

KCUR 920064



**INTENDED USE**

The QuikScreen® 7 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
BARBITURATES	300 ng/ml
BENZODIAZEPINES	300 ng/ml
COCAINE/BENZOYLECGONINE	300 ng/ml
METHAMPHETAMINE	1000 ng/ml
OPIATES/MORPHINE	2000 ng/ml
PHENCYCLIDINE	25 ng/ml
MARIJUANA	50 ng/ml

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

**SUMMARY AND EXPLANATION OF THE TEST**

The QuikScreen® 7 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® 7 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® 7 is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of any of the drug combinations from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen- antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose pink-color band is produced in each Control Zone (top bands) by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.



**REAGENTS AND MATERIALS PROVIDED**

1. Test Devices Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide. [REF] 60711
2. Test Instructions [REF] 60711
- Optional:
3. Negative Control I Contains buffered protein solution with sodium azide. [REF] 4010N
4. Barbiturates Positive Control Contains BAR at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 18040-BP
5. Benzodiazepines Positive Control Contains BZD at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 18020-BP
6. Cocaine Positive Control Contains BEG at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 12000-BP
7. Methamphetamine Positive Control Contains MET at 3000 ng/ml in a buffered protein solution with sodium azide. [REF] 11320-BP
8. Opiates Positive Control Opiates Positive Control Contains MOR at 5000 ng/ml in a buffered protein solution with sodium azide. [REF] 11220-BP
9. PCP Positive Control Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. [REF] 14020P
10. Marijuana Positive Control Contains THC at 150 ng/ml in a buffered solution with sodium azide. [REF] 13020P

**MATERIALS REQUIRED BUT NOT PROVIDED**

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

**WARNINGS AND PRECAUTIONS**

1. For *in vitro* diagnostic and professional use only.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the device might be compromised.

**STORAGE AND STABILITY**

Store test kit below 28°C; **do not freeze**. If stored at 2°-8°C, allow the test kit to reach room temperature (15°-28°C) before performing the test. Refer to the expiration date for stability.

**SPECIMEN COLLECTION AND PREPARATION**

Fresh urine specimens should be collected directly into the cup. The QuikScreen® 7 device employs a **thermal strip which should be checked immediately** after collection to validate urine specimen. SAMHSA regulations specify that any temperature below 90.5°F must be considered adulterated. No additives or preservatives are required. *Note: Urine specimens can be transferred from a urine collection container into the cup QuikScreen® 7 test cup, if necessary.*

**TEST PROCEDURE**

1. Do not break the seal of the pouch until ready to begin testing.
2. Remove the Test Cup from the foil pouch.
3. Collect urine specimen directly into the Test Cup. Insure that the sample amount meets the minimum level as indicated on the side of the Test Cup.
4. Read the results at 5 minutes.

**NOTE:** The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.





## INTERPRETATION OF RESULTS

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

**Negative:** A rose-pink band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

**Retest:** If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

**Note:** There is no meaning attributed to line color intensity or width.

## QUALITY CONTROL

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

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

## LIMITATIONS OF THE TEST

- This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
- Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
- The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
- Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

## PERFORMANCE CHARACTERISTICS

- Sensitivity** The QuikScreen® 7 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® 7 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 Barbiturates-related substances yield positive results for Barbiturates at 300ng/ml cut-off:

Amobarbital	200 ng/ml	Pentobarbital	200 ng/ml
Barbital	200 ng/ml	Phenobarbital	200 ng/ml
Bromocriptine	200 ng/ml	Secobarbital	200 ng/ml
Butabarbital	200 ng/ml	Zolofl	200 ng/ml
Clean Jane (sodium dodecylsulfate)	260 ng/ml		

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

Alprazolam	62.5 ng/ml	1-N-Hydroxyethylflurazepam	130 ng/ml
Bromazepam	230 ng/ml	$\alpha$ -Hydroxyriazolam	200 ng/ml
Chlordiazepoxide	950 ng/ml	Ketazolam	210 ng/ml
Clonazepam	2500 ng/ml	Lorazepam	200 ng/ml
Clonazepam	500 ng/ml	Lormetazepam	250 ng/ml
Clonazepam	50 ng/ml	Meflazepam	1000 ng/ml
Clonazepam	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	230 ng/ml	Temazepam	200 ng/ml
Flurazepam	100 ng/ml	Tetraazepam	200 ng/ml
Halazepam	160 ng/ml	Triazolam	500 ng/ml
$\alpha$ -Hydroxyalprazolam	200 ng/ml		

The following Cocaine-related substances yield positive results for Cocaine

at 300 ng/ml Cut-Off Level

Benzoylcegonine	300 ng/ml
Cocaine	300 ng/ml
Isosuprine	2,500 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-Methylenedioxyamphetamine (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	2,300 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:

Morphine	2,000 ng/ml	Leworphanol	6,000 ng/ml
Morphine-3- $\beta$ -D-Glucuronide	2,000 ng/ml	Naloxone	10,000 ng/ml
Codeine	2,000 ng/ml	Thebaine	15,000 ng/ml
Heroin	2,000 ng/ml	Imipramine	500,000 ng/ml
Norcodeine	20,000 ng/ml	Atiropine	1,000,000 ng/ml
Hydrocodone	5,000 ng/ml	Meperidine	1,000,000 ng/ml
Hydromorphone	2,000 ng/ml	Ramitidine	1,000,000 ng/ml
Oxycodone	100,000 ng/ml		

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

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

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

11-Nor- $\Delta^8$ -THC-9-COOH	50 ng/ml
11-Nor- $\Delta^8$ -THC-9-COOH	50 ng/ml
$\Delta^8$ -THC	1 $\mu$ g/ml
$\Delta^9$ -THC	4 $\mu$ g/ml
Cannabinol	10 $\mu$ g/ml
11-Hydroxy- $\Delta^8$ -THC	10 $\mu$ g/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 (300 ng/ml cut-off) Barbiturates at a 100  $\mu$ g/ml concentration in urine:

Acetanaphen	5,5-Diphenylhydantoin	Morphine Sulfate
Acetylsalicylic Acid	Doxylamine	Oxazepam
Amikacin	Ecgonine HCl	Oxycodone
Antripryline	Ecgonine Methyl Ester	Penicillin G
Ampicillin	Glucose	Pentobarbital
Arterenol	Histamine	Phendimetrazine
Aspartame	Hydrochlorothiazide	Phentermine
Atropine Sulfate	Hydrocodone	l-Phenylephrine
Benzoic Acid	Hydromorphone	Phenylpropanolamine
Benzoylcegonine HCl	Indomethacin	Prednisone
Caffeine	Keoprafen	Quinine
Chlorpheniramine	Leworphanol	Ramitidine
Chlorpromazine HCl	$\Delta^8$ -THC	Sodium Salicylate
Cimetidine	11-Nor- $\Delta^8$ -THC-9-COOH	Tetracycline
Codeine	Meperidine	Tetrahydrozoline
Deoxyephedrine	Methylphenidate	Theophylline
Dextromethorphan	Methadone	Thioridazine
Diazepam	Methaqualone	Trifluoperazine
Diethylpropion	Morphine-3- $\beta$ -D-Glucuronide	Tryptophan

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

Acetanaphen	Doxylamine	Oxycodone
Acetylsalicylic Acid	Ecgonine HCl	Phendimetrazine
Amikacin	Ecgonine Methyl Ester	Penicillin G
Antripryline	Glucose	Pentobarbital
Ampicillin	Histamine	Phencyclidine
Arterenol	Hydrochlorothiazide	Phenobarbital
Aspartame	Hydrocodone	Phentermine
Atropine Sulfate	Hydromorphone	Phenylpropanolamine
Benzoic Acid	Indomethacin	l-Phenylephrine
Benzoylcegonine HCl	Keoprafen	d-Propoxyphene
Caffeine	Leworphanol	l-Propranolol
Chlorpheniramine	$\Delta^8$ -THC	Quinine
Chlorpromazine HCl	(-)-11-Nor- $\Delta^8$ -THC-9-COOH	Ramitidine
Cimetidine	Meperidine	Sodium Salicylate
Codeine	Methylphenidate	Tetracycline
Deoxyephedrine	Methadone	Tetrahydrozoline
Dextromethorphan	Methaqualone	Theophylline
Diethylpropion	Morphine-3- $\beta$ -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	Egonine HCl	Phendimetrazine
Acetylsalicylic Acid	Egonine Methyl Ester	Penicillin G
Amikacin	Glucose	Pentobarbital
Amitriptyline	Histamine	D-Propoxyphene
Ampicillin	Hydrochlorothiazide	1-Propranol
Arterenal	Hydrocodone	Phencyclidine
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Indomethacin	Phentermine
Benzoic Acid	Ketoprofen	Phenylpropanolamine
Caffeine	Levorphanol	1-Phenylephrine
Chlorpheniramine	Δ <sup>9</sup> -THC	Quinine
Chlorpromazine HCl	11-Nor-Δ <sup>9</sup> -THC-9-COOH	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Cocaine	Methylphenidate	Tetracycline
Deoxyephedrine	Methodone	Tetrahydrozoline
Dextromethorphan	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 (1000 ng/ml cut-off) Methamphetamine at a 100 µg/ml concentration in urine:

Acetaminophen	Doxylamine	Oxazepam
Acetylsalicylic Acid	Egonine HCl	Oxycodone
Amikacin	Egonine Methyl Ester	Phendimetrazine
Amitriptyline	Glucose	Penicillin G
Ampicillin, Sodium Salt	Histamine	d-Propoxyphene
Arterenal	Hydrocodone	1-Propranol
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Hydrochlorothiazide	Phentermine
Benzoic Acid	Indomethacin	Phenylpropanolamine
Benzoylecgonine HCl	Ketoprofen	1-Phenylephrine
Caffeine	Levorphanol	Quinine
(-)-Chlorpheniramine, Maleate-Salt	Δ <sup>9</sup> -THC	Ranitidine
(-)-Chlorpromazine HCl	11-Nor-Δ <sup>9</sup> -THC-9-COOH	Sodium Salicylate
Cimetidine	Meperidine	Tetracycline
Cocaine	Methylphenidate	Tetrahydrozoline
Deoxyephedrine	Methodone	Theophylline
Dextromethorphan HBr	Methaqualone	Thioridazine
Diazepam	Morphine-3-β-D-Glucuronide	Trifluoperazine
Diethylpropion	Morphine Sulfate	Tryptophan

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

Acetaminophen	5,5-Diphenylhydantoin	Pentobarbital
Acetylsalicylic Acid	Doxylamine	d-Propoxyphene
Amikacin	Egonine HCl	1-Propranol
Amitriptyline	Egonine Methyl Ester	Phencyclidine
Ampicillin	Glucose	Phenobarbital
Arterenal	Histamine	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Benzoic Acid	Indomethacin	1-Phenylephrine
Benzoylecgonine HCl	Ketoprofen	Quinine
Caffeine	Δ <sup>9</sup> -THC	Sodium Salicylate
Chlorpheniramine	11-Nor-Δ <sup>9</sup> -THC-9-COOH	Tetracycline
Chlorpromazine HCl	Methylphenidate	Tetrahydrozoline
Cimetidine	Methodone	Theophylline
Deoxyephedrine	Methaqualone	Thioridazine
Dextromethorphan	Oxazepam	Trifluoperazine
Diazepam	Phendimetrazine	Tryptophan
Diethylpropion	Penicillin G	

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

Acetaminophen	Doxylamine	Oxazepam
Acetylsalicylic Acid	Egonine HCl	Oxycodone
Amikacin	Egonine Methyl Ester	Phendimetrazine
Amitriptyline	Glucose	Penicillin G
Ampicillin	Histamine	d-Propoxyphene
Arterenal	Hydrocodone	1-Propranol
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Hydrochlorothiazide	Phentermine
Benzoic Acid	Indomethacin	Phenylpropanolamine
Benzoylecgonine HCl	Ketoprofen	1-Phenylephrine
Caffeine	Levorphanol	Quinine
Chlorpheniramine	Δ <sup>9</sup> -THC	Ranitidine
Chlorpromazine HCl	11-Nor-Δ <sup>9</sup> -THC-9-COOH	Sodium Salicylate
Cimetidine	Meperidine	Tryptophan
Deoxyephedrine	Methylphenidate	Tetracycline
Dextromethorphan	Methodone	Tetrahydrozoline
Diazepam	Methaqualone	Theophylline
Diethylpropion	Morphine-3-β-D-Glucuronide	Thioridazine
5,5-Diphenylhydantoin	Morphine Sulfate	Trifluoperazine

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	Methodone
Acetylsalicylic Acid	Egonine HCl	Methaqualone
Amikacin	Egonine Methyl Ester	Naloxone
Ampicillin	Ephedrine	Neomycin
d,l-Amphetamine	Epinephrine	Niacinamide
Amitriptyline	Genisic Acid	Oxazepam
Arterenal	Glucose	Perphenazine
Aspartame	Guaiacol	Penicillin G
Atropine Sulfate	Glyceryl Ether	Phencyclidine
Benzoic Acid	Histamine	Phenobarbital
Benzoylecgonine	Hydrochlorothiazide	α-Phenylethylamine
Caffeine	Hydrocodone	Phenylpropanolamine
Camphor	Hydromorphone	Promethazine
Chloroquine	Homatropine	Pseudoephedrine
Chlorpheniramine	Imipramine	Ranitidine
Chlorpromazine HCl	Isoproterenol	Salicylic Acid
Cocaine HCl	Ketamine	Secobarbital
Cocaine	Lidocaine	Tetracycline
Cimetidine	Methylphenidate	Tetrahydrozoline
Cortisone	Morphine	Theophylline
Deoxyephedrine	Morphine-3-β-D-Glucuronide	Thioridazine
Dextromethorphan	Morphine Sulfate	Trifluoperazine
Diazepam	d-Methamphetamine	Tryptophan

3. Accuracy: The accuracy of the QuikScreen® 7 Test was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. The laboratory used EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The results are summarized as follows:

3.1 BARBITURATE (BAR) 300ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	23	0
QuikScreen® Negative	0	542

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

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

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	33	1
QuikScreen® Negative	2	529

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

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

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	165	2
QuikScreen® Negative	0	151

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

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

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	162	0
QuikScreen® Negative	8	237

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



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

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	195	0
QuikScreen® Negative	0	500

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

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

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	14	0
QuikScreen® Negative	0	551

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

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

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	52	0
QuikScreen® Negative	0	513

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

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Opiate Test

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Marijuana Test


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 = Order Number, Catalog Number


 = In-Vitro Diagnostic Device

 = Use only once.

 = Read instructions carefully before use.

 = LOT Number, Batch Number

 = Use Before Expiration Date

 = Ce Mark

Doc ID 60711  
Revision: 01  
Eff. Date 02-01-05



**ADDENDUM (B)  
TO SERVICE AGREEMENT  
01/1/2007  
Services Pricing**

**I. PRICING:**

- Prices shall remain firm for the first two years of the Agreement. Thereafter, price increases may occur on a yearly anniversary date per mutual agreement and shall not exceed 3% per year.
- A minimum of 425 pounds is required for basic pick-up.
- Fuel surcharge will apply of 3% . CRL will only be charged one fuel surcharge (not for each location)

<b>Price/pound</b>	<b>Volume (Net Tare weight)</b>	<b>Location</b>
\$0.17	Greater than 40,000 pounds	All Locations
\$0.18	Greater than or equal to 35,000 lbs. and less than 40,000	All locations
\$0.19	Greater than or equal to 25,000 lbs. less than 35,000 lbs.	All locations
\$0.205	Greater than or equal to 15,000 lbs. and less than 25,000 lbs.	All locations
\$0.21	Less than 15,000 lbs.	All locations

- CRL has the option to place a Trailer for pre-staging waste
- Ancillary Labs:
  - Ancillary Labs have the availability to utilize the ENSERV contract pricing if the waste is staged centrally for pick up and on the Participants main campus.
- Satellite Ancillary Buildings and offices:
  - Satellite, owned facilities have a special pricing available on a per container basis.
    - \$17.00 per Rubbermaid 28 gallon container with liner.
    - \$13.00 per 23-gallon cardboard medical waste box with liner.

**II. CONTAINERS:**

- ENSERV will provide the following Department of Transportation (DOT) Compliant containers to Participants at no extra charge.
  - 23-Gallon Boxes (18x14x20.5) with liner provided
  - 28-Gallon Rubbermaid Tubs (21.5x21.5x22.5) with liner provided
  - 95-Gallon Rollout Carts (28x33x45) with liner provided
  - Tags to designate containers that contain Pathological and Chemo waste
- ENSERV has set the following container weight limits:
  - Box 50 lbs.
  - Tub 63 lbs.
  - Cart 150 lbs.

*ENSERV will add a surcharge of \$0.65 per pound in excess of rating for overweight containers.*
- Clinical Reference Lab, Inc. has the option to receive a monthly report via Internet or mail per request that details Monthly Waste Generation by date specific Manifest numbers and Bar code numbers, type and weight of each Container (net weight) and reports the corresponding charge for the month.
- Any charges for each month must be billed within 30 days of the end of the monthly cycle.