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Accutest® MultiDrug ER 11 Drug Screen Test Device

(CLIA Waived)

Instruction Sheet for testing of any combination of the following drugs:

AMP/BAR/BZO/COC/THC/MDMA/OPI/OXY/PCP/PPX/TCA

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine with on-board procedural controls.

For professional, in vitro diagnostic use only.

INTENDED USE

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations listed below. A certificate of waiver is needed for your laboratory in order to run this test. Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test or the test is considered high complexity and is no longer CLIA waived.

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methylenedioxymeth-amphetamine (MDMA)	3,4-Methylenedioxy-methamphetamine	500 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Opiates (OPI)	Morphine	300 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Anti-depressants (TCA)	Nortriptyline	1,000 ng/mL

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. It is also important to note that Amphetamine is a metabolite of Methamphetamine and will appear in the urine of a person who has taken Methamphetamine. d-Methamphetamine, commonly known as crystal", ice" and "speed", metabolizes into d-Amphetamine, which will be detected by the Amphetamine (AMP) assay on this device.

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of Amphetamines in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine. The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[2]

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of Barbiturates in urine exceeds 300 ng/mL.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced

barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in urine is 3-7 days.

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of Benzodiazepines in urine exceeds 300 ng/mL.

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.[3] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[3]

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

MARIJUANA (THC)

THC (Δ^9--tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug. The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.[4] The detection period for MDMA in urine is 1-3 days.

The **Accutest® MultiDrug ER 11 Drug Screen Test** Device yields a preliminary positive result when the concentration of MDMA in urine exceeds 500 ng/mL.

OPIATES (OPI)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin.[3] The detection period for opiates in urine is 1-5 days.

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of opiates in urine exceeds 300 ng/mL.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin,

OxyContin consists solely of oxycodone hydrochloride in a time-release form.

Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%)[3]. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cutoff for oxycodone positive samples.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[6]

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive samples set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PROPOXYPHENE (PPX)

Propoxyphene is a narcotic analgesic compound bearing structural similarity to methadone. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. After a typical 100 mg oral dose of propoxyphene napsylate, peak plasma concentrations of 0.05 µg/mL to 0.1 µg/mL are achieved from 2 to 2½ hours post dose. Repeat doses of propoxyphene at 6-hour intervals leads to increasing plasma concentrations, with a plateau after the ninth dose at 48 hours. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours).[5]

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cutoff for propoxyphene positive samples.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** yields a preliminary positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

PRINCIPLE

The **Accutest® MultiDrug ER 11 Drug Screen Test Device** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine sample compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine sample migrates upward by capillary action. A drug, if present in the urine sample below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine sample will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine sample will generate a line in the test line region because of the absence of drug competition.

Internal Procedural Controls

To serve as an internal procedural control, the test includes both a Positive and Negative Control Region.

Positive Control

When the test is manufactured, an antigen-BSA conjugate is striped in the Positive Control Region (POS) with a water-soluble blue dye as a visual marker. The positive control antigen is included in the label pad. When the test is run properly, the migration of the sample will make this blue line disappear. Therefore, the absence of a line in the Positive Control Region (POS) serves as an internal positive procedural control. The presence of a blue line in the Positive Control Region (POS) could indicate that an immunochemical

reaction did not occur and the results should be considered invalid.

Negative Control

A line in the Negative Control Region (NEG) confirms that proper volume of sample has been added and membrane wicking has occurred. There must be a line present in the Negative Control Region (NEG) for the test results to be valid.

The absence of a Positive Control line confirms the internal procedural control and, along with the appearance of the Negative Control line, the validity of the test results. If the test is working properly, a line should always appear in the Negative Control Region (NEG) and NO line should appear in the Positive Control Region (POS).

REAGENTS

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. Control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

PRECAUTIONS

- For professional, *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All samples should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to federal, state and local regulations
- Color blindness may affect interpretation of results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Urine Assay

The urine sample must be collected in a clean and dry container. Urine collected at any time of the day may be used. Do not use cloudy samples or urine samples with visible precipitates for testing.

Sample Storage

Urine samples may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, samples may be frozen and stored below -20°C. Frozen samples should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable droppers
- Package insert
- Procedure card

Materials Required But Not Provided

- Sample collection container
- Timer
- Positive and Negative Controls

DIRECTIONS FOR USE

Allow test device and urine sample to reach room temperature (15-30°C) before testing.

1. Remove the test device from the sealed pouch and use it within 1 hour of opening.
2. Place the test device on a clean and level surface. Add 100 µL of urine (3 full drops using the included pipette) to each of the sample wells of the test device. **[See image (1).]** Start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored lines(s) to appear. **[See image (2).]** The results should be read at 5 minutes. Do not read past 15 minutes.

RESULT INTERPRETATION

[Please refer to image (4).]

First, confirm the validity of the results by reviewing the Negative and Positive Control Lines. If there is a line in the Positive Control Region (POS), the result is INVALID. There must be a line in the Negative Control Region (NEG) for the result to be VALID. Before interpreting testing results, make sure that there is no line next to "POS" and a visible line next to "NEG". [See image (3).]

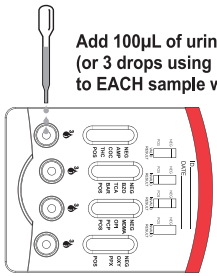
NEGATIVE RESULT:* A colored line appears in the Negative Control region (NEG), no line appears in the Positive Control Region (POS) and a colored line appears in the Test region next to a specific drug tested. Up to four colored lines may appear in each result window. One line will be in the Negative Control region (NEG). Up to three lines will be next to the drug names in the Test region. This negative result means that the drug concentration in the urine sample is below the detectable level for a certain drug tested.

***NOTE:** The shade of the colored line(s) in the Test region may vary. The result should be considered negative when there is even a faint color line.

PRELIMINARY POSITIVE RESULT: A colored line appears in the Negative Control region (NEG), no line appears in the Positive Control Region (POS) and NO line appears in the Test region next to the name of a certain drug tested. The preliminary positive result means that the drug concentration in the urine sample is greater than the detectable level for a certain drug tested.

INVALID: No line appears in the Negative Control region (NEG) and/or a line appears in the Positive Control Region (POS). Not enough sample volume or incorrect procedural techniques are the most likely reasons for an invalid result. Review the directions for use and repeat the test with a new test device. If the problem continues, contactical Service.

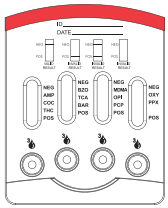
1



Add 100µL of urine (or 3 drops using pipette) to EACH sample well.

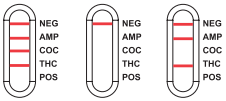
2

Wait 5 minutes to read results.



3

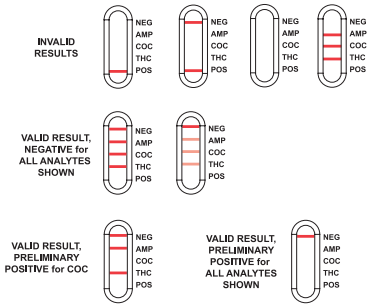
Confirm validity of result by checking NEG and POS Control Regions.
There should be NO line in the Positive Control Region (POS) and a visible line in the Negative Control Region (NEG).



EXAMPLES OF VALID RESULTS

4

Interpret Results at 5 minutes.



QUALITY CONTROL

Internal Quality Control

A procedural control is included in the test. The presence of a red line in the Negative Control region (NEG) and the absence of a line in the Positive Control Region (POS) are considered internal procedural controls. This confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.

The internal procedural controls contained within the device satisfy the daily control testing requirement provided they are used in conjunction with a comprehensive laboratory Quality Assurance program.

External Quality Control

It is recommended that external positive and negative controls be tested with:

- Each new lot or shipment of product.
- Each new operator (i.e. one who has not performed the test recently).
- Monthly, as a check on continued storage conditions.
- When problems (storage, operator, instrument or other) are suspected or identified and as otherwise required by your laboratory's standard quality system procedures.

Control specimens should be performed the same as patient specimens (refer to Directions for Use and Interpretation of Results).

External Positive and Negative Controls are available separately. Please contact your distributor for a list of approved controls that have been validated with the **Accutest® MultiDrug ER 11 Drug Screen Test Device**. Use of any other control material is not advised and could produce irregular results.

If unexpected results are seen when running the controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another device. If the problem persists, discontinue use of the test kit immediately and contact Jant Pharmacal Corp. at 800-676-5565.

CLIA waived laboratories must follow the manufacturer's instructions for quality control testing.

LIMITATIONS

1. The **Accutest® MultiDrug ER 11 Drug Screen Test Device** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.[1]
2. There is a possibility that clinical, technical or procedural errors, as well as other interfering substances in the urine sample may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine samples may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine sample.
4. A preliminary positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A preliminary positive test result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **Accutest® MultiDrug ER 11 Drug Screen Test Device** and commercially available drug rapid tests. Testing was performed on 1,704 samples previously collected from subjects presenting for Drug Screen Testing. Preliminary positive results were confirmed by GC/MS. Negative urine samples were screened initially by Predicate test. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in preliminary positive urine samples tested in the following clinical studies:

Test	Compounds Contributing to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, Alprazolam, α-OH, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MDMA	3,4-Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results were tabulated:

Method		GC/MS					
		Negative*	Negative (<-25% cutoff)	Near cutoff Negative(-25% cutoff to cutoff)	Near cutoff Positive (cutoff to +25% cutoff)	Positive (>+25% cutoff)	% agreement with GC/MS
AMP	+	0	0	6	20	114	98%
	-	300	2	6	2	0	
BAR	+	0	1	3	3	96	99%
	-	300	0	5	1	1	
BZO	+	0	1	1	3	136	>99%
	-	300	2	6	1	0	
COC	+	0	2	15	14	105	96%
	-	300	3	5	0	0	
THC	+	0	9	7	11	105	95%
	-	300	9	2	3	2	
MDMA	+	0	0	4	6	82	99%
	-	300	0	1	0	0	
OPI	+	0	2	7	10	130	98%
	-	300	0	0	0	0	
OXY	+	0	1	2	2	138	99%
	-	300	2	4	1	0	
PCP	+	0	4	0	11	74	99%
	-	300	0	0	1	0	
PPX	+	0	0	0	2	143	>99%
	-	300	0	4	1	0	
TCA**	+	0	13	9	14	18	94%
	-	300	16	0	0	0	

*** Negative urine samples were screened by predicate tests and approximately 10% were confirmed negative by GC/MS.**

****Note: TCA concentration was based on HPLC data.**

Method			Predicate Test Results		% Agreement with Predicate Test
			Pos.	Neg.	
Accutest® MultiDrug ER 11 Drug Screen Test Device	AMP	Pos.	140	0	>99%
		Neg.	3	307	
	BAR	Pos.	103	0	>99%
		Neg.	0	307	
	BZO	Pos.	122	1	>99%
		Neg.	0	302	
	COC	Pos.	132	4	99%
		Neg.	0	308	
	THC	Pos.	132	0	98%
		Neg.	9	307	
	MDMA	Pos.	91	1	>99%
		Neg.	0	301	
	OPI	Pos.	149	0	>99%
		Neg.	0	300	
	OXY	Pos.	141	2	>99%
		Neg.	0	307	
	PCP	Pos.	89	0	>99%
		Neg.	0	301	
	PPX	Pos.	135	0	>99%
		Neg.	0	305	
	TCA	Pos.	54	0	>99%
		Neg.	0	316	

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to various concentrations. >99% agreement with expected results was found at ± 50% cut-off for each drug tested (with a 95% confidence interval).

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected as preliminary positives in urine by the **Accutest® MultiDrug ER 11 Drug Screen Test Device** at 5 minutes.

Compound	ng/mL
AMPHETAMINE	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
p-Hydroxyamphetamine	3,125
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
BARBITURATES	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethanol	100
Cyclobarbital	400
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
Alprazolam, α-OH	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Oxazepam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000

Compound	
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
METHYLENEDIOXYMETHAMPHETAMINE(MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
l-Methamphetamine	100,000
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (OPI)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine	400
Morphine 3-β-d-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Thebaine	6,250
OXYCODONE	
Oxycodone	100
6-Acetylcodeine	100,000
Codeine	25,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	6,250
Hydromorphone	12,500
Levorphanol	100,000
6-Monoacetylmorphine	100,000
Morphine	100,000
Morphine 3-β-d-glucuronide	100,000
Norcodeine	100,000
Normorphone	100,000
Oxymorphone	780
Procaine	100,000
Thebaine	25,000
PHENCYCLIDINE	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE	
d-Propoxyphene	300
Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	12,500
Cyclobenzaprine	6,250
Desipramine	200
Doxepin	2,000
Imipramine	400
Maprotiline	2,000
Nordoxepin	1,000
Perphenazine	50,000
Promazine	1,500
Promethazine	25,000
Trimipramine	3,000

CLIA Waiver Performance

A total of 75 untrained, inexperienced, non-laboratory participants were enrolled at three separate locations to demonstrate that they could follow the product instructions and perform the **Accutest® MultiDrug ER 11 Drug Screen Test Device** and obtain results similar to the expected results determined by GC/MS. Each participant received seven blinded spiked urine samples (one sample for each of following spiked solutions: invalid, negative, -50% of cutoff, -25% of cutoff, +25% of cutoff, +50% of cutoff and +200% of cutoff).

Study participants followed the Package Insert and Procedure Card instructions to test the provided samples and recorded their test results. No other instruction or training was given. Upon completion of the test, participants filled out a brief questionnaire regarding the test procedure and ease of use of the labeling. The user study data confirmed that the untrained study participants are able to read the test endpoint with a high degree of precision as compared to the expected results determined by GC/MS. The results were summarized and tabulated as follows:

AMP Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	22/25 = 88%	24/25 = 96%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	172/175 = 98% (95%-99%)*	174/175 = 99% (97%-99%)*	174/175 = 99% (97%-99%)*

* Denotes 95% Confidence Intervals

COC Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	22/25 = 88%	24/25 = 96%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	172/175 = 98% (95%-99%)*	174/175 = 99% (97%-99%)*	174/175 = 99% (97%-99%)*

* Denotes 95% Confidence Intervals

THC Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	24/25 = 96%	24/25 = 96%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	174/175 = 99% (97%-99%)*	174/175 = 99% (97%-99%)*	174/175 = 99% (97%-99%)*

* Denotes 95% Confidence Intervals

BZO Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	20/25 = 80%	23/25 = 92%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	170/175 = 97% (93%-99%)*	173/175 = 99% (96%-99%)*	174/175 = 99% (97%-99%)*

* Denotes 95% Confidence Intervals

TCA Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	24/25 = 96%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	20/25 = 80%	23/25 = 92%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	169/175 = 97% (93%-99%)*	173/175 = 99% (96%-99%)*	174/175 = 99% (97%-99%)*

* Denotes 95% Confidence Intervals

BAR Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	20/25 = 80%	23/25 = 92%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	170/175 = 97% (93%-99%)*	173/175 = 99% (96%-99%)*	174/175 = 99% (97%-99%)*

* Denotes 95% Confidence Intervals

MDMA Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	24/25 = 96%
+25% of Cutoff	21/25 = 84%	25/25 > 99%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	171/175 = 98% (94%-99%)*	175/175 > 99% (98%-99%)*	173/175 = 99% (96%-99%)*

* Denotes 95% Confidence Intervals

OPI Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	20/25 = 80%	24/25 = 96%	25/25 > 99%
+50% of Cutoff	23/25 = 92%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	168/175 = 96% (92%-98%)*	174/175 = 99% (97%-99%)*	175/175 > 99% (98%-99%)*

* Denotes 95% Confidence Intervals

PCP Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	24/25 = 96%	25/25 > 99%	25/25 > 99%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	174/175 = 99% (97%-99%)*	175/175 > 99% (98%-99%)*	175/175 > 99% (98%-99%)*

* Denotes 95% Confidence Intervals

OXY Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	23/25 = 92%	25/25 > 99%	24/25 = 96%
+25% of Cutoff	23/25 = 92%	24/25 = 96%	24/25 = 96%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	171/175 = 98% (94%-99%)*	174/175 = 99% (97%-99%)*	173/175 = 99% (96%-99%)*

* Denotes 95% Confidence Intervals

PPX Conc.	Agreement (%) - Test Results from Untrained Participants vs. GC/MS Data		
	Site 1	Site 2	Site 3
Negative	25/25 > 99%	25/25 > 99%	25/25 > 99%
-50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
-25% of Cutoff	22/25 = 88%	25/25 > 99%	25/25 > 99%
+25% of Cutoff	22/25 = 88%	24/25 = 96%	25/25 > 99%
+50% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
+200% of Cutoff	25/25 > 99%	25/25 > 99%	25/25 > 99%
Invalid	25/25 > 99%	25/25 > 99%	25/25 > 99%
Total Correct	169/175 = 97% (93%-99%)*	174/175 = 99% (97%-99%)*	175/175 > 99% (98%-99%)*

* Denotes 95% Confidence Intervals

Precision

A study was conducted at three physician offices for Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclics by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded samples, containing drugs at the concentration of ± 50% cut-off level was labeled as a blind and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

Effect of Urinary Specific Gravity

Urine samples of low, normal and high specific gravity (1.004-1.034) were spiked with drugs at ± 50% cut-off levels and analyzed. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Urine samples with pH ranges from 5-9 in 1 pH unit increments were spiked with drugs at ± 50% cut-off levels and analyzed. The results demonstrate that varying ranges of pH (5-9) do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic positive urine. The following compounds show no cross-reactivity when tested with the **Accutest® MultiDrug ER 11 Drug Screen Test Device** at a concentration of 100 µg/mL.

Non-Cross Reacting Compounds

Acetaminophen
Acetone
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Albumin
Albuterol
Aminopyrine
Amoxapine
Amoxicillin
Ampicillin
Apomorphine
l-Ascorbic acid
Aspartame
Atropine
Baclofen
Benzilic acid
Benzocaine
Benzoic acid
Benzphetamine*
Bilirubin
d/l-Brompheniramine
Buprenorphine
Buspirone
Caffeine
Cannabidiol
Carisoprodol
Chloralhydrate
Chloramphenicol
Chloroquine
Chlorothiazide
d/l-Chlorpheniramine
Chlorpromazine
Chlorpropamide
Chlorprothixene
Cholesterol
Cimetidine
Clonidine
Clozapine
Cortisone
l-Cotinine
Creatinine
Deoxycorticosterone
R(-)Deprenyl
Dextromethorphan
Diclofenac
Dicyclomine
Diflunisal
Digitoxin
Digoxin
(+)-cis-Diltiazem
Dimenhydrinate
4-Dimethylaminoantipyrine
Diphenhydramine
5,5-Diphenylhydantoin
Disopyramide
Dopamine
Doxylamine
Droperidol
Ecgonine methyl ester
EDDP
Efavirenz*
EMDP
Ephedrine
l-Ephedrine
[1R,2S](-)Ephedrine
l-Epinephrine
(±)Epinephrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethanol (Ethyl alcohol)
Ethyl-p-aminobenzoate
Etodolac
Famprofazone
Fenfluramine
Fenoprofen
Fentanyl
Fluoxetine
Furosemide
Gentamicin
Gentisic acid
d(+)Glucose
Guaiacol Glyceryl Ether
Haloperidol
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
o-Hydroxyhippuric acid
p-Hydroxymethamphetamine
p-Hydroxynorephedrine
Hydroxyzine
Ibuprofen
Indomethacin
Insulin
Iproniazidl
l-Isoproterenol
Isoxsuprine
Kanamycin
Ketamine
Ketoprofen
Labetalol
Lidocaine
Lindane
Lithium
Loperamide
Meperidine
Mephentermine
Meprobamate
Methadone
d-Methamphetamine
Methaqualone
Methoxyphenamine
Methylphenidate
Methyprylon
Metoprolol
Metronidazole
Nalidixic acid
Nalorphine
Naloxone
Naltrexone

α-Naphthaleneacetic Acid
Niacinamide
Nimesulide
Norfluoxetine
d/l-Octopamine
Oxalic acid
Oxymetazoline
Pemoline
Pentazocine
Pheniramine
Trans-2-phenylcyclopropylamine
β-Phenylethylamine
(±) Phenylpropanolamine (d/l-Norephedrine)
Prednisone
Procaine
d-Pseudoephedrine
Quinine
Ranitidine
Salbutamol
Serotonin
Spironolactone
Sulfamethoxazole
Sulindac
Tetrahydrocortisone 3-acetate
Theophylline
Thioridazine
l-Thyroxine
Tolbutamide
Trazodone
Triamterene
Trimethoprim
d/l-Tryptophan
d/l-Tyrosine
Verapamil
Zopiclone

Naproxen
Nifedipine
Norethindrone
Noscapine
Orphenadrine
Oxolinic acid
Papaverine
Penicillin-G
Phenelzine
Phenothiazine
l-Phenylephrine
Phenylpropanolamine
Prednisolone
5-β-pregnane-3α, 17α, 21-triol-20-one
d/l-Propranolol
Quinacrine
Quindine
Riboflavin
Salicylic acid
Sodium chloride
Sulfamethazine
Sulfisoxazole
Tetracycline
Tetrahydrozoline
Thiamine
Thiothixene
Tobramycin
Tramadol
Trimethobenzamide
Trifluoperazine
Tryptamine
Tyramine
Uric acid
Zomepirac

*Parent compound only

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CLIA Category: Waived

Printed in China

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■ US　□ OUS　□ DOMESTIC　□ OTHER

Description 描述	Jant Accutest MultiDrug ER 11 CLIA-Waived Multi-Clin Clinical DOA PI	***Part Number*** PN号码	1155967204	***Size*** 尺寸	127x177.8mm
Printing Contents 印刷内容	/	***L Number*** L号码	/	***Size*** 尺寸	/
Designer 设计者	Apple	***Design Date/Version*** 设计日期/版本	Sep 23,2013/A	***Mold Num.*** 模具号	/
Artwork Checked By 设计审核		***Material/ Checked By*** 材质/审核	80g双铜纸		
Approved By Customer/Date 客户确认/日期		***Approved By Marketing/Date*** 市场部确认/日期			
Approved By QA/RA/Date QA / RA确认/日期		***Approved By P.M.T. /Date*** 产品管理确认/日期			
Approved By ABON QA/Date ABON QA确认/日期		***Effective Date*** 生效日期			