

Syntron Bioresearch, Inc.
QuikScreen® 11 Plus 4
 One Step Onsite Drug Cup With Adulteration
 Catalog 65201-7

Instructions



INTENDED USE

The QuikScreen® 11 Plus 4 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. 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/BENZOYLECGONINE	300 ng/ml
MARIJUANA	50 ng/ml
METHADONE	300 ng/ml
METHAMPHETAMINE	1000 ng/ml
OPIATES/MORPHINE	2000 ng/ml
OXYCODONE	100 ng/ml
PHENCYCLIDINE	25 ng/ml
PROPOXYPHENE	300 ng/ml

An added feature to assess the integrity of the urine samples prior to drug testing, is a visual determination of **pH, NBP (Nitrite, Bleach, Pyridinium Chlorochromate), Creatinine** and **Specific Gravity**. These adulteration strips are built into the test device which may provide information regarding urine sample tampering.

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® 11 Plus 4 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® 11 Plus 4 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® 11 Plus 4 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.



Included in this device are the following 4-parameter adulteration strips to determine whether the urine sample is adulterated:

pH, NBP (Nitrite, Bleach & Pyridinium Chlorochromate), Creatinine and **Specific Gravity**, the results of which can be achieved by comparing to the color chart provided.

REAGENTS AND MATERIALS PROVIDED

- | | |
|------------------------------------|---|
| 1. Test Devices | Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide. |
| 2. Test Instructions | Catalog # 65201-7 |
| 3. Color Chart | Catalog # COL-007 |
| Optional: | |
| 4. Negative Control I | Contains buffered protein solution with sodium azide. Catalog # 4010N |
| 5. Amphetamine Positive Control | Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide. Catalog # 11120P |
| 6. Barbiturates Positive Control | Contains BAR at 1000 ng/ml in a buffered protein solution with sodium azide. Catalog # 18040P |
| 7. Benzodiazepines Pos. Control | Contains BZD at 1000 ng/ml in a buffered protein solution with sodium azide. Catalog # 18020P |
| 8. Cocaine Positive Control | Contains COC at 1000 ng/ml in a buffered protein solution with sodium azide. Catalog # 12000P |
| 9. Marijuana Positive Control | Contains THC at 150 ng/ml in a buffered protein solution with sodium azide. Catalog # 13020P |
| 10. Methadone Positive Control | Contains MAD at 1000 ng/ml in a buffered protein solution with sodium azide. Catalog # 19020P |
| 11. Methamphetamine Pos. Control | Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. Catalog # 11320P |
| 12. Opiates Positive Control | Contains OPI at 5000 ng/ml in a buffered protein solution with sodium azide. Catalog # 11220P |
| 13. Oxycodone Positive Control | Contains OXY at 300 ng/ml in a buffered protein solution with sodium azide. Catalog # 19090P |
| 14. Phencyclidine Positive Control | Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. Catalog # 14020P |
| 15. Propoxyphene Positive Control | Contains PPX at 1000 ng/ml in a buffered protein solution with sodium azide. Catalog # 19097P |

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. Properly handle and dispose of all used reaction devices and urine specimens in an appropriate waste 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® 11 Plus 4 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 QuikScreen® 11 Plus 4 test cup, if necessary.*

TEST PROCEDURE

- Do not break the seal of the pouch until ready to begin testing.
- Remove the Test Cup from the foil pouch.
- Collect urine specimen directly into the Test Cup. Ensure that the sample amount meets the minimum level as indicated on the side of the Test Cup.
- Wait 1 minute and immediately read the adulteration strips for pH and Specific Gravity. At 5 minutes read the adulteration strips for Creatinine and NBP (nitrite, bleach, pyridinium chlorochromate).** Obtain results by comparing them to the color chart provided. Color comparison must be performed under a good light source. If results show that the urine sample was **adulterated, do not read the drug test result.**
- If urine sample is found to be **unadulterated, read the drug test results.**

NOTE: The results must be interpreted at five minutes, except for pH and Specific Gravity. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

DEVICE FEATURE:

Included in this device are the following 4-parameter adulteration strips to determine whether the urine sample is adulterated:

pH test is based on multiple indicators which give a broad range of colors covering the entire urinary pH range. Colors range from maroon to pinkish-red through orange and dark green.

Creatinine interacts with a creatinine indicator in an alkaline medium and forms an orange-red complex. The color intensity is directly proportional to the concentration of creatinine when compared visually to the color chart to obtain result.

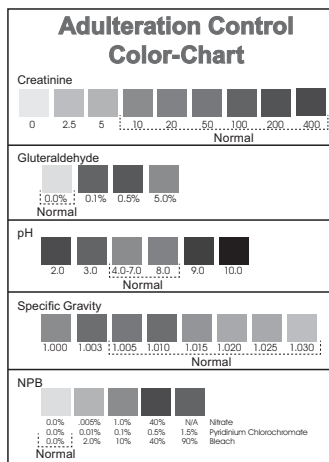
Nitrite, Bleach and Pyridinium Chlorochromate (NBP) test is based on the development of colors ranging from cream, for negative reading, to a positive color of green, brownish-green, or brown when the chromogen is oxidized by nitrite, bleach, or pyridinium chlorochromate.

Specific Gravity (SG) is based on the apparent pKa change of certain pre-treated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark green or blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.

INTERPRETATION OF RESULTS

Adulteration Strip

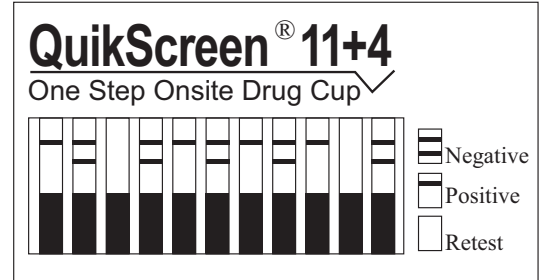
Results are obtained by direct comparison of the reacted strip with the color chart provided, similar to the illustration below. Adulterated urine sample will show result colors under the "Abnormal" block colors of the chart. Unadulterated urine sample will show the strip colors similar to the "Normal" block colors of the color chart.



Based on the information gathered from a review of current clinical and forensic toxicology literature and recommendations made by the U.S. Substance Abuse

and Mental Health Services Administration's Drug Testing Advisory Board, a specimen is defined to be:

- Dilute** if the Specific Gravity is <1.005 mg/dl, unless the criteria for a **substituted** specimen are met.
- Dilute** if the creatinine is <20 mg/dl unless the criteria for a **substituted** specimen are met.
- Adulterated** if the Nitrite concentration is ≥ 0.5 mg/dl.
- Adulterated** if the pH is ≤ 4 or ≥ 8 .
- Adulterated** if an exogenous substance (i.e., a substance which is not a normal constituent of urine such as glutaraldehyde, bleach, pyridinium chlorochromate) or an endogenous substance at a higher concentration than normal physiological concentration is present in the specimen.



Drug Test Strips

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® 11 Plus 4 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® 11 Plus 4 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	25,000 ng/ml
d,l-Amphetamine	10,000 ng/ml
b-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
Amobarbital	1,600 ng/ml
Barbital	3,500 ng/ml
Bromocriptine	200 ng/ml
Butobarbital	2,000 ng/ml
Clean Jane (sodium dodecylsulfate)	260 ng/ml
Phenobarbital	3,500 ng/ml
Pentobarbital	800 ng/ml
Zolofit	200 ng/ml

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

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
Clobazam	2500 ng/ml	Lorazepam	200 ng/ml
Clonazepam	500 ng/ml	Lormetazepam	250 ng/ml
Clorazepate	50 ng/ml	Medazepam	1,000 ng/ml
Clotiazepam	460 ng/ml	Midazolam	130 ng/ml
Daypro (Chemically not a BZD)	200 ng/ml	Nitrazepam	200 ng/ml
Demoxepam	600 ng/ml	Norchlordiazepoxide	770 ng/ml
n-Desalkylflurazepam	300 ng/ml	Nordiazepam	200 ng/ml
Desmethyldiazepam	50 ng/ml	Oxazepam	200 ng/ml
Diazepam	50 ng/ml	Prazepam	100 ng/ml
Flunitrazepam	250 ng/ml	Temazepam	200 ng/ml
Flurazepam	100 ng/ml	Tetraazepam	200 ng/ml
Halazepam	160 ng/ml	Triazolam	500 ng/ml
α-Hydroxyalprazolam	200 ng/ml		

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

Benzoyllecgonine	300 ng/ml
Cocaine	300 ng/ml
Isoxsuprine	2,500 ng/ml

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

Δ-9-Carboxy-THC-9	50 ng/ml
Δ ⁸ -THC	1 µg/ml
Δ ⁹ -THC	4 µg/ml
Cannabinol	10 µg/ml
11-Hydroxy-Δ ⁹ -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
EDDP	100,000 ng/ml
Methadol	25,000 ng/ml
Perphenazine	75,000 ng/ml
Protriptyline	2,000 ng/ml
Trimipramine	10,000 ng/ml

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

d-Amphetamine	250,000 ng/ml
d, l-Amphetamine	500,000 ng/ml
(+) Methamphetamine	1,000 ng/ml
(±) 3,4-Methylenedioxyamphetamine (MDA)	250,000 ng/ml
(±) 3,4-Methylenedioxymethamphetamine (MDMA, Ecstasy)	1,250 ng/ml
Deoxyephedrine	1,000 ng/ml
Phentermine	2,000 ng/ml
Phenyl Propanolamine (PPA)	10,000,000 ng/ml
Pseudoephedrine	2,500 ng/ml
Ephedrine	10,000,000 ng/ml

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

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

The following Oxycodone-related substances yield positive results for Oxycodone at 100 ng/ml cut-off level:

Oxycodone-HCl	100 ng/ml
Codeine	700 ng/ml
Hydrocodone	500 ng/ml
Hydromorphone	1500 ng/ml
Morphine-Sulfate	7000 ng/ml
Morphine-3-β-D-Glucuronide	40000 ng/ml
Norcodeine	40000 ng/ml
Oxymorphone	300 ng/ml

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

Phencyclidine	25 ng/ml
Tenocyclidine	2000 ng/ml

The following Propoxyphene-related (PPX) substances yield positive results for PPX at 300ng/ml cut-off level:

Propoxyphene	300 ng/ml
Norpropoxyphene	1000 ng/ml
Methadone	1,350,000 ng/ml
2-ethyl-1,5-dimethyl-3,3-diphenylpyrrolone (EDDP)	200,000 ng/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 µg/ml concentration in urine:

Acetaminophen	5,5-Diphenylhydantoin	Morphine Sulfate
Acetylsalicylic Acid	Doxylamine	Oxazepam
Amikacin	Ecgonine HCl	Oxycodone
Amitriptyline	Ecgonine Methyl Ester	Phendimetrazine
Ampicillin, Sodium Salt	Glucose	Penicillin G
Arterenol	Histamine	Pentobarbital
Aspartame	Hydrochlorothiazide	d-Propoxyphene
Atropine	Hydrocodone	1-Propanol
Benzoic Acid	Hydromorphone	Phencyclidine HCl
Benzoyllecgonine	Indomethacin	Phenobarbital
Caffeine	Ketoprofen	l-Phenylephrine
(+)Chlorpheniramine Maleate	Levorphanol	Quinine
(±)Chlorpheniramine Maleate	Δ ⁹ -THC	Ranitidine
Chlorpromazine HCl	Δ-9-Carboxy-THC-9	Sodium Salicylate
Cimetidine	Meperidine	Tryptophan
Codeine	Methylphenidate	Tetracycline
Dextromethorphan HBr	Methadone	Tetrahydrozoline
Diazepam	Methaqualone	Theophylline
	Morphine-3-β-D-Glucuronide	Thioridazine
		Trifluoperazine

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

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



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

Acetaminophen	Doxylamine	Oxycodone
Acetylsalicylic Acid	Ecgonine ·HCl	Phendimetrazine
Amikacin	Ecgonine Methyl Ester	Penicillin G
Amitriptyline	Glucose	Pentobarbital
Ampicillin	Histamine	Phencyclidine
Arterenol	Hydrochlorothiazide	Phenobarbital
Aspartame	Hydrocodone	Phentermine
Atropine Sulfate	Hydromorphone	Phenylpropanolamine
Benzoic Acid	Indomethacin	l-Phenylephrine
Benzoyllecgonine HCl	Ketoprofen	d-Propoxyphene
Caffeine	Levorphanol	l-Propranol
Chlorpheniramine	Δ ⁹ -THC	Quinine
Chlorpromazine ·HCl	Δ-9-Carboxy-THC-9	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Codeine	Methylphenidate	Tetracycline
Deoxyephedrine	Methadone	Tetrahydrozoline
Dextromorphan	Methaqualone	Theophylline
Diethylpropion	Morphine-3-β-D-Glucuronide	Thioridazine
5,5-Diphenylhydantoin	Morphine Sulfate	Trifluoperazine
		Tryptophan

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	Δ ⁹ -THC	Quinine
Chlorpromazine ·HCl	Δ-9-Carboxy-THC-9	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Codeine	Methylphenidate	Tetracycline
Deoxyephedrine	Methadone	Tetrahydrozoline
Dextromorphan	Methaqualone	Theophylline
Diazepam	Morphine-3-β-D-Glucuronide	Thioridazine
Diethylpropion	Morphine Sulfate	Trifluoperazine
5,5-Diphenylhydantoin	Oxazepam	Tryptophan
Doxylamine	Oxycodone	

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	Gentisic Acid	Oxazepam
Arterenol	Glucose	Perphenazine
Aspartame	Guaiacol	Penicillin G
Atropine Sulfate	Glyceryl Ether	Phencyclidine
Benzoic Acid	Histamine	Phenobarbital
Benzoyllecgonine	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-3-β-D-Glucuronide	Thioridazine
Dextromorphan	Morphine Sulfate	Trifluoperazine
Diazepam	d-Methamphetamine	Tryptophan

The following compounds do not cross-react with (300 ng/ml cut-off) Methadone 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
Benzoyllecgonine HCl	Levorphanol	l-Phenylephrine
Caffeine	Δ ⁹ -THC	Quinine
Chlorpheniramine	Δ-9-Carboxy-THC-9	Ranitidine
Chlorpromazine HCl	Meperidine	Sodium Salicylate
Cimetidine	Methylphenidate	Tryptophan
Codeine	Methaqualone	Tetracycline
Deoxyephedrine	Morphine-3-b-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 µg/ml concentration in urine:

Acetylsalicylic Acid	Ecgonine-HCl	Penicillin G
Amikacin	Ecgonine Methyl Ester	Pentobarbital
Amitriptyline	Glucose	d-Propoxyphene
Ampicillin	Histamine	Hydrochlorothiazide
Arterenol	Hydrocodone	Propranol
Atropine Sulfate	Hydromorphone	Phencyclidine
Benzoic Acid	Indomethacin	Phenobarbital
Benzoyllecgonine HCl	Levorphanol	Phentermine
Caffeine	Δ ⁹ -THC	Phenylpropanolamine
Chlorpheniramine	Δ-9-Carboxy-THC-9	L-Phenylephrine
Chlorpromazine HCl	Meperidine	Quinine
Cimetidine	Methylphenidate	Ranitidine
Codeine	Methadone	Sodium Salicylate
Deoxyephedrine	Methylqualone	Tryptophan
Dextromorphan	Morphine Glucuronide	Tetracycline
Diazepam	Morphine Sulfate	Tetrahydrozoline
Diethylpropion	Oxazepam	Theophylline
Diphenylhydantoin	Oxycodone	Thioridazine
Doxylamine	Pendimetrazine	Trifluoperazine

The following compounds do not cross-react with (2000 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
Arterenol	Histamine	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Benzoic Acid	Indomethacin	l-Phenylephrine
Benzoyllecgonine ·HCl	Ketoprofen	Quinine
Caffeine	Δ ⁹ -THC	Sodium Salicylate
Chlorpheniramine	Δ-9-Carboxy-THC-9	Tetracycline
Chlorpromazine ·HCl	Methylphenidate	Tetrahydrozoline
Cimetidine	Methadone	Theophylline
Deoxyephedrine	Methaqualone	Thioridazine
Dextromorphan	Oxazepam	Trifluoperazine
Diazepam	Phendimetrazine	Tryptophan
Diethylpropion	Penicillin G	

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

Acetaminophen	Benzoyllecgonine ·HCl	Diethylpropion
Acetylsalicylic Acid	Caffeine	5,5-Diphenylhydantoin
Amikacin	Chlorpheniramine	Doxylamine
Amitriptyline	Chlorpromazine ·HCl	Ecgonine ·HCl
Ampicillin	Cimetidine	Ecgonine Methyl Ester
Arterenol	Deoxyephedrine	Glucose
Aspartame	Dextromorphan	Histamine
Benzoic Acid	Diazepam	Hydrochlorothiazide
		Indomethacin



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

Acetaminophen	Ecgonine HCl	Penicillin G
N-Acetylprocainamide	Ecgonine Methyl Ester	Pentobarbital
Acetylsalicylic Acid	Glucose	d-Propoxyphene Hydrochlorothiazide
Amikacin	Histamine	Propanol
Amitriptyline	Hydrocodone	Phenobarbital
Ampicillin	Hydromorphone	Phentermine
Arterenol	p-Hydroxymethamphetamine	Phenylpropranolamine
Aspartame	Indomethacin	L-Phenylephrine
Atropine Sulfate	Ketoprofen	Quinine
Benzoic Acid	Levorphanol	Ranitidine
Benzoyllecgonine HCl	D-9-THC	Sodium Salicylate
Caffeine	Δ-9-Carboxy-THC-9	Tryptophan/Tetracycline
Chlorpheniramine	Meperidine	Tetrahydrozoline
Chlorpromazine HCl	Methylphenidate	Thebaine
Cimetidine	Methadone	Theophylline
Deoxyephedrine	Methaqualone	Thioridazine
Dextromethorphan	Morp. Glucuronide	Trifluoperazine
Diethylpropion	Morphine Sulfate	Tryptophan
Diphenhydantoin	Oxycodone	
Doxylamine	Pendimethazine	

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

(+)-Chlorpheniramine Maleate	Cocaine	Oxalic Acid
(±)-Chlorpheniramine Maleate	Codeine	Oxazepam
11-Nor-D9-THC-9-COOH	Cortisone	Penicillin G Benzathine Salt
Acetaminophen	Cyclobenzaprine	Phencyclidine- HCl
Acetylsalicylic Acid	Desipramine	Dextromethorphan
Amikacin	Dextromethorphan	Doxylamine Succinate Salt
Amitriptyline	Doxylamine Succinate Salt	EDDP
Ampicillin	EDDP (2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolidine)	Imipramine-HCl
Arterenol	Imipramine-HCl	Methadone-HCl
Aspartame (ASP-PHE Methyl Ester)	Methadone-HCl	Morphine 3-2-D-Glucuronide
Atropine Sulfate	Morphine 3-2-D-Glucuronide	Morphine Sulfate Salt
Benzoic Acid	Nortriptyline	Oxalic Acid
Benzoyllecgonine-HCl	Oxazepam	Penicillin G Benzathine Salt
Bilirubin	Phencyclidine- HCl	
Caffeine		
Camphore		

3. Accuracy: The accuracy of the QuikScreen® II Plus 4 Test was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. The laboratory used Syva® EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The relative sensitivity results by either GCMS or Syva® EMIT II are summarized as follows:

3.1 AMPHETAMINE (AMP) 1000 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

QuikScreen® Positive	47	2
QuikScreen® 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%.

3.2 BARBITURATES (BAR) 200 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

QuikScreen® Positive	148	0
QuikScreen® Negative	2	157

When compared to GC/MS the relative sensitivity between positive samples was 98%. The relative specificity between negative samples was 100%.

3.3 BENZODIAZEPINE (BZD) 300 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

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%.

3.4 COCAINE (COC) 300 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

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%.

3.5 MARIJUANA (THC) 50 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

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%.

3.6 METHADONE (MAD) 300 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

QuikScreen® Positive	42	0
QuikScreen® Negative	0	52

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

3.7 METHAMPHETAMINE (MET) 1000 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

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%.

3.8 OPIATES (OPI) 2000 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

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%.

3.9 OXYCODONE (OXY) 100 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

QuikScreen® Positive	55	1
QuikScreen® Negative	0	43

When compared to GC/MS the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 97.7%.

3.10 PHENCYCLIDINE (PCP) 25 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

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%.

3.11 PROPOXYPHENE (PPX) 300 NG/ML CUT-OFF LEVEL

GC/MS Positive GC/MS Negative

QuikScreen® Positive	43	2
QuikScreen® Negative	0	53

When compared to GC/MS the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 96.4%.

BIBLIOGRAPHY

General

- Baselt, R.C., Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed., *Biomedical Publ.*, Davis, CA, p.488 (1982).
- Cody, J.T., Schwarzhoff, R., *J. Anal. Toxicol.*, 17: 2630 (1993).
- Urine Testing for Drugs of Abuse, *NIDA Research Monograph* 73, (1986).
- Dasgupta, A., Saldana, S., Kinnaman, G., Smith M., Johansen, K., *Clin.Chem.*, 39(1):104-108 (1993).



- Department of Health and Human Services, *Fed. Regist.*, 53(69): 11970-11989 (1988), (1989).
- FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing*, Kshitij Mohan, 7/21/1987.
- Blum, K., *Handbook of Abusable Drugs*, Gardner Press, Inc., New York, 1st Ed., (1984).
- Tietz, N.W.: *Clinical Guide to Laboratory Tests*; W.B. Saunders Company, (1976).

Amphetamine/Methamphetamine Test

- Ellerbe, P., Long, T., Welch, M.J., *J. Anal. Toxicol.*, 17: 165-170 (1993).

Barbiturate Test

- Hoffmann, F.E. *A Handbook of Drug and Alcohol Abuse: The Biomedical Aspects*. Oxford University Press, New York, 1983.
- Wyngarrden, J.B., Smith, L.H. (eds.) *Cecil Textbook of Medicine*. W.B. Saunders Co., Philadelphia, 1988, pp. 53-54.
- Ellenhorn, M.J., Barceloux, D.J. *Medical Toxicology*. Elsevier Science Publishing Co., New York, 1988, pp. 575-580.
- Gorodetzky, Z.V. *Detection of Drugs of Abuse in Biological Fluids*. In: Martin, W.R. (ed.) *Drug Addiction. I*. Springer-Verlag, New York, 1977, pp. 319-409.

Benzodiazepines Test

- S.J., Mule and G.A. Gasella. "Quantitation and Confirmation of the Diazolo and Triazolobenzodiazepines in Human Urine by GC/MS," *J. Anal. Toxicol.*, Vol. 13 (1989), pp. 179-184.
- C. Drouet-Coassolo, C. Aubert, P. Coassolo, and J. Cano. "Capillary GC/MS Method for the Identification and qualification of some Benzodiazepines and Their Unconjugated Metabolites in Plasma," *J. Chromatogr.*, Vol. 487 (1989), pp. 295-311.
- C. Ballanto, V. Reggi, G. Tognoni, et al. "Benzodiazepines: Clinical Pharmacology and Therapeutic Use," *Drugs*, Vol. 19 (1980): 195-219.
- A.J. Giannini and E.A. Slaby. *rugs of Abuse* (MEDEC Books: 1989), Ch., pp. 59-80.
- M.A. Pear and L. Kopjak, "The Screening and Quantitation of Diazepam, Flurazepam, Chlordiazepoxide, and Their Metabolites in Blood and Plasma by Electron-Capture Gas Chromatography and High Pressure Liquid Chromatography," *J. Forensic Sci.*, Vol. 24(1979) pp. 46-54.
- H. Schultz, "Modern Screening Strategies in Analytical Toxicology with Special Regard to New Benzodiazepines," *J. Legal. Med.*, Vol. 100 (1988) pp. 19-37.
- J.G. Langner, B.K. Gan, R.H. Liu, L.D. Baugh, P. Chand, J.L. Weng, et al. "Enzymatic Digestion, Solid Phase Extraction, and GC/MS of Derivatized Intact Oxazepam in Urine," *Clin. Chem.*, Vol. 37 (1991) pp.1596-1601.
- R.L. Fitzgerald, D.A. Rexin, and D.A. Herold. "Benzodiazepine Analysis by Negative Chemical Ionization GC/MS," *J. Anal. Toxicol.*, Vol. 17, pp.342-347.

Cocaine Test

- D.W. Hoyt et al. *J. Am. Med. Assoc.*, Vol. 258 (1987), pp. 504-509.
- R.R. MacGregor, J.S. Fowler, and A.P. Wolf. *J. of Chromatography*, Vol. 590 (1992), pp. 354-58.
- E.J. Cone, D. Yousefnejad, and S.L. Dickerson. *J. of Forensic Sciences*, Vol. 35, No.4 (1990), pp. 786-91.
- E.J. Cone et al. *J. of Forensic Sciences*, Vol. 34, No. 1 (1989), pp. 15-31.
- B. Holmstedt and A. Fredga. *J. of Ethnopharmacology*, Vol. 3 (1981), pp. 113-47.
- T. Inaba and J. Can. *Physiol. Pharmacol.*, Vol. 67 (1989), pp. 1154-57
- A.R. Jeffcoat et al. *Drug Metabolism and Disposition*, Vol. 17, No. 2.

Marijuana Test

- Johansson, E., Gillespie, H.K., Halldin, M.M. *J. Anal. Toxicol.*, 14: 176-180 (1990).
- El Sohly, M.A., Jones, A.B., El Sohly, H.N. *J. Anal. Toxicol.*, 14: 277-279 (1990); 14: 227-279 (1990).
- Foltz, R.L., Sunshine, I.J. *J. Anal. Toxicol.*, 14: 375-378 (1990).
- Wimbish, G.H., Johnson, K.D. *J. Anal. Toxicol.*, 14: 292-295 (1990).
- Nakamura, G.R., Meeks, R.D., Stall, W.J. *J. Forensic Sci.*, 35(4): 792-796 (1990).

- Jenkins, A.J., Mills, L.C., Darwin, W.D., Huestis, M.A., Cone, E.J., Mitchell, J.M. *J. Anal. Toxicol.*, 17:6.
- Hollister, L.E., Kanter, S.L., Board, R.D., Green D.E. *Res. Com. Chem. Pathol. Pharmacol.*, 8: 579-584 (1974).

Methadone Test

- B.J. Rounsaville, M.M. Weissman, P.H. Rosenberger, et al. "Diagnosis and Symptoms of Depression in Opiate Addicts: Course and Relationship to Treatment Outcome", *Arch. Gen. Psychiatry* 39 (1982): 151-56.
- B.J. Rounsaville and H.D. Kleber, "Psychiatric Disorders and the Course of Diagnostic Stability", in S.M. Mirin, ed., *Substance Abuse and Psychopathology* (American Psychiatric Press, Washington, D.C., 1984):134-51.
- C.A. Dackis and M.S. Gold. "Depression in Opiate Addicts," *ibid*, pp. 20-40.
- J.B. Wyngarrden, LH Jr., eds., *Cecil Textbook of Medicine* (WB Saunders Co.: Philadelphia, 1988), pp. 57 and 60.
- M.J. Ellenhorn and D.G. Barceloux. *Medical Toxicology* (Elsevier Science Publishing Co., Inc., NY, 1988), pp. 714-18.

Opiate Test

- Huang, W., Andollo, W., Hearn W.L.J. *J. Anal. Toxicol.*, 16: 307-310 (1992).
- Cone, E.J., Dickerson, S., Paul, B.D., Mitchell, J.M., *J. Anal. Toxicol.*, 17: 156-164 (1993).
- Glare, P.A., Walsh, T.D., and Pippenger, C.E., *Ther. Drug Monit.*, 13: 226-232 (1991).
- Walsh, T.D., Cheater, F.M., *Pharm. J.*, 10: 525-527 (1983).
- Mitchell, J.M., Paul, B.D., Welch, P., Cone, E.J. *J. Anal. Toxicol.*, 15: 49-53 (1991).

Oxycodone Test

- Bolan, E.A., et al., Synergy between μ opioid ligands: evidence for functional interactions among opioid receptor subtypes. *J. Pharmacol. Exp. Ther.* **303**,557-562 (2002).
- Ross, F.B., and Smith, M.T., The intrinsic antinociceptive effects of oxycodone appear to be μ -opioid receptor mediated. *Pain* **73**, 151-157 (1997).


Phencyclidine Test


- Froelich, P.E., Gross, G.: Separation and Detection of Phencyclidine in Urine by Gas Chromatography. *J. Chromatograph* 1977;137;135-143.
- Gupta R.C. et al: Determination of Phencyclidine in Urine and Illicit Street Drug Samples. *Clin. Toxicol* 1975; 8:611-621.
- Oellerich, M.: Enzyme Immunoassays In Clinical Chemistry: Present Status and Trends. *J. Clin. Chem. Biochem.*, 1980;18:197-208.
- Anilineo, Pitts, F.N.: *Phencyclidine (PCP): A Review and Perspectives*. *CRC Crit. Rev. Toxicol* 1982;10:145-177.

Propoxyphene Test

- Gilman AG, Rall TW, Nies AS, Taylor P eds., *Goodman and Gilman's the Pharmacological Basis of Therapeutics*, 8th ed., New York, Pergamon Press, 1990, p509.
- Wilson J, *Abused Drugs II – A Laboratory Pocket Guide*, AACC Press, Washington, DC, 1994, p64.

 = In-Vitro Diagnostic Device

 = Authorized Rep
in the EU Community

 = Manufacturer

