

KCURE9 20063

Syntron Bioresearch, Inc.
Dip DrugScan 9 Test
 for AMP/BZD/COC/THC/MAD/MET/OPI/PCP/BAR
 [REF] 30901
 Instructions

INTENDED USE

The Dip DrugScan 9 Test is an immunochromatographic assay for rapid, qualitative detection of six drugs and their principal metabolites in urine at specified cut-off concentrations. A six drug combination is composed from any the following drugs:

DRUG CLASS	SENSITIVITY
AMPHETAMINE	500 ng/ml
BENZODIAZEPINE	300 ng/ml
COCAINE/BENZOYLECGONINE	300 ng/ml
MARIJUANA	50 ng/ml
METHADONE	300 ng/ml
METHAMPHETAMINE	500 ng/ml
OPIATES/MORPHINE	2000 ng/ml
PHENCYCLIDINE	25 ng/ml
BARBITURATE	200 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 Syntron Bioresearch Dip DrugScan 9 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 monoclonal and polyclonal antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA). Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the Dip DrugScan 9 Test is set as required for the screening immunoassays of these drugs in the reference guidelines set by SAMHSA and the U.S. Department of Health and Human Services.

PRINCIPLE OF THE TEST

The Dip DrugScan 6 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 six drugs from a single sample. The approximate run time is 5 minutes. In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen- antibody complex, preventing the development of a rose-pink color band.

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



REAGENTS AND MATERIALS PROVIDED

- Test Devices. Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
- Test Instructions. [REF] PI-30901

Optional:

- Negative Control 1. Contains buffered protein solution with sodium azide. [REF] 4010A
- Amphetamine Positive Control. Contains AMP at 1500 ng/ml in a buffered protein solution with sodium azide. [REF] 11120P
- Cocaine Positive Control. Contains COC at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 12000P
- Marijuana Positive Control. Contains THC at 150 ng/ml in a buffered solution with sodium azide. [REF] 13020P
- Methadone Positive Control. Contains MAD at 1000 ng/ml in a buffered protein solution with sodium azide. [REF] 19020P
- Methamphetamine Positive Control. Contains MET at 1500 ng/ml in a buffered protein solution with sodium azide. [REF] 11320P
- Opiates Positive Control. Contains OPI at 5000 ng/ml in a buffered protein solution with sodium azide. [REF] 11220P
- Benzodiazepine Positive Control. Contains BZD at 1000 ng/ml in a buffered solution with sodium azide. [REF] 18020P
- Phencyclidine Positive Control. Contains PCP at 1000 ng/ml in a buffered solution with sodium azide. [REF] 14020P
- Barbiturate Positive Control. Contains BAR at 1000 ng/ml in a buffered solution with sodium azide. [REF] 18040P

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- Specimen collection containers

WARNINGS AND PRECAUTIONS

- This test is an in vitro diagnostic medical device for healthcare professional use only.
- Do not use the test device beyond the expiration date.
- Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
- 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

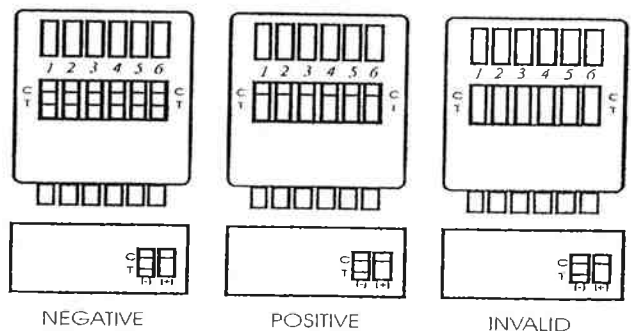
Store test kit below 28°C; do not freeze. Refer to the expiration date for stability.

TEST PROCEDURE

- Bring a urine sample and a foil test pouch to room temperature (15°-28°C).
- Do not break the seal of the pouch until ready to begin testing.
- Remove a Test Device from the foil pouch.
- Remove the protective cap and place the revealed strips into the urine sample for 10 seconds. Do not allow the urine level to touch the plastic device.
- 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,

INTERPRETATION OF RESULTS



Positive: A rose-pink band is visible in each control zone. No color band appearing in the appropriate test zone indicates a positive result for the corresponding drug of that specific test zone.

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

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

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

QUALITY CONTROL

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

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

LIMITATIONS OF THE TEST

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

PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The Dip DrugScan 9 Test detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by SAMHSA and the U.S. Department of Health and Human Services for the immunoassay method.
2. **Specificity.** A study was conducted with the Dip DrugScan 9 Test to determine the cross-reactivity of drug-related compounds with the test. Substances listed in Table I produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in Table II.

Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

The following Amphetamine-related substances yield a positive result for Amphetamine at 500 ng/ml Cut-Off level:

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

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

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

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

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

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

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

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

Cocaine	300 ng/ml
Benzoyl Ecgonine	300 ng/ml

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

Methadone	300 ng/ml
Doxylamine	50,000 ng/ml
EMDP (2-Ethylidene-1,5-dimethyl-1-3,3-Diphenylpyrrolidine)	100,000 ng/ml
Methadol	25,000 ng/ml
Perphenazine	75,000 ng/ml
Protriptyline	2,000 ng/ml
Tiapropramine	10,000 ng/ml

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

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

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

Phencyclidine	25 ng/ml
Tetacycline	2000 ng/ml

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

Secobarbital	300 ng/ml
Amobarbital	1600 ng/ml
Barbital	3500 ng/ml
Butobarbital	2000 ng/ml
Pentobarbital	800 ng/ml
Phenobarbital	3500 ng/ml

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

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

Acetaminophen	Diphenhydantoin	Oxazepam
Acetylsalicylic Acid	Doxylamine	Oxycodone
Amikacin	Ecgonine HCl	Pendimethazine
Amiripryline	Ecgonine Methyl Ester	Penicillin G
Amoxicillin	Glucose	Pentobarbital
Arteranol	Histamine	α-Propoxyphene
Aspartame	Hydrocodone	Hydrochlorothiazide
Atropine Sulfate	Hydromorphone	Propanol
Benzoic Acid	Indomethacin	Phencyclidine
Benzoyllecgonine HCl	Ketoprofen	Phenobarbital
Caffeine	Levorphanol	Phentermine
Chlorpheniramine	Δ-9-THC	l-Phenylephrine
Chlorpromazine HCl	11-nor-Δ-9-carboxy-THC-9-COOH	Quinine
Cimetidine	Citron	Ranitidine
Codaine	Aceperidine	Sodium Salicylate
Deoxyephedrine	Methylphenidate	Tryptophan
Dextromethorphan	Methadone	Tetracycline
Diazepam	Methaqualone	Tetrahydrozoline
Diethylpropion	Morphine Glucuronide	Theophylline
	Morphine Sulfate	Thioridazine
		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
Amiripryline	Glucose	Pentobarbital
Ampicillin	Histamine	Phencyclidine
Arterenal	Hydrochlorothiazide	Phenobarbital
Aspartame	Hydrocodone	Phentermine
Atropine Sulfate	Hydromorphone	Phenylpropanolamine
Benzoic Acid	Indomethacin	L-Phenylephrine
Benzoylcegonine HCl	Ketoprofen	d-Propoxyphene
Caffeine	Levorphanol	l-Propanol
Chlorpheniramine	Δ ⁹ -THC	Quinine
Chlorpromazine HCl	(-)-11-Nor-Δ ⁹ -THC-9-COOH	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Cocaine	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 (50 ng/ml cut-off) Marijuana at a 100 µg/ml concentration in urine:

Acetaminophen	Digoxin	Meperidine
4-Acetamidophenol	Digoxin	Methadone
Acetylsalicylic Acid	Ecgonine HCl	Methaqualone
Amikacin	Ecgonine Methyl Ester	Naloxone
Ampicillin	Ephedrine	Neomycin
d,l-Amphetamine	Epinephrine	Nicotinamide
Amiripryline	Genisic Acid	Oxazepam
Arterenal	Glucose	Perphenazine
Aspartame	Guaifacil	Penicillin G
Atropine Sulfate	Glycerol Ether	Phencyclidine
Benzoic Acid	Histamine	Phenobarbital
Benzoylcegonine	Hydrochlorothiazide	α-1-Phenylethylamine
Caffeine	Hydrocodone	Phenylpropanolamine
Camphor	Hydromorphone	Pramethazine
Chlorazepate	Homatropine	Pseudoephedrine
Chlorpheniramine	Imipramine	Ranitidine
Chlorpromazine HCl	Isoproterenol	Salicylic Acid
Cocaine HCl	Ketamine	Secobarbital
Cocaine	Lidocaine	Tetracycline
Cimetidine	Methylphenidate	Tetrahydrozoline
Carfene	Morphine	Theophylline
Deoxyephedrine	Morphine Glucuronide	Thioridazine
Dextromethorphan	Morphine Sulfate	Trifluoperazine
Diazepam	d-Methamphetamine	Tryptophan

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

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

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
Amiripryline	Histamine	d-Propoxyphene
Ampicillin	Hydrochlorothiazide	l-Propanol
Arterenal	Hydrocodone	Phencyclidine
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Indomethacin	Phentermine
Benzoic Acid	Ketoprofen	Phenylpropanolamine
Caffeine	Levorphanol	L-Phenylephrine
Chlorpheniramine	Δ ⁹ -THC	Quinine
Chlorpromazine HCl	11-Nor-Δ ⁹ -THC-9-COOH	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Cocaine	Methylphenidate	Tetracycline
Deoxyephedrine	Methadone	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 (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
Amiripryline	Histamine	d-Propoxyphene
Arterenal	Hydrochlorothiazide	l-Propanol
Aspartame	Hydrocodone	Phencyclidine
Atropine Sulfate	Hydromorphone	Phenobarbital
Benzoic Acid	Indomethacin	Phentermine
Benzoylcegonine HCl	Ketoprofen	Phenylpropanolamine
Caffeine	Levorphanol	L-Phenylephrine
Chlorpheniramine	Δ ⁹ -THC	Quinine
Chlorpromazine HCl	11-Nor-Δ ⁹ -carboxy-THC-9-COOH	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Cocaine	Methylphenidate	Tryptophan
Deoxyephedrine	Methaqualone	Tetracycline
Diazepam	Morphine-3-β-D-Glucuronide	Tetrahydrozoline
Diethylpropion	Morphine Sulfate	Theophylline
5,5-Diphenylhydantoin	Oxazepam	Thioridazine
	Oxycodone	Trifluoperazine

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

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

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

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

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

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



3. Accuracy: The accuracy of the Dip DrugScan 6 Test was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. In the patient study, each analyte test strip was subjected to evaluation involving a comparison between the device and GC/MS, unless otherwise noted. The summary results of that testing are presented below:

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DrugScan 9 Positive	140	13
DrugScan 9 Negative	0	155

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

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

The accuracy of the QuikStrip OneStep Benzodiazepine Test was first tested through an in-house study by Syntrol and subsequently in a clinical trial submitted to a SAMHSA certified laboratory. Each urine specimen was tested with the QuikStrip OneStep Benzodiazepine Test and a commercially available test (Syva EMIT II). Positive results were confirmed by GC/MS. The results are summarized as follows:

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
DrugScan 9 Positive	210	0
DrugScan 9 Negative	9	221

When compared to EMIT II the relative sensitivity between positive samples was 95.9%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 97.95%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DrugScan 9 Positive	149	1
DrugScan 9 Negative	0	153

When compared to GC/MS the relative sensitivity between positive samples was 99.3%. The relative specificity between negative samples was 100%.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DrugScan 9 Positive	195	0
DrugScan 9 Negative	0	500

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

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DrugScan 9 Positive	167	0
DrugScan 9 Negative	0	151

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

3.6 METHADONE (MAD) 300ng/ml Cut-Off Level

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DrugScan 9 Positive	155	6
DrugScan 9 Negative	0	709

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

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DrugScan 9 Positive	129	14
DrugScan 9 Negative	0	162

When compared to GC/MS the relative sensitivity between positive samples was 86.0%. The relative specificity between negative samples was 100%.

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

The accuracy of the QuikStrip OneStep PCP Test was first tested through an in-house study by Syntrol and subsequently in a clinical trial submitted to a NIDA certified laboratory. Each urine specimen was tested with the QuikStrip OneStep Phencyclidine Test and a commercially available test (Syva EMIT II). Positive results were confirmed by GC/MS. The results are summarized as follows:

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
DrugScan 9 Positive	223	0
DrugScan 9 Negative	0	290

When compared to EMIT II the relative sensitivity was 100%. The relative specificity was 100%. The concordance of the combined data with respect to EMIT II was 100%. When compared to GC/MS both screening methods reported 2 false positives and no false negatives.

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

	<u>GC/MS Positive</u>	<u>GC/MS Negative</u>
DrugScan 9 Positive	148	2
DrugScan 9 Negative	0	157

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

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