

QuikScreen® X Multidrug Plus

ONE STEP ONSITE DRUG CUP WITH ADULTERATION

Catalog # 65xxx

CLIA-Waived

— Instructions —



INTENDED USE

The QuikScreen® X Multidrug Plus test is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. In the QuikScreen® X Multidrug Plus, X may denote any number of drugs, 1 through 11. These drug combinations may be composed from any of the following drugs, at the noted cut-off concentrations:

DRUG CLASS	ABBREVIATIONS	SENSITIVITY
AMPHETAMINE	AMP	1000 ng/ml
BARBITURATES	BAR	300 ng/ml
BENZODIAZEPINES	BZD	300 ng/ml
COCAINE/BENZOYLECGONINE	COC/BEG	300 ng/ml
MARIJUANA	THC	50 ng/ml
METHADONE	MAD	300 ng/ml
METHAMPHETAMINE	MET	1000 ng/ml
OPIATES/MORPHINE	OPI/MOR	2000 ng/ml
OXYCODONE	OXY	100 ng/ml
PHENCYCLIDINE	PCP	25 ng/ml
TRICYCLIC ANTIDEPRESSANT	TCA	1000 ng/ml

An added feature to assess the integrity of the urine samples prior to drug testing, is a visual determination of *Creatinine (CRE)*, *Glutaraldehyde (GLU)*, *pH*, *Specific Gravity (SG)* and *Nitrite*, *Pyridinium Chlorochromate*, *Bleach (NPB)*. 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® X Multidrug Plus 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. Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the QuikScreen® X Multidrug Plus test 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® X Multidrug Plus 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.

Included in this device are any 4 of the following 5 different adulteration strips to determine whether the urine sample is adulterated: *Creatinine*, *Glutaraldehyde*, *pH*, *Specific Gravity* and *NPB* the results of which can be achieved by comparing to the color chart provided.

REAGENTS AND MATERIAL PROVIDED

1. Test Devices	Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
2. Test Instructions	Catalog# PI-65xxx
3. Color Chart	Catalog# COL-007
Optional:	
4. Negative Control I	Contains buffered protein solution with sodium azide. [REF] 4010N
5. Amphetamine Positive Control	Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide. [REF] 11120P-B
6. Barbiturates Positive Control	Contains BAR at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 18040P
7. Benzodiazepines Positive Control	Contains BZD at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 18020P
8. Cocaine Positive Control	Contains COC/BEG at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 12000P
9. Marijuana Positive Control	Contains THC at 150 ng/ml in a buffered protein solution with sodium azide. [REF] 13020P
10. Methadone Positive Control	Contains MAD at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 19020P
11. Methamphetamine Positive Control	Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. [REF] 11320P-B
12. Opiates Positive Control	Contains OPI/MOR at 5000 ng/ml in a buffered protein solution with sodium azide. [REF] 11220P-B
13. Oxycodone Positive Control	Contains OXY at 300 ng/ml in a buffered protein solution with sodium azide. [REF] 19080P
14. Phencyclidine Positive Control	Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. [REF] 14020P
15. 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. For forensic use only.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of urine in the toilet by draining it out of the test device. Fasten cap on the device and throw the empty urine cup in the garbage.
4. Read the results at 5 minutes. Do not interpret results after 30 minutes.
5. 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® X Multidrug Plus** 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 QuikScreen® X Multidrug Plus 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. Ensure that the sample amount meets the minimum level as indicated on the side of the test cup.
4. **Wait 1 minute and immediately read the adulteration strips for pH and Specific Gravity. At 5 minutes read the adulteration strips for Creatinine, Glutaraldehyde and NPB.** 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.**
5. 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 any 4 of the following 5 different adulteration strips to determine whether the urine sample is adulterated:

Creatinine (CRE) 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.

Glutaraldehyde (GLU) is based on the reaction of the aldehyde group of glutaraldehyde with aldehyde detecting reagent on the strip. A pink, purple, or light blue- purple color is obtained if glutaraldehyde is present in the urine.

pH 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, green and dark green.

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

Nitrite, Pyridinium Chlorochromate and Bleach (NPB) 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, pyridinium chlorochromate or bleach.

The **QuikScreen® X Multidrug Plus** also provides internal control to determine adulteration of the urine sample in the form of up to 5 reagent strips, to test for CRE, GLU, pH, SG and NPB on urine samples submitted for drugs of abuse testing.

INTERPRETATION OF RESULTS

ADULTERATION STRIPS

Results are obtained by direct comparison of the reacted strip with the color chart provided, similar to the illustration in Fig 1. An adulterated urine sample will show result colors under the “**Abnormal**” block colors of the chart. An 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:

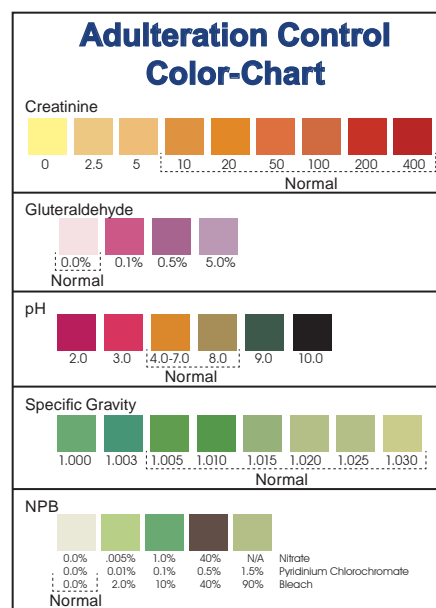


Fig. 1

- Dilute** if the Creatinine is <20 mg/dl unless the criteria for a substituted specimen are met.
- Adulterated** if the pH is ≤4 or ≥8.
- Dilute** if the Specific Gravity is <1.005 mg/dl, unless the criteria for a substituted specimen are met.
- Adulterated** if the Nitrite concentration is ≥5 mg/ml.
- Adulterated** if an exogenous substance (i.e., a substance which is not a normal constituent of urine such as CRE, GLU, pH, SG and NPB) or an endogenous substance at a higher concentration than normal physiological concentration is present in the specimen.

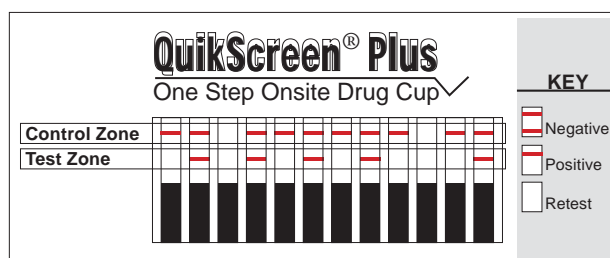
DRUG TEST STRIPS

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.*



QUALITY CONTROL

An internal procedure control has been incorporated into the test to insure 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.

- 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® X Multidrug Plus** 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 the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method.
- Specificity.** A study was conducted with the **QuikScreen® X Multidrug Plus** test device to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cut-off 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 level:

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

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

Allobarbitol	600 ng/ml
Amobarbitol	600 ng/ml
Barbitol	300 ng/ml
Butobarbitol	300 ng/ml
Butalbital	300 ng/ml
Pentobarbitol	300 ng/ml
Phenobarbitol	300 ng/ml
Secobarbitol	300 ng/ml

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

Benzoylecgonine	300 ng/ml
Cocaine	300 ng/ml

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

Cannabinol	10,000 ng/ml
11-nor-Δ-8-THC-9-COOH	.50 ng/ml
11-nor-Δ-9-THC-9-COOH	.50 ng/ml
Δ8-THC	.7500 ng/ml
Δ9-THC	10,000 ng/ml
11-hydroxy-Δ-9-THC	.2500 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-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 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
Δ-,l-Amphetamine Sulfate	200,000 ng/ml

The following Opiates/Morphine-related substances yield a positive result for Opiates/Morphine 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 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

Buprenorphine-3-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	(+/-)-Phenylpropanolamine
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 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 (AMP) 1000 NG/ML CUT-OFF LEVEL

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
QuikScreen® Positive	47	3
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%.

3.2 BARBITURATES (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%.

3.3 BENZODIAZEPINE (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%.

3.4 COCAINE/BENZOYLECGONINE (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%.

3.5 MARIJUANA (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 was computed to be 32/32 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 63/63 or 100%.

3.6 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%.

3.7 METHAMPHETAMINE (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%.

3.8 OPIATES/MORPHINE (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%.

3.9 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%.

3.10 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%.

3.11 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%.

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