml
Flurazepam	50 ng/ml		

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

Alprazolam	600 ng/ml	Flurazepam	150 ng/ml
Bromazepam	100 ng/ml	Lorazepam	500 ng/ml
Chlordiazepoxide	300 ng/ml	Lormetazepam	500 ng/ml
Clobazam	300 ng/ml	Nitrazepam	250 ng/ml
Clonazepam	300 ng/ml	Nordiazepam	150 ng/ml
Clorazepate	200 ng/ml	Oxazepam	300 ng/ml
Delorazepam	3,000 ng/ml	Prazepam	1,500 ng/ml
Diazepam	300 ng/ml	Temazepam	150 ng/ml
Estazolam	300 ng/ml	Triazolam	200 ng/ml
Flunitrazepam	300 ng/ml		

The following Cocaine-related substances yield positive results for Cocaine at 150 ng/ml Cut-Off Level

Cocaine	150 ng/ml
Benzoyl Ecgonine	150 ng/ml
Isosuprine	3000 ng/ml

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

Cocaine	300 ng/ml
Benzoyl Ecgonine	300 ng/ml

The following Methamphetamine-related substances yield positive results for Methamphetamine at 500 ng/ml Cut-Off Level:

(±) 3,4-Methylenedioxyamphetamine (MDMA)	500 ng/ml
Deoxyephedrine	500 ng/ml
Pseudoephedrine	100,000 ng/ml
δ, l-Amphetamine	100,000 ng/ml
d-Amphetamine	50,000 ng/ml
l-Amphetamine	100,000 ng/ml
(±) 3,4-Methylenedioxyamphetamine (MDA)	50,000 ng/ml
(±) 3,4-Methylenedioxyethylamphetamine ((±) 3,4-MDEA)	500 ng/ml
(+)-Methamphetamine	500 ng/ml

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

(+) Methamphetamine	1000 ng/ml
(±)3,4-Methylenedioxyamphetamine (MDMA)	1000 ng/ml
(±)3,4-Methylenedioxyamphetamine (MDA)	200,000 ng/ml
d-Amphetamine Sulfate	200,000 ng/ml
l-amphetamine Sulfate	200,000 ng/ml
d-,l-Amphetamine Sulfate	200,000 ng/ml

The following Opiates-related substances yield a positive result for Opiates at 300 ng/ml Cut-Off Level:

Opiate (Morphine Sulfate)	300 ng/ml
Morphine-3-β-D-Glucuronide	300 ng/ml
Codeine	300 ng/ml
Heroin	300 ng/ml
Hydromorphone	300 ng/ml
Hydrocodone	1000 ng/ml
Levorphanol	600 ng/ml
Oxycodone	50,000 ng/ml
Naloxone	3,000 ng/ml
Thebaine	2000 ng/ml
Norcodeine	1,000 ng/ml
Imipramine	100,000 ng/ml
Meperidine	100,000 ng/ml
Ranitidine	50,000 ng/ml

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The following Opiates-related substances yield a positive result for Opiates at 2000 ng/ml cut-off Level:

Morphine	2000 ng/ml
Morphine Sulfate Pentahydrate	2000 ng/ml
Morphine-3-β-D Glucuronide	2000 ng/ml
Cocaine	2000 ng/ml
Heroin	2000 ng/ml
Levorphanol	4000 ng/ml
Ranitidine	100,000 ng/ml
6-Acetylmorphine	50 ng/ml

The following Phencyclidine-related substances yield a positive result for PCP at 25 ng/ml cut-off Level:

Phencyclidine	25 ng/ml
Tenocyclidine	2000 ng/ml

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

11-nor-D -8-THC-9-COOH	50 ng/ml
11-nor-D -9-THC-9-COOH	50 ng/ml
D 8-THC	7500 ng/ml
D 9-THC	10,000 ng/ml
Cannabinol	10,000 ng/ml
11-hydroxy-D 9-THC	2500 ng/ml

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

The following compounds do not cross-react with (500 ng/ml cut-off) Amphetamine at a 100 µg/ml concentration in urine:

Acetaminophen	Ecgonine HCl	Oxycodone
Acetylsalicylic Acid	Ecgonine Methyl Ester	Phendimetrazine
Amikacin	Glucose	Penicillin G
Amitriptyline	Histamine	Pentobarbital
Ampicillin, Sodium Salt	Hydrochlorothiazide	d-Propoxyphene
Arterenol	Hydrocodone	l-Propranol
Aspartame	Hydromorphone	Phencyclidine HCl
Atropine	Indomethacin	Phenobarbital
Benzoic Acid	Ketoprofen	l-Phenylephrine
Benzoyllecgonine	Levorphanol	Quinine
Caffeine	Δ ⁸ -THC	Ranitidine
(+) Chlorpheniramine Maleate	(-)11-Nor-Δ ⁸ -THC-9-COOH	Sodium Salicylate
(±) Chlorpheniramine Maleate	Meperidine	Tetracycline
Chlorpromazine HCl	Methylphenidate	Tetrahydrozoline
Cimetidine	Methadone	Theophylline
Codeine	Dextromethorphan HBr	Thioridazine
Dextromethorphan HBr	Diazepam	Trifluoperazine
Diazepam	5,5-Diphenylhydantoin	Tryptophan
5,5-Diphenylhydantoin	Doxylamine	
Doxylamine	Oxazepam	

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

Acetaminophen	Ecgonine HCl	Penicillin G
Acetylsalicylic Acid	Ecgonine Methyl Ester	Pentobarbital
Amikacin	Glucose	d-Propoxyphene
Amitriptyline	Histamine	Hydrochlorothiazide
Ampicillin	Hydrocodone	Propranol
Arterenol	Hydromorphone	Phencyclidine
Aspartame	Indomethacin	Phenobarbital
Atropine Sulfate	Ketoprofen	Phentermine
Benzoic Acid	Levorphanol	Phenylpropanolamine
Benzoyllecgonine HCl	Δ ⁹ -THC	L-Phenylephrine
Caffeine	11-nor-A-9-carboxy-THC-9-COOH	Quinine
Chlorpheniramine	Meperidine	Ranitidine
Chlorpromazine HCl	Methylphenidate	Sodium Salicylate
Cimetidine	Methadone	Tryptophan
Codeine	Dextromethorphan	Tetracycline
Deoxyephedrine	Diazepam	Tetrahydrozoline
Dextromethorphan	Diethylpropion	Theophylline
Diazepam	Diphenylhydantoin	Thioridazine
Diethylpropion	Doxylamine	Trifluoperazine
Diphenylhydantoin		
Doxylamine		

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

Acetaminophen	Diphenylhydantoin	Oxycodone
Acetylsalicylic Acid	Doxylamine	Pendimetrazine
Amikacin	Ecgonine HCl	Penicillin G
Amitriptyline	Ecgonine Methyl Ester	d-Propoxyphene Hydrochlorothiazide
Ampicillin	Glucose	Propranol
Arterenol	Histamine	Phencyclidine
Aspartame	Hydrocodone	Phentermine
Atropine Sulfate	Hydromorphone	Phenylpropanolamine
Benzoic Acid	Indomethacin	L-Phenylephrine
Benzoic Acid	Ketoprofen	Quinine
Benzoyllecgonine HCl	Levorphanol	Ranitidine
Bromocriptine	D-9-THC	Sodium Dodecylsulfate
Caffeine	11-nor-D-9-carboxy-THC-9-COOH	Sodium Salicylate
Chlorpheniramine	COOH	Tetracycline
Chlorpromazine HCl	Meperidine	Tetrahydrozoline
Cimetidine	Methylphenidate	Theophylline
Codeine	Methadone	Thioridazine
Deoxyephedrine	Methaqualone	Trifluoperazine
Dextromethorphan	Morp. Glucuronide	Tryptophan
Diazepam	Morphine Sulfate	Zoloft (Sertraline)
Diethylpropion	Oxazepam	

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

Acetaminophen	Diphenylhydantoin	Pendimetrazine
Acetylsalicylic Acid	Doxylamine	Penicillin G
Amikacin	Ecgonine HCl	Pentobarbital
Amitriptyline	Ecgonine Methyl Ester	Phencyclidine
Ampicillin	Glucose	Phenobarbital
Arterenol	Histamine	Phentermine
Aspartame	Hydrocodone	L-Phenylephrine
Atropine Sulfate	Hydromorphone	Phenylpropanolamine
Benzoic Acid	Indomethacin	Propranol
Benzoyllecgonine HCl	Ketoprofen	d-Propoxyphene Hydrochlorothiazide
Caffeine	Levorphanol	Quinine
Chlorpheniramine	D-9-THC	Ranitidine
Chlorpromazine HCl	11-nor-D-9-carboxy-THC-9-COOH	Sodium Salicylate
Cimetidine	Meperidine	Tetracycline
Codeine	Methadone	Tetrahydrozoline
Deoxyephedrine	Methaqualone	Theophylline
Dextromethorphan	Methylphenidate	Thioridazine
Diazepam	Morp. Glucuronide	Trifluoperazine
Diethylpropion	Morphine Sulfate	Tryptophan
	Oxycodone	

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

Acetaminophen	Ecgonine HCl	Phendimetrazine
Acetylsalicylic Acid	Ecgonine Methyl Ester	Penicillin G
Amikacin	Glucose	Pentobarbital
Amitriptyline	Histamine	Phencyclidine
Ampicillin	Hydrochlorothiazide	Phenobarbital
Arterenol	Hydrocodone	Phentermine
Aspartame	Hydromorphone	Phenylpropanolamine
Atropine Sulfate	Indomethacin	l-Phenylephrine
Benzoic Acid	Ketoprofen	d-Propoxyphene
Benzoyllecgonine HCl	Levorphanol	l-Propranol
Caffeine	Δ ⁸ -THC	Quinine
Chlorpheniramine	(-)11-Nor-Δ ⁸ -THC-9-COOH	Ranitidine
Chlorpromazine HCl	Meperidine	Sodium Salicylate
Cimetidine	Methylphenidate	Tetracycline
Codeine	Methadone	Tetrahydrozoline
Deoxyephedrine	Methaqualone	Theophylline
Dextromethorphan	Morphine-3-β-D-Glucuronide	Thioridazine
Diethylpropion	Morphine Sulfate	Trifluoperazine
5,5-Diphenylhydantoin	Oxycodone	Tryptophan
Doxylamine		

The following compounds do not cross-react with (150 ng/ml cut-off) Cocaine at a 100 µg/ml concentration in urine:

Acetaminophen	Ecgonine HCl	Phendimetrazine
Acetylsalicylic Acid	Ecgonine Methyl Ester	Penicillin G
Amikacin	Glucose	Pentobarbital
Amitriptyline	Histamine	D-Propoxyphene
Ampicillin	Hydrochlorothiazide	l-Propranol
Arterenol	Hydrocodone	Phencyclidine
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Indomethacin	Phentermine
Benzoic Acid	Ketoprofen	Phenylpropanolamine
Caffeine	Levorphanol	l-Phenylephrine
Chlorpheniramine	D ⁹ -THC	Quinine
Chlorpromazine HCl	11-Nor-D ⁹ -THC-9-COOH	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Codeine	Methylphenidate	Tetracycline
Deoxyephedrine	Methadone	Tetrahydrozoline
Dextromethorphan	Methaqualone	Theophylline
Diazepam	Morphine-3-b-D-Glucuronide	Thioridazine
Diethylpropion	Morphine Sulfate	Trifluoperazine
5,5-Diphenylhydantoin	Oxazepam	Tryptophan
Doxylamine	Oxycodone	

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

Acetaminophen	Ecgonine HCl	Phendimetrazine
Acetylsalicylic Acid	Ecgonine Methyl Ester	Penicillin G
Amikacin	Glucose	Pentobarbital
Amitriptyline	Histamine	D-Propoxyphene
Ampicillin	Hydrochlorothiazide	l-Propranol
Arterenol	Hydrocodone	Phencyclidine
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Indomethacin	Phentermine
Benzoic Acid	Ketoprofen	Phenylpropanolamine
Caffeine	Levorphanol	l-Phenylephrine
Chlorpheniramine	D ⁹ -THC	Quinine
Chlorpromazine HCl	11-Nor-D ⁹ -THC-9-COOH	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Codeine	Methylphenidate	Tetracycline
Deoxyephedrine	Methadone	Tetrahydrozoline
Dextromethorphan	Methaqualone	Theophylline
Diazepam	Morphine-3-b-D-Glucuronide	Thioridazine
Diethylpropion	Morphine Sulfate	Trifluoperazine
5,5-Diphenylhydantoin	Oxazepam	Tryptophan
Doxylamine	Oxycodone	

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The following compounds do not cross-react with (500 ng/ml cut-off) Methamphetamine at a 100 µg/ml concentration in urine:

Acetylsalicylic Acid	Ecgonine HCl	Oxycodone
Amikacin	Ecgonine Methyl Ester	Pendimetrozine
Amitriptyline	Glucose	Penicillin G
Ampicillin	Histamine	Pentobarbital
Arteranol	Hydrocodone	d-Propoxyphene
Aspartame	Hydrochlorothiazide	Propranol
Atropine Sulfate	Hydromorphone	Phencyclidine
Benzoic Acid	Indomethacin	Phenobarbital
Benzoylecgonine HCl	Ketoprofen	Phentermine
Caffeine	Levorphanol	Phenylpropanolamine
Chlorpheniramine	D-9-THC	L-Phenylephrine
Chlorpromazine HCl	11-nor-D-9-carboxy-THC-9-COOH	Quinine
Cimetidine	Meperidine	Ranitidine
Codeine	Methylphenidate	Sodium Salicylate
Dextromethorphan	Methadone	Tryptophan
Diazepam	Methaqualone	Tetracycline
Diethylpropion	Morp. Glucuronide	Tetrahydrozoline
Diphenhydantoin	Morphine Sulfate	Theophylline
Doxylamine	Oxazepam	Thioridazine
		Trifluoperazine

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

Acetylsalicylic Acid	Ecgonine HCl	Penicillin G
Amikacin	Ecgonine Methyl Ester	Pentobarbital
Amitriptyline	Glucose	d-Propoxyphene
Ampicillin	Histamine	Hydrochlorothiazide
Arteranol	Hydrocodone	Propranol
Aspartame	Hydromorphone	Phencyclidine
Atropine Sulfate	Indomethacin	Phenobarbital
Benzoic Acid	Ketoprofen	Phentermine
Benzoylecgonine HCl	Levorphanol	Phenylpropanolamine
Caffeine	Δ 9-THC	L-Phenylephrine
Chlorpheniramine	11-nor-Δ 9-carboxy-THC-9-COOH	Quinine
Chlorpromazine HCl	Meperidine	Ranitidine
Cimetidine	Methylphenidate	Sodium Salicylate
Codeine	Methadone	Tryptophan
Deoxyephedrine	Methaqualone	Tetracycline
Dextromethorphan	Morphine Glucuronide	Tetrahydrozoline
Diazepam	Morphine Sulfate	Theophylline
Diethylpropion	Oxazepam	Thioridazine
Diphenhydantoin	Oxycodone	Trifluoperazine
Doxylamine	Pendimetrozine	

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

Acetaminophen	5,5-Diphenylhydantoin	Pentobarbital
Acetylsalicylic Acid	Doxylamine	d-Propoxyphene
Amikacin	Ecgonine HCl	l-Propranol
Amitriptyline	Ecgonine Methyl Ester	Phencyclidine
Ampicillin	Glucose	Phenobarbital
Arteranol	Histamine	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Benzoic Acid	Indomethacin	l-Phenylephrine
Benzoylecgonine HCl	Ketoprofen	Quinine
Caffeine	D ⁹ -THC	Sodium Salicylate
Chlorpheniramine	11-Nor-D ⁹ -THC-9-COOH	Tetracycline
Chlorpromazine HCl	Methylphenidate	Tetrahydrozoline
Cimetidine	Methadone	Theophylline
Deoxyephedrine	Methaqualone	Thioridazine
Dextromethorphan	Oxazepam	Trifluoperazine
Diazepam	Phendimetrazine	Tryptophan
Diethylpropion	Penicillin G	

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

Acetaminophen	Diphenylhydantoin	Pentobarbital
Acetylsalicylic Acid	Doxylamine	d-Propoxyphene
Amikacin	Ecgonine HCl	Propranol
Amitriptyline	Ecgonine Methyl Ester	Phencyclidine
Ampicillin	Glucose	Phenobarbital
Arteranol	Histamine	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Atropine Sulfate	Indomethacin	L-Phenylephrine
Benzoic Acid	Ketoprofen	Quinine
Benzoylecgonine HCl	Levorphanol	Sodium Salicylate
Caffeine	Δ - 9 THC	Tetracycline
Chlorpheniramine	11-nor-Δ 9-carboxy-THC-9-COOH	Tetrahydrozoline
Chlorpromazine HCl	Methylphenidate	Theophylline
Cimetidine	Methadone	Thioridazine
Deoxyephedrine	Methaqualone	Trifluoperazine
Dextromethorphan	Oxazepam	Tryptophan
Diazepam	Pendimetrozine	
Diethylpropion	Penicillin G	

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

Acetaminophen	Ecgonine HCl	Penicillin G
N-Acetylprocainamide	Ecgonine Methyl Ester	Pentobarbital
Glucose	Glucose	d-Propoxyphene Hydrochlorothiazide
Amikacin	Histamine	Propranol
Amitriptyline	Hydrocodone	Phenobarbital
Ampicillin	Hydromorphone	Phentermine
Arteranol	p-Hydroxymethamphetamine	Phenylpropanolamine
Aspartame	Indomethacin	L-Phenylephrine
Atropine Sulfate	Ketoprofen	Quinine
Benzoic Acid	Levorphanol	Ranitidine
Benzoylecgonine HCl	D-9-THC	Sodium Salicylate
Caffeine	11-nor-D-9-carboxy-THC-9-COOH	Tryptophan/Tetracycline
Chlorpheniramine	Meperidine	Tetrahydrozoline
Chlorpromazine HCl	Methylphenidate	Thebaine
Cimetidine	Methadone	Theophylline
Deoxyephedrine	Methaqualone	Thioridazine
Dextromethorphan	Morp. Glucuronide	Trifluoperazine
Diethylpropion	Morphine Sulfate	Tryptophan
Diphenylhydantoin	Oxycodone	
Doxylamine	Pendimetrozine	

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

Acetaminophen	Digitoxin	Meperidine
4-Acetamidophenol	Digoxin	Methadone
Acetylsalicylic Acid	Ecgonine HCl	Methaqualone
Amikacin	Ecgonine Methyl Ester	Naloxone
Ampicillin	Ephedrine	Neomycin
d,l-Amphetamine	Epinephrine	Niacinamide
Amitriptyline	Genistic Acid	Oxazepam
Arteranol	Glucose	Perphenazine
Aspartame	Guaiacol	Penicillin G
Atropine Sulfate	Glycerol Ether	Phencyclidine
Benzoic Acid	Histamine	Phenobarbital
Benzoylecgonine	Hydrochlorothiazide	α-Phenylethylamine
Caffeine	Hydrocodone	Phenylpropanolamine
Camphor	Hydromorphone	Promethazine
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 Glucuronide	Thioridazine
Dextromethorphan	Morphine Sulfate	Trifluoperazine
Diazepam	d-Methamphetamine	Tryptophan

3. **Accuracy:** The accuracy of the QuickScreen® Test was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. In the patient study, each analyte test strip was subjected to evaluation involving a comparison between the device and GC/MS. The summary results of that testing are presented below:

3.1 AMPHETAMINE (AMP) 500ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuickScreen® Positive	140	0
QuickScreen® Negative	13	155

When compared to GC/MS the relative sensitivity between positive samples was 91.5% . The relative specificity between negative samples was 100%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuickScreen® Positive	47	2
QuickScreen® Negative	0	61

When compared to GC/MS the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 96.8%.

3.3 BARBITURATES (BAR) 200ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuickScreen® Positive	148	0
QuickScreen® Negative	2	157

When compared to GC/MS the relative sensitivity between positive samples was 98.7% . The relative specificity between negative samples was 100%.

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3.4 BENZODIAZEPINE (BZD) 200ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	36	0
QuikScreen® Negative	0	529

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

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	42	2
QuikScreen® Negative	0	52

When compared to GC/MS the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 96.3%

3.6 COCAINE (COC) 150 ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	150	0
QuikScreen® Negative	3	151

When compared to GC/MS the relative sensitivity between positive samples was 98.0% . The relative specificity between negative samples was 100%.

3.7 COCAINE (COC) 300 ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	42	1
QuikScreen® Negative	0	53

When compared to GC/MS the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 98.1%.

3.8 METHAMPHETAMINE (MET) 500 ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	129	0
QuikScreen® Negative	14	162

When compared to GC/MS the relative sensitivity between positive samples was 90.2% . The relative specificity between negative samples was 100%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	41	1
QuikScreen® Negative	0	59

When compared to GC/MS the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 98.3%.

3.10 OPIATES (OPI) 300 ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	148	0
QuikScreen® Negative	0	150

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

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	41	1
QuikScreen® Negative	0	54

When compared to GC/MS the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 98.2%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	40	4
QuikScreen® Negative	0	53

When compared to GC/MS the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 93.0%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	42	1
QuikScreen® Negative	0	53

When compared to GC/MS the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 98.1%.

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Marijuana Test


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