



One Step Multi-Drug Screen Test

(Amphetamine, Cocaine, Opiates, THC, Methamphetamine, Benzodiazepines and MDMA)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

The Advanced Quality One Step Multi-Drug Screen Test is a rapid, qualitative, competitive immunoassay for the determination of Drug-of-Abuse (DOA) and/or their metabolites in human saliva. The device allows the detection of multiple drugs in one simple step. The Advanced Quality One Step Multi-Drug Screen Test is intended to be used in Professional Medical & Forensic laboratories.

This test provides only preliminary data which should be confirmed by other methods such as gas chromatography / mass spectrophotometry (GC/MS). This test is not intended to monitor drug levels, but only to screen saliva for the presence of the drugs mentioned and their metabolites.

SUMMARY AND EXPLANATION OF THE TEST

The Advanced Quality One Step Multi-Drug Screen Test employs unique antibodies to selectively identify the following drugs of abuse and/or their metabolites in saliva with high degree of sensitivity and specificity:

AMPHETAMINES are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Amphetamine could cause the development of tolerances and physiological dependency and lead to its abuse. SAMHSA (NIDA) recommended cutoff level for Amphetamine screening tests is 50 ng/ml in saliva.

COCAINE is derived from the leaves of the cocoa plant and is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological effects induced by Cocaine are: euphoria, confidence and sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of Cocaine could induce tolerances and physiological dependency that lead to its abuse. Cocaine is excreted in the saliva primarily as Benzoyllecgonine within a short period of time. Benzoyllecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of Cocaine (0.5 to 1.5 hours), and can be generally detected for 24-60 hours after cocaine use or exposure. SAMHSA (NIDA) recommended cutoff level for Benzoyllecgonine screening tests is 20ng/ml in saliva.

OPIATES (Morphine)

have been a preferred drug for the management of pain in advanced cancer. Large doses of Morphine could cause the development of tolerances and physiological dependency and lead to its abuse. Morphine and its metabolites detected in saliva may be present as a result of Heroin, Morphine, Codeine, or poppy seed intake. SAMHSA (NIDA) recommended cutoff level for Opiates screening tests is 40ng/ml in saliva.

THC (Marijuana) is a hallucinogenic agent derived from the flowering portion of the hemp plant. Smoking is the primary method of use of marijuana. Cannabinoids have been proposed for therapy for acute glaucoma and parsea due to chemotherapy. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased

heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. When marijuana is ingested, the drug is metabolized by the liver. The primary urinary metabolite of marijuana is 11-nor- Δ -9-tetrahydrocannabinol-9-carboxylic acid and its glucuronide. The presence of Cannabinoids, including the primary carboxyl metabolite, in saliva indicates marijuana use. All cannabinoids are controlled substances, and the SAMHSA (NIDA) recommended cutoff level for cannabinoid screening tests is 4ng/ml in saliva.

METHAMPHETAMINE is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. Large doses of methamphetamine could cause the development of tolerances and physiological dependency and lead to its abuse. SAMHSA (NIDA) recommended cutoff level for Methamphetamine screening tests is 50ng/ml in saliva.

BENZODIAZEPINES are therapeutically used for anxiolytic, hypnotic, anticonvulsant, and muscle relaxant effects. Acute higher doses lead to drowsiness, dizziness, muscle relaxation, lethargy and even coma. Many of the benzodiazepines share a common metabolic route, and are excreted as oxazepam and its glucuronide in saliva. Thus the presence of the oxazepam in the saliva indicates parent benzodiazepines use. SAMHSA (NIDA) recommended cutoff level for Benzodiazepines screening tests is 50ng/ml in saliva.

PRINCIPLE OF THE PROCEDURE

The Advanced Quality One Step Multi-Drug Screen Test card is a device composed of 2-6 chromatographic strips designed to detect 2-6(as per the format) individual drugs of abuse. Each strip consists of a sample pad treated with antibody colloidal gold conjugate and membrane treated with drug conjugate and control reagent. Saliva sample initially reacts with the antibody gold conjugate, and then migrates up the strip, by capillary action, to the test area. If sufficient drug is present in the saliva, it binds with the conjugate, preventing it from binding to the drug conjugate immobilized on the membrane in the test region. Any unbound conjugate continues to migrate up the strip to the control region where it binds to the control reagent producing a pink/purple band. The control band indicates that the result is valid.

A negative specimen produces two (2) distinct color lines, one in the test area and one in the control area.

A positive specimen produces only one (1) color line in the control area.

REAGENTS AND MATERIALS SUPPLIED

1. Test cards individually foil pouched with a desiccant
2. Saliva cups
3. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Positive and negative saliva controls available from commercial distributors.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional Medical and Forensic use only.
3. Do not use the kit beyond the expiration date imprinted on the outside of the foil pouch.
4. Do not open the foil pouch until the saliva is collected and ready to be tested.
5. Avoid cross contamination of saliva samples by using a new saliva sample cup for each sample.
6. Saliva specimens may be infectious. Upon completion of all testing dispose of residual saliva in an approved manner. Properly handle and dispose of all used reaction devices in a

biohazard container.

STORAGE AND STABILITY

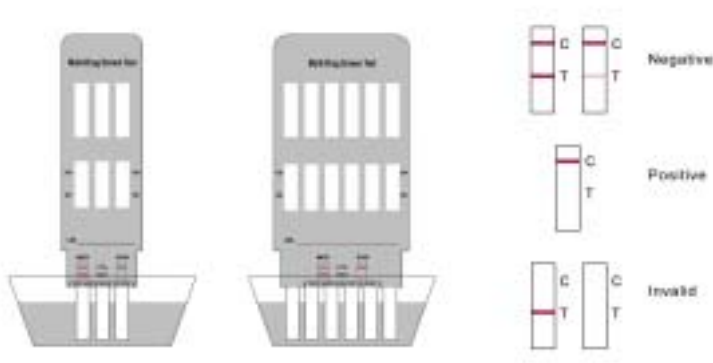
The device can be stored under refrigeration or at room temperature (2-30°C) and will be stable until the expiration date.

SAMPLE COLLECTION AND PREPARATION

The sample must be collected in the provided container or any clean dry plastic or glass container of a similar size. Saliva specimens may be refrigerated (2-8°C) and stored up to 48 hours, or frozen (-20°C or colder) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Saliva samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove test device from the sealed foil pouch.
3. Remove the cap from the device.
4. Immerse the bottom end of the test strips (the sample pads) into saliva sample with the arrows pointing toward the specimen. (keep the level of saliva sample below the bottom of plastic card or the maximum line marked on the strips.)
5. Hold the device in the saliva until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
6. Withdraw the device from saliva sample, and replace the cover.
7. Read results between 3 - 8 minutes.



READING THE TEST RESULTS

Read Test results between 3 and 8 minutes. Do not interpret results after 8 minutes.

Read and record the results for each individual drug as follows:

Negative: Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region.

Note: This immunoassay is a screening test. A negative result indicates the drug level is below the detection sensitivity. It is important to understand that concentrations of the drug below cut off may

cause a faint "ghost line" to form in the test region. This "ghost line" should be considered a negative result.

Positive: One (1) pink/purple band appears in the control region. No band is found in the test region. This is an indication that the drug level is above the detection sensitivity level.

Invalid: If there are no distinct color bands in either the test or control region of the device, the test result is invalid. Retest the sample using a new device.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when results are positive. Positive results should be confirmed by an alternate method such as GC/MS.

QUALITY CONTROL

1. Each strip has its own control band to indicate that the test is adequately performed. Any invalid result must be repeated using a new Advanced Quality Test Card.
2. Good laboratory practice recommends the use of positive and drug free saliva controls to validate reagent performance and establish test reliability. Commercial drug saliva controls are available to assess the performance of this device.

WARNING

Saliva specimens may be infectious. Upon completion of all testing discard the residual saliva in an approved manner. Properly handle and dispose of all used devices in a biohazard container.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Advanced Quality One step Multi-Drug Screen Tests have been individually assayed using a comparable reference screen. The compounds detected by this assay have been identified and the levels that produce positive result are listed below. GC/MS testing must be performed to confirm a positive result.

Compounds Detected by The Advanced Quality DOA Tests:

AMPHETAMINES:

Compound	Level of Reactivity
d-Amphetamine	50ng/ml
l-Amphetamine	25µg/ml
d,l-Amphetamine	625ng/ml
(±)3,4-Methylenedioxyamphetamine	1 µg/ml
(±) Phenylpropanolamine (PPA)	4 µg/ml
Phentermine	1µg/ml

COCAINE:

Compound	Level of Reactivity
Benzoylcegonine	20ng/ml
Cocaine	15 µg/ml
Ecgonine	100µg/ml
Tropacocaine	100µg/ml

OPIATES:

Compound	Level of Reactivity
Morphine	40ng/ml
Morphine-3-d-glucuronide	40ng/mL
Hydromorphone	40ng/mL

Nalorphine	40ng/mL
Codeine	50ng/mL
Ethylmorphine	50ng/mL
Norcodeine	200ng/mL
Hydrocodone Bitartrate	100ng/mL
Normorphine	3700ng/mL
Oxycodone	2500ng/mL
Heroin	4000ng/mL
Thebaine	5000ng/mL
Naloxone	6000ng/mL
Ofloxacin	30,000ng/mL
Naltrexone	160,000ng/mL

THC:

<u>Compound</u>	<u>Level of Positive Reaction</u>
11-nor- Δ 8-THC-9-COOH	4ng/ml
11-nor- Δ 9-THC-9-COOH	4ng/ml
Δ 8-THC	1800 ng/mL
Δ 9-THC	2000 ng/mL
Cannabinol	5000 ng/mL
11-hydroxy- Δ 9-THC	800ng/mL

METH:

<u>Compound</u>	<u>Level or Concentration</u>
d-Amphetamine	5 ul/mL
Δ ,1-Amphetamine	10 ul/mL
(+) Methamphetamine	50ng/ml
\pm 3,4-Methylenedioxyamphetamine	10 ul/mL
\pm 3,4-Methylenedioxymethamphetamine	1 ul/mL
Pseudoephedrine	10 ul/mL
Ephedrine	25 ul/mL
Phenyl propanolamine (PPA)	50 ul/mL

BENZODIAZEPINES:

<u>Compound</u>	<u>Level or Concentration</u>
Alprazolam	50ng/ml
Clorazepate-HCl	50ng/ml
Desmethyldiazepam	50ng/ml
Diazepam	50ng/ml
Estazolam	50ng/ml
Flurazepam	50ng/ml
Nitrazepam	50ng/ml
Oxazepam	50ng/ml
Temazepam	50ng/ml
Chloradiazepoxide HCl	2 μ g /ml
Clobazam	3 μ g /ml
Clonazepam	2 μ g /ml
Delorazepam	2 μ g /ml
Flunitrazepam	1 μ g /ml
Medazepam	1 μ g /ml

MDMA

<u>Compound</u>	<u>Level or Concentration (ng/ml)</u>
L-MDMA	100
d-MDMA	100
L-methMDMA	100
d- methMDMA	100
HydroxymethMDMA(HAM)	100
DihydroxymethMDMA(HMMA)	100
N-methyl-1(1-3-benzodioxol-5-yl)-2-butanamine(MBDB)	100

Specificity and Interfering substances

The following substances did not interfere with the Advanced Quality DOA Tests.

Glucose	2000mg/dl	Uric Acid	10 mg/dl
Human Albumin	2000mg/dl	Urea	4000mg/dl
Hemoglobin	10mg/dl	Bilirubin	2 mg/dl

Compounds that give negative results for Amphetamine Test at concentrations up to 100 μ g/ml (unless noted):

Acetaminophen	Morphine Sulfate
Acetylsalicylic acid	Methylphenidate
Ampicillin	Methadone
Benzoic Acid	Methaqualone
Benzoylcegonine Hcl	Oxazepam
Caffeine	Oxycodone
Chlorpheniramine	Propranolol
Chlorpromazine Hcl	Phencyclidine
Cimetidine	d-Propoxyphene
Codeine	Hydrochlorothiazide
Dextromethorphan	Phenylpropanolamine
Ecgonine HCL	Pendimethazine
Ecgonine Methyl Ester	Phentobarbital
Hydrocodone	Penicillin G
Hydromorphone	1-Phenylephrine
Indomethacin	Quinine
Ketoprofen	Ranitidine
Levorphanol	Tryptophan
Sodium Salicylate	Δ -9-THC
Meperidine	11-nor- Δ -9-carboxy-THC
Morphine Glucuronide	

Compounds that give negative results for Cocaine Test at concentrations up to 100 μ g/ml (unless noted):

4-Acetamidophenol	Meperidine(200ug/mL)
Acetylsalicylic Acid	Methadone
Amikacin	d,l,Methamphetamine
ethyl-p-aminobenzoate	d,Methamphetamine
Amitriptyline	Morphine
Amphetamine	Naloxone
Arterenol	Neomycin
Aspartame	Niacinamide

Atropine	11-Nor- 8-THC-9-COOH(10 ug/mL)
Caffeine	11-Nor-9 THC-9-COOH(10 ug/mL)
Camphor	Oxazepam
Chloroquine	Perphenazine
Chlorpheniramine	Phencyclidine
Cortisone	Phenobarbital
Deoxyepinephrine	Phenylethylamine
Dextromethorphan	5.5-diphenylhydantoin
Digitoxin	Phenylpropanolamine
Digoxin	Procaine
Epinephrine	Promethazine
Ephedrine	Pseudoephedrine
Gentisic Acid	Rantidine
Guaiacol glyceryl ether	Salicylic Acid
Histamine	Secobarbital
Homatropine	Tetracycline
Imipramine	Tetrahydrozoline
Isoproterenol	Theophylline
Ketamine	Thioridazine
Lidocaine	Trifluoperazine

Compounds that give negative results for Opiates Test at concentrations up to 100 µg/ml (unless noted):

4-Acetamidophenol	Ketamine
Acetylsalicylic Acid	Lidocaine
Amikacin	Meperidine(200ug/mL)
Amitriptyline	Methadone
Amphetamine	Methamphetamine
Arterenol	3,4-Methylenedioxyeth
Aspartame	Amphetamine
Benzoyllecgonine	Neomycin, niacinamide
Caffeine	11-Nor- 8-THC-9-COOH(10 ug/mL)
Camphor	11-Nor-9 THC-9-COOH(10 ug/mL)
Chloroquine	Oxazepam
Chlorpheniramine	Perphenazine
Cortisone	Phencyclidine
Deoxyepinephrine	Phenobarbital
Dextromethorphan	Phenylethylamine-a
Digitoxin	Phenylpropanolamine
Digoxin	Promethazine
Epinephrine	Pseudoephedrine
Ephedrine	Rantidine
Gentisic Acid	Salicylic Acid
Glucose	Secobarbital
Guaiacol	Tetracycline
Glyceryl Ether	Tetrahydrozoline
Histamine	Theophylline
Imipramine	Thioridazine
Isoproterenol	Trifluoperazine

Compounds that give negative result for THC Test at concentrations up to 100 µg/ml (unless noted):

Acetaminophen	Ketamine
4-Acetamidolphenol	d-methamphetamine
Acetylsalicylic Acid	Meperidine(200µg/ml)
Amikacin	Methadone
Amitriptyline	d,l-methamphetamine
d,l-amphetamine	Morphine
Arterenol	Naloxone
Aspartame	Niacinamide
Ampiciline	Neomycin
Atropine Sulfate	11-nor-8-THC-9-COOH(10µg/mL)
Benzoyllecgonine	11-nor-9-THC-9-COOH(10µg/mL)
Benzoyic Acid	Oxazepam
Caffeine	Phenobarbital
Camphor	Perphenazine
Chloroquine	Phencyclidine
Chorpheniramine	Phenylpropanolamine
Cortisone	Promoethazine
Cimetidine	Pseudoephedrine
Deoxyepinephrine	Rantidine
Dextromethorphan	Salicylic acid
Digitoxin	Secobarbital
Gentisic acid	Tetracycline
Glucose	Tetrahydrozoline
Guaiacol glyceryl ether	Theophylline
Histamine	Thioridazine
Hydromorphone	Trifluoperazine
	Tryptophan

Compounds that give negative result for Methamphetamine Test at concentrations up to 100 µg/ml (unless noted):

4-acetamidolphenol	Ketamine
Acetylsalicylic Acid	Lidocaine
Amikacin	Morphine
Amitriptyline	Methadone
Arterenol	Naloxone
Aspartame	Neomycin
Atropine sulfate	Niacinamide
Benzoyllecgonine	11-Nor-8-THC-9-COOH(10µg/ml)
Caffeine	11-Nor-9-THC-9-COOH(10µg/ml)
Camphor	Perphenazine
Chloroquine	Phencyclidine
Chorpheniramine	Phenobarbital
Cortisone	Phenylethylamine-a
Deoxyepinephrine	Phencylidine
Dextromethorphan	Promoethazine
Digitoxin	Pseudoephedrine
Digoxin	Rantidine
Epinephrine(±)	Salicylic acid
Glucose	Secobarbital
Guaiacol glyceryl ether	Tetrahydrozoline
Imipramine	Tetracycline
Isoproterenol	Theophylline
Histamine	Thioridazine
Homatropine	Trifluoperazine

Compounds that give negative result for Benzodiazepines Test at concentrations up to 100 µg/ml (unless noted):

Acetamidolphenol	Isoproterenol
Acetylsalicylic Acid	Ketamine
Amikacin	Lidocaine
Amitriptyline	Morphine
d,l-amphetamine	Methadone
Arterenal	Methamphetamine
Aspartame	Naloxone
Atropine sulfate	Neomycin
Caffeine	11-Nor-8-THC-9-COOH(10µg/ml)
Camphor	11-Nor-9-THC-9-COOH(10µg/ml)
Chorpheniramine	Perphenazine
Chloroquine	Phencyclidine
Cortisone	Phenobarbital
Deoxyepinephrine	Phenylethylamine-a
Dextromethorphan	Phenylpropanolamine
Digitoxin	Promoethazine
Digoxin	Rantidine
Ephedrine	Salicylic acid
Gentisic acid	Secobarbital
Glucose	Tetrahydrozoline
Guaiacol glycery ether	Tetracycline
Histamine	Theophylline
Homatropine	Thioridazine
Imipramine	Trifluoperazine

The following structurally unrelated analytes were spiked into known drug-free saliva pools, as well as the MDMA positive (50ng/ml) saliva pools and were tested with the MDMA one step Saliva Test. No interference was observed with either negative or positive specimens.

Compound	Conc.	Compound	Conc.
Acetaminophen	100µg/ml	Oxazepam	100µg/ml
Acetylsalicylic Acid	100µg/ml	Penicillin-G	100µg/ml
Amikacin	100µg/ml	Propoxyphene	100µg/ml
Amitriptyline	100µg/ml	Pheniramine	100µg/ml
Ampicillin	100µg/ml	Phencyclidine	100µg/ml
Arterenal	100µg/ml	Phenylpropanolamine	100µg/ml
Atropine	100µg/ml	Ranitidine	100µg/ml
Benzoic Acid	100µg/ml	Secobarbital	100µg/ml
Benzoylcegonine	100µg/ml	Salicylic Acid	100µg/ml
Caffeine	100µg/ml	11-nor- ⁹ -THC-9-COOH	100µg/ml
(+)-Chlorpheniramine	100µg/ml	Thioridazine	100µg/ml
(+/-)-Chlorpheniramine	100µg/ml	Trifluoperazine	100µg/ml
Cocaine	100µg/ml	Albumin	200µg/ml
Codeine	100µg/ml	Bilirubin	100µg/ml
Cortisone	100µg/ml	Creatine	100µg/ml
Dextromethorphan	100µg/ml	Glucose	100µg/ml
Methadone	100µg/ml	Hemoglobin	200µg/ml
Morphine	100µg/ml	PH	5.0-9.0
Morphine-3-b-D-glucuronide	100µg/ml	Vitamin C	100µg/ml
Nortriptyline	100µg/ml	Uric Acid	100µg/ml
Oxalic Acid	100µg/ml		

There is a possibility that other factors such as technical or procedural errors, as well as other substances in the saliva sample that are not listed above, may interfere with the test and cause erroneous results.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of DOA and/or their metabolites in human saliva only.
2. Although the Advanced Quality DOA Test is very accurate in detecting the saliva drug levels, there is a possibility of false results due to the presence of interfering substances in the saliva.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative level of DOA in saliva.
4. Adulterants, such as bleach or other strong oxidizing agents, when added to saliva specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another saliva specimen.

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