

# QuikScreen® X Multidrug Plus Alcohol

ONE STEP ONSITE DRUG CUP

Catalog # 6xxxx

— Instructions —



## INTENDED USE

The **QuikScreen® X Multidrug Plus Alcohol** is an immunochromatographic assay for rapid, qualitative detection of drugs of abuse and the presence of alcohol greater than 0.04% in human urine.

In the **QuikScreen® X Multidrug Plus Alcohol**, X may denote any number of drugs. The drug combinations may be composed from any of the following drugs, at the noted cut-off concentrations:

DRUG CLASS	ABBREVIATIONS	SENSITIVITY
AMPHETAMINE-I	AMP	500 ng/ml
AMPHETAMINE-II	AMP	1000 ng/ml
BARBITURATES-I	BAR	200 ng/ml
BARBITURATES-II	BAR	300 ng/ml
BENZODIAZEPINES-I	BZD	200 ng/ml
BENZODIAZEPINES-II	BZD	300 ng/ml
BUPRENORPHINE	BUP	10 ng/ml
COCAINE/BENZOYLECGONINE-I	COC/BEG	150 ng/ml
COCAINE/BENZOYLECGONINE-II	COC/BEG	300 ng/ml
MARIJUANA	THC	50 ng/ml
METHADONE	MAD	300 ng/ml
METHAMPHETAMINE-I	MET	500 ng/ml
METHAMPHETAMINE-II	MET	1000 ng/ml
METHYLENEDIOXYMETHAMPHETAMINE-I	MDMA	500 ng/ml
METHYLENEDIOXYMETHAMPHETAMINE-II	MDMA	1000 ng/ml
OPIATES/MORPHINE-I	OPI/MOR	300 ng/ml
OPIATES/MORPHINE-II	OPI/MOR	2000 ng/ml
OXYCODONE	OXY	100 ng/ml
PHENCYCLIDINE	PCP	25 ng/ml
PROPOXYPHENE	PPX	300 ng/ml
TRICYCLIC ANTIDEPRESSANT	TCA	1000 ng/ml

**Note:** The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS) or non-enzyme technology such as headspace gas chromatograph. Clinical considerations and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

FOR FORENSIC USE ONLY

## INTRODUCTION

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.

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dl) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since the urine alcohol concentration is normally higher than in saliva and blood, the cut-off concentration was set at 0.04%

Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids.

## SUMMARY AND EXPLANATION OF THE TEST

The **QuikScreen® X Multidrug Plus Alcohol** 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, drug metabolites, and alcohol in test samples with a high degree of sensitivity.

The sensitivity of the **QuikScreen® X Multidrug Plus Alcohol** is set as a 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® X Multidrug Plus Alcohol** contains test strips for drugs of abuse and alcohol that are one-step immuno assays. The test 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.

The rapid one step alcohol test is based on the high specificity of alcohol oxidase (ALOX) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following

EtOH + TMB + Alcohol Oxidase CH33OH = Colored TMB

The alcohol test is a chromatographic assay which utilizes the urine alcohol migration to the pad which contain the alcohol oxidase and colorless dye. The distinct blue color on the reactive pad should be observed in less than 60 seconds after the reaction pad was wetted with the urine specimens with the ethyl alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propanol and allyl alcohol would develop the similar alcohol on the reactive pad. However, these alcohols are not normally present in human urine

## REAGENTS AND MATERIAL PROVIDED

1. Test Devices	Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide [REF]
2. Test Instructions	[REF] PI-6xxxxALC
<b>Optional:</b>	
3. Negative Control I	Contains buffered protein solution with sodium azide. [REF] 4010N
4. Amphetamine-I Positive Control	Contains AMP at 1500 ng/ml in a buffered protein solution with sodium azide. [REF] 11120P
5. Amphetamine-II Positive Control	Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide. [REF] 11120P-B
6. Barbiturates-I & II Positive Control	Contains BAR at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 18040P
7. Benzodiazepines-I & II Positive Control	Contains BZD at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 18020P
8. Buprenorphine Positive Control	Contains BUP at 100 ng/ml in a buffered protein solution with sodium azide. [REF] 19094P
9. Cocaine/Benzoylecgonine-I & II Positive Control	Contains COC/BEG at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 12000P
10. Marijuana-I Positive Control	Contains THC at 150 ng/ml in a buffered protein solution with sodium azide. [REF] 13020P
11. Methadone Positive Control	Contains MAD at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 19020P
12. Methamphetamine-I Positive Control	Contains MET at 1500 ng/ml in a buffered protein solution with sodium azide. [REF] 11320P
13. Methamphetamine-II Positive Control	Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. [REF] 11320P-B
14. Methyleneoxyamphetamine-I Positive Control	Contains MDMA at 1500 ng/ml in a buffered protein solution with sodium azide. [REF] 19060P
15. Methyleneoxyamphetamine-II Positive Control	Contains MDMA at 3000 ng/ml in a buffered protein solution with sodium azide. [REF] 19060P-B
16. Opiates/Morphine-I Positive Control	Contains OPI/MOR at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 11220P
17. Opiates/Morphine-II Positive Control	Contains OPI/MOR at 5000 ng/ml in a buffered protein solution with sodium azide. [REF] 11220P-B
18. Oxycodone Positive Control	Contains OXY at 300 ng/ml in a buffered protein solution with sodium azide. [REF] 19080P
19. Phencyclidine Positive Control	Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. [REF] 14020P
20. Propoxyphene Positive Control	Contains PPX at 1000 ng/ml in a buffered

For forensic use only

Emergo Europe • Molenstraat 15 2513 BH • The Hague • Netherlands +31.70.345.8570 [EC] [REP]

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21. Tricyclic Antidepressant Positive Control Contains TCA at 3000 ng/ml in a buffered protein solution with sodium azide. [REF] 19092P-B

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.
2. Specimen collection containers.

## WARNINGS AND PRECAUTIONS

1. Do not use reagents or test device beyond the expiration date.
2. 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.
3. Read the results at 5 minutes. Do not interpret results after 30 minutes.
4. Do not allow smoking or eating in areas where specimens are handled and tested.
5. Decontaminate and dispose of all specimens, reaction kits, and potentially contaminated materials as if they were infectious.
6. The product is sensitive to the presence of alcohol and moisture. After opening the package, the test device should be used immediately.

## 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 device employs a **thermal strip which should be checked immediately** after collection to validate urine specimen. SAM-HSA 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 QuikScreen® X Multidrug test cup, if necessary.*

## TEST PROCEDURE

1. Bring test components and specimens to room temperature prior to testing.
2. Do not break the seal of the pouch until ready to begin testing.
3. Remove the test cup from the foil pouch.
4. Identify the test device for each specimen or control
5. 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.
6. Read the results at 2-5 minutes. Do not interpret results after 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

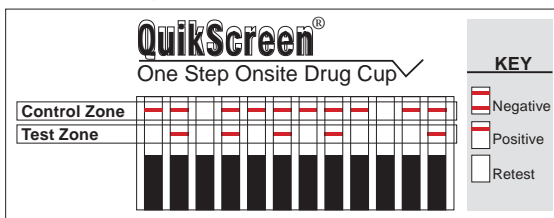
### When testing for drugs of abuse:

**Positive:** 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.

**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.*



When testing for alcohol:

**Positive:** A distinctive blue color developed all over the pad. The positive result indicates that the urine alcohol concentration is less than 0.04%.

**Negative:** No color change by comparing with the background. The negative result indicates that alcohol concentration is less than 0.04%.

**Invalid:** The test should be considered invalid if only the edge of the reaction pad turned color that might be described to insufficient sampling. The subject should be re-tested.

## QUALITY CONTROL

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

Good laboratory practice recommends the use of an external control verify proper kit performance.

Quality control samples should be tested according to the quality control requirements established by the testing laboratory. Use controls in the same manner as specimens by following the test procedure. The expected results should be obtained when using controls. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity can not be used with QuikScreen® X Multidrug Plus Alcohol test device.

## LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of drugs of abuse and their metabolites and alcohol in human urine only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.
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 alcohol, drug levels in urine, or the level of intoxication.
4. There is a possibility that technical or procedure errors as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to interference section for list of substances that will interfere the test results
5. 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.
6. If adulteration is suspected, obtain another urine specimen.

## PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The QuikScreen® X Multidrug Plus Alcohol detects drugs of abuse, their major metabolites and alcohol in urine at concentrations equal to or greater than the cut-off level for the specific drug or alcohol, which is suggested by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method.
2. **Specificity.** A study was conducted with the QuikScreen® X Multidrug Plus Alcohol 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-I at 500 ng/ml cut-off level:*

<i>d-Amphetamine</i> . . . . .	500 ng/ml
<i>l-Amphetamine</i> . . . . .	25,000 ng/ml
<i>Δ-l-Amphetamine</i> . . . . .	600 ng/ml
<i>Ephedrine</i> . . . . .	250,000 ng/ml
<i>(±)3,4-Methylenedioxyamphetamine</i> . . . . .	600 ng/ml
<i>(±)Phenylpropanolamine (PPA)</i> . . . . .	50,000 ng/ml
<i>β-Phenylthylamine</i> . . . . .	90,000 ng/ml
<i>Pseudoephedrine</i> . . . . .	100,000 ng/ml
<i>Thyramine</i> . . . . .	100,000 ng/ml

*The following Amphetamine-related substances yield a positive result for Amphetamine-II at 1000 ng/ml cut-off level:*

<i>d-Amphetamine</i> . . . . .	1,000 ng/ml
<i>l-Amphetamine</i> . . . . .	25,000 ng/ml
<i>Δ-l-Amphetamine</i> . . . . .	10,000 ng/ml
<i>β-Phenylthylamine</i> . . . . .	180,000 ng/ml
<i>Thyramine</i> . . . . .	100,000 ng/ml
<i>(±)3,4-Methylenedioxyamphetamine HCl (MDA)</i> . . . . .	1,200 ng/ml

*The following Barbiturate-related substances yield a positive result for Barbiturates-I at 200 ng/ml cut-off level:*

<i>Amobarbital</i> . . . . .	200 ng/ml
<i>Barbital</i> . . . . .	200 ng/ml
<i>Bromocriptine</i> . . . . .	200 ng/ml
<i>Butabarbital</i> . . . . .	200 ng/ml
<i>Clean Jane (Sodium Dodecylsulfate)</i> . . . . .	260 ng/ml
<i>Phenobarbital</i> . . . . .	200 ng/ml
<i>Pentobarbital</i> . . . . .	200 ng/ml
<i>Secobarbital</i> . . . . .	200 ng/ml
<i>Zolofit</i> . . . . .	200 ng/ml

*The following Barbiturate-related substances yield a positive result for Barbiturates-II at 300 ng/ml cut-off level:*

<i>Allobarbital</i> . . . . .	600 ng/ml
<i>Amobarbital</i> . . . . .	600 ng/ml
<i>Barbital</i> . . . . .	300 ng/ml

Butabarbital . . . . .	300 ng/ml
Butalbital . . . . .	300 ng/ml
Pentobarbital. . . . .	300 ng/ml
Phenobarbital . . . . .	300 ng/ml
Secobarbital . . . . .	300 ng/ml

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

<i>α</i> -Hydroxytriazolam . . . . .	200 ng/ml
<i>α</i> -Hydroxyalprazolam . . . . .	200 ng/ml
Alprazolam . . . . .	62.5 ng/ml
Bromazepam . . . . .	250 ng/ml
Chlorazepate . . . . .	.50 ng/ml
Chlordiazepoxide . . . . .	950 ng/ml
Clobazam . . . . .	2,500 ng/ml
Clonazepam . . . . .	500 ng/ml
Clotiazepam . . . . .	460 ng/ml
Daypro (Chemically not a Benzodiazepine) . . . . .	200 ng/ml
Demoxepam . . . . .	600 ng/ml
Desmethyldiazepam . . . . .	.50 ng/ml
Diazepam . . . . .	.50 ng/ml
Flunitrazepam . . . . .	250 ng/ml
Flurazepam . . . . .	100 ng/ml
1-N-Hydroxyethylflurazepam . . . . .	130 ng/ml
Halazepam . . . . .	160 ng/ml
Ketazolam . . . . .	210 ng/ml
Lorazepam . . . . .	200 ng/ml
Lormetazepam . . . . .	250 ng/ml
Medazepam . . . . .	1000 ng/ml
Midazolam . . . . .	130 ng/ml
N-Desalkylflurazepam . . . . .	300 ng/ml
N-Desmethyldiazepam . . . . .	160 ng/ml
Nitrazepam . . . . .	200 ng/ml
Nordiazepam . . . . .	200 ng/ml
Oxazepam . . . . .	200 ng/ml
Prazepam . . . . .	100 ng/ml
Temazepam . . . . .	200 ng/ml
Tetrazepam . . . . .	200 ng/ml
Triazolam . . . . .	500 ng/ml

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

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

**The following Buprenorphine-related substances yield positive result for Buprenorphine at 10 ng/ml cut-off level:**

Buprenorphine-3- $\beta$ -D-Glucuronide . . . . .	2.5 ng/ml
Buprenorphine . . . . .	.10 ng/ml
Nalorphine . . . . .	1,000 ng/ml
Norbuprenorphine . . . . .	30,000 ng/ml
Norbuprenorphine-3- $\beta$ -D-Glucuronide . . . . .	30,000 ng/ml

**The following Cocaine/Benzoyllecgonine-related substances yield positive results for Cocaine/Benzoyllecgonine-I at 150 ng/ml cut-off level:**

Benzoyllecgonine . . . . .	150 ng/ml
Cocaine . . . . .	150 ng/ml
Isoxsuprine . . . . .	1,500 ng/ml

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

Benzoyllecgonine . . . . .	300 ng/ml
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Cocaine . . . . .	300 ng/ml
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**The following Marijuana-related substances yield positive results for Marijuana at 50 ng/ml cut-off level:**

Cannabinol . . . . .	10,000 ng/ml
11-nor- $\Delta$ -8-THC-9-COOH . . . . .	.50 ng/ml
11-nor- $\Delta$ -9-THC-9-COOH . . . . .	.50 ng/ml
$\Delta$ 8-THC . . . . .	7,500 ng/ml
$\Delta$ 9-THC . . . . .	10,000 ng/ml
11-hydroxy- $\Delta$ -9-THC . . . . .	2,500 ng/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 (2 Ethylidene-1,5-dimethyl 1-3,3-Diphenylpyrrolidin) . . . . .	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-I at 300 ng/ml cut-off level:**

d-Amphetamine . . . . .	50,000 ng/ml
$\Delta$ ,l-Amphetamine . . . . .	10,000 ng/ml
Ephedrine . . . . .	25,000 ng/ml
(+) Methamphetamine . . . . .	500 ng/ml
( $\pm$ )3,4Methylenedioxyamphetamine . . . . .	500 ng/ml
( $\pm$ )3,4Methylenedioxyamphetamine . . . . .	50,000 ng/ml
Pseudoephedrine . . . . .	1,000 ng/ml
Phenyl Propanolamine (PPA) . . . . .	98,000 ng/ml

**The following Methamphetamine-related substances yield positive results for Methamphetamine-II at 500 ng/ml cut-off level:**

(+) Methamphetamine . . . . .	1000 ng/ml
( $\pm$ )3,4Methylenedioxyamphetamine (MDMA) . . . . .	1000 ng/ml
( $\pm$ )3,4Methylenedioxyamphetamine (MDA) . . . . .	200,000 ng/ml
d-Amphetamine Sulfate . . . . .	200,000 ng/ml
l-Amphetamine Sulfate . . . . .	200,000 ng/ml
$\Delta$ ,l-Amphetamine Sulfate . . . . .	200,000 ng/ml

**The following Methylenedioxyamphetamine-related substances yield positive results for Methylenedioxyamphetamine-I at 500 ng/ml cut-off level:**

( $\pm$ ) 3,4-Methylenedioxyamphetamine (MDMA, Ecstasy) . . . . .	500 ng/ml
$\Delta$ -Amphetamine . . . . .	50,000 ng/ml
( $\pm$ ) 3,4-Methylenedioxyamphetamine (MDA) . . . . .	50,000 ng/ml
(+) Methamphetamine . . . . .	500 ng/ml
$\Delta$ -l-Amphetamine . . . . .	100,000 ng/ml
Deoxyephedrine . . . . .	500 ng/ml
Ephedrine . . . . .	2,500,000 ng/ml
Phenylpropanolamine . . . . .	9,800,000 ng/ml
Pseudoephedrine . . . . .	1,000 ng/ml

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

( $\pm$ ) 3,4-Methylenedioxyamphetamine (MDMA, Ecstasy) . . . . .	1000 ng/ml
d-Amphetamine . . . . .	50,000 ng/ml
( $\pm$ ) 3,4-Methylenedioxyamphetamine (MDA) . . . . .	50,000 ng/ml
(+) Methamphetamine . . . . .	500 ng/ml
$\Delta$ -l-Amphetamine . . . . .	100,000 ng/ml
Deoxyephedrine . . . . .	500 ng/ml
Ephedrine . . . . .	5,000,000 ng/ml
Pseudoephedrine . . . . .	1,000 ng/ml

**The following Opiates/Morphine-related substances yield a positive result for Opiates/Morphine-I at 300 ng/ml cut-off level:**

Atropine . . . . .	100,000 ng/ml
Codeine . . . . .	300 ng/ml
Heroin . . . . .	300 ng/ml
Hydrocodone . . . . .	500 ng/ml
Hydromorphone . . . . .	300 ng/ml
Imipramine . . . . .	50,000 ng/ml
Levorphanol . . . . .	600 ng/ml
Meperidine . . . . .	100,000 ng/ml
Morphine-3- $\beta$ -D Glucuronide . . . . .	300 ng/ml
Naloxone . . . . .	1000 ng/ml
Norcodeine . . . . .	2,000 ng/ml
Opiate . . . . .	300 ng/ml
Oxycodone . . . . .	1000 ng/ml
Ranitidine . . . . .	100,000 ng/ml
Thebaine . . . . .	1,500 ng/ml

**The following Opiates/Morphine-related substances yield a positive result for Opiates/Morphine-II 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
Codeine	2000 ng/ml
Heroin	2000 ng/ml
Levorphanol	4000 ng/ml
Ranitidine	100,000 ng/ml
6-Acetylmorphine	.50 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	1,500 ng/ml
Morphine-Sulfate	7,000 ng/ml
Morphine-3-b-D-Glucuronide	40,000 ng/ml
Norcodeine	40,000 ng/ml
Oxymorphone	300 ng/ml

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

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

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

Amitriptyline	1,000 ng/ml
Cyclobenzaprine	1,500 ng/ml
Clomipramine	5,000 ng/ml
Desipramine	600 ng/ml
Doxepin	1,000 ng/ml
Imipramine	600 ng/ml
Notriptyline	1,000 ng/ml
Nordoxepin	1,000 ng/ml

**Table II: Compounds tested and found not to cross-react with the test at a 100 µg / ml concentrate in urine.**

Acetaminophen	Furosemide
Acetone	Glucosamine
Acetyl Salicylic Acid	Guaiacol Glyceryl Ether
Amikacin	Hydrochlorothiazide
Amitriptyline	Hydrocodone
Ampicillin	Ibuprofen
l-Ascorbic Acid (Vitamin C)	Ketamine
Aspartame	Lidocaine
Aspirin	Maprotiline
Atropine	Meperidine
Benzocaine	Methanol
Benzoic Acid	Methylphenidate
(+)- Brompheniramine	Naltrexone
Buprenorphine	(+/-) Naproxen
Buprenorphine3-β-D-Glucuronide	Nicotene
Caffeine	Nor-Buprenorphine
(+)-Chlorpheniramine	Noscapine Hydrochloride
(+/-)-Chlorpheniramine	Oxalic Acid
Chlorpromazine	Omega-3-Fatty Acid
Cortisone	Penicillin G
(-)-Cotinine	Phenazone
Creatinine	l-Phenylephrine
Dextromethorphan	(+/-)-Phenylpropranolamine

4-Dimethylaminoantipyrine	Promethazine
Diphenhydramine	Pseudoephedrine
5,5-Diphenylhydantoin	Quinine
Dopamine	Quinidine
EDDP	Salicylic Acid
+ Ephedrine	Sulindac
- Ephedrine	Sustiva
(+/-) Epinephrine	Theophylline
Erythromycin	Thioridazine
Ethanol	Tramadol
Fentanyl	d(+)-Trehalose
Fluxetine	Trifluoperazine

**Accuracy:** The accuracy of the QuikScreen® X Multidrug Plus Alcohol 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 is summarized as follows:

**3.1 AMPHETAMINE-I (AMP) 500 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	16	1
QuikScreen® Negative	1	549

When compared to GC/MASS the relative sensitivity was computed to be 16/16 or 100%. The relative specificity was computed to be 549/549 or 100%. The concordance of the combined data with respect to GC/MASS was 565/565 or 100%.

**3.2 AMPHETAMINE-II (AMP) 1000 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	47	0
QuikScreen® Negative	0	40

When compared to GC/Mass the relative sensitivity was computed to be 47/47 or 100%. The relative specificity was computed to be 40/43 or 93%. The concordance of the combined data with respect to GC/Mass was 87/90 or 96.6%.

**3.3 BARBITURATES-I (BAR) 200 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	23	0
QuikScreen® Negative	0	542

When compared to GC/Mass the relative sensitivity was computed to be 23/23 or 100%. The relative specificity was computed to be 542/542 or 100%. The concordance of the combined data with respect to GC/Mass was 565/565 or 100%.

**3.4 BARBITURATES-II (BAR) 300 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	27	2
QuikScreen® Negative	0	31

When compared to GC/Mass the relative sensitivity was computed to be 27/27 or 100%. The relative specificity was computed to be 31/33 or 94%. The concordance of the combined data with respect to GC/Mass was 58/60 or 97%.

**3.5 BENZODIAZEPINE-I (BZD) 200NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	36	3
QuikScreen® Negative	0	529

When compared to GC/Mass the relative sensitivity was computed to be 36/36 or 100%. The relative specificity was computed to be 529/529 or 100%. The concordance of the combined data with respect to GC/Mass was 565/565 or 100%.

**3.6 BENZODIAZEPINE-II (BZD) 300NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	29	1
QuikScreen® Negative	0	30

When compared to GC/Mass the relative sensitivity was computed to be 29/29 or 100%. The

relative specificity was computed to be 30/31 or 96.7%. The concordance of the combined data with respect to GC/Mass was 59/60 or 98.3%.

**3.7 BUPRENORPHINE (BUP) 10NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	48	2
QuikScreen® Negative	0	53

When compared to GC/Mass the relative sensitivity was computed to be 48/48 or 100%. The relative specificity was computed to be 53/55 or 96.3%. The concordance of the combined data with respect to GC/Mass was 101/103 or 98.0%.

**3.8 COCAINE/BENZOYLECGONINE-I (COC/BEG) 150 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	39	0
QuikScreen® Negative	0	526

When compared to GC/Mass the relative sensitivity was computed to be 39/39 or 100%. The relative specificity was computed to be 526/526 or 100%. The concordance of the combined data with respect to GC/Mass was 565/565 or 100%.

**3.9 COCAINE/BENZOYLECGONINE-II (COC/BEG) 300 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	30	0
QuikScreen® Negative	0	30

When compared to GC/Mass the relative sensitivity was computed to be 30/30 or 100%. The relative specificity was computed to be 30/30 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

**3.10 MARIJUANA-I (THC) 50 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	32	0
QuikScreen® Negative	0	31

When compared to GC/MASS the relative sensitivity between positive samples was 32/32=100%. The relative specificity between negative samples was 31/31= 100%. The concordance of the combined data with respect to GC/MASS was 63/63=100%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	30	0
QuikScreen® Negative	0	30

When compared to GC/Mass the relative sensitivity was computed to be 30/30 or 100%. The relative specificity was computed to be 30/30 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

**3.12 METHAMPHETAMINE-I (MET) 500 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	22	0
QuikScreen® Negative	0	543

When compared to GC/MASS the relative sensitivity was computed to be 22/22 or 100%. The relative specificity was computed to be 543/543 or 100%. The concordance of the combined data with respect to GC/MASS was 565/565 or 100%.

**3.13 METHAMPHETAMINE-II (MET) 1000 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	30	0
QuikScreen® Negative	0	30

When compared to GC/Mass the relative sensitivity was computed to be 30/30 or 100%. The relative specificity was computed to be 30/30 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

**3.14 METHYLENEDIOXYMETHAMPHETAMINE-I (MDMA) 500 NG/ML CUT-OFF LEVEL**

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
QuikScreen® Positive	193	0
QuikScreen® Negative	0	256

When compared to GC/Mass the relative sensitivity was computed to be 193/193 or 100%. The relative specificity was computed to be 256/262 or 97.7%. The concordance of the combined

data with respect to GC/Mass was 449/455 or 98.6%

**3.15 METHYLENEDIOXYMETHAMPHETAMINE-II (MDMA) 1000 NG/ML CUT-OFF LEVEL**

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
QuikScreen® Positive	232	0
QuikScreen® Negative	8	277

When compared to GC/Mass the relative sensitivity was computed to be 232/232 or 100%. The relative specificity was computed to be 277/285 or 97.1%. The concordance of the combined data with respect to GC/Mass was 509/517 or 98.4%.

**3.16 OPIATES/MORPHINE-I (OPI/MOR) 300 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	65	0
QuikScreen® Negative	0	500

When compared to GC/Mass the relative sensitivity was computed to be 65/65 or 100%. The relative specificity was computed to be 500/500 or 100%. The concordance of the combined data with respect to GC/Mass was 565/565 or 100%.

**3.17 OPIATES/MORPHINE-II (OPI/MOR) 2000 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	29	0
QuikScreen® Negative	0	31

When compared to GC/Mass the relative sensitivity was computed to be 29/29 or 100%. The relative specificity was computed to be 31/31 or 100%. The concordance of the combined data with respect to GC/Mass was 60/60 or 100%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	50	0
QuikScreen® Negative	0	20

When compared to GC/Mass the relative sensitivity was computed to be 50/50 or 100%. The relative specificity was computed to be 20/20 or 100%. The concordance of the combined data with respect to GC/Mass was 70/70 or 100%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	22	4
QuikScreen® Negative	0	34

When compared to GC/Mass the relative sensitivity was computed to be 22/22 or 100%. The relative specificity was computed to be 34/38 or 90%. The concordance of the combined data with respect to GC/Mass was 56/60 or 93.3%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	26	2
QuikScreen® Negative	0	32

When compared to GC/Mass the relative sensitivity was computed to be 26/26 or 100%. The relative specificity was computed to be 32/34 or 94%. The concordance of the combined data with respect to GC/Mass was 58/60 or 96.6%.

**3.21 TRICYCLIC ANTIDEPRESSANT (TCA) 1000 NG/ML CUT-OFF LEVEL**

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	41	1
QuikScreen® Negative	0	42

When compared to GC/Mass the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 42/43 or 97.6%. The concordance of the combined data with respect to GC/Mass was 83/84 or 98.8%.

Performance Characteristics of Alcohol

A. Accuracy

The following data was obtained based on 56 urine samples

	>0.04% (Spiked)	0 (No Spike)
QuickStrip ( + )	26	0
QuickStrip ( - )	1	29
Sensitivity	96%	
Specificity		100%
Overall agreement	98%	98%

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