

# Accu News® Multi-Drug Screen Test

Accu News® Multi-Drug Screen Test is a rapid, qualitative drug screening test designed to detect any combination of the following drugs:

Amphetamine (AMP), Methamphetamine (MET), Morphine (MOP), Cocaine (COC), and Marijuana (THC).

*For in vitro diagnostic use only.*

## INTENDED USE

Accu News® Multi-Drug Screen Test is a rapid lateral flow assay intended for fast qualitative screening for all or any combination of the following drugs of abuse in urine at or above the cutoff concentration listed below:

Test	Calibrator	Cutoff (ng/ml)
Amphetamine (AMP)	D-Amphetamine	1000
Methamphetamine (MET)	D-Methamphetamine	1000
Morphine (MOP)	Morphine	300
Cocaine (COC)	Benzoyllecgonine	300
Marijuana (THC)	11-nor- $\Delta^9$ -THC-9-COOH	50

For in vitro diagnostic use only.

**This assay offers only a preliminary result. To confirm a positive result, a more specific method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.**

## WARNING & PRECAUTIONS

- Do not use the device if the pouch is damaged.
- Do not use expired device.
- For in vitro diagnostic use only. Not for internal use.
- Test procedure should be followed precisely for accurate results.
- Single-use device. Do not reuse.
- Do not freeze.

## STORAGE & STABILITY

Store at 36-86°F inside the sealed pouch. Keep away from direct sunlight, moisture and heat. Keep the pouch sealed until the test is ready to be performed. Do not use expired device. DO NOT FREEZE.

## CONTENTS OF THE TEST KIT

1. One pouch containing the test device and desiccant. The desiccant is for storage purpose only.
2. An instruction sheet per box.

## WHAT ELSE DO YOU NEED

1. Timer or watch.
2. A dry, clean container for urine samples.

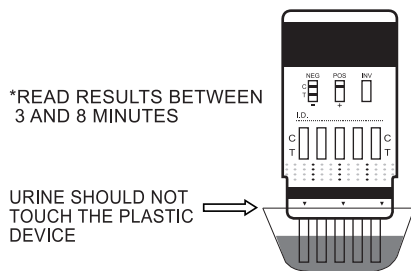
## SAMPLE COLLECTION & PREPARATION

Only fresh urine samples should be tested with this device.

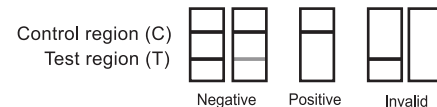
## TEST PROCEDURE

1. Do not open sealed pouch until ready to begin testing. The device should be brought to normal temperature 57°F-86°F (14°C-30°C) before testing.
2. Remove the device from the sealed pouch.
3. Collect a urine sample in a clean and dry container.
4. Remove the cap from the device and dip the strip end in urine for at least 10 seconds. The plastic should not touch urine.
5. Put the cap back. Lay the device on a clean flat surface. Start the timer or note the time on the watch. Read the result at 3-8 minutes.

**IMPORTANT:** Do not read the test results after 8 minutes.



## READING THE RESULTS



**Negative:** Two pink bands appear. One band in the control (C) region and one in the test (T) region. A negative test result does not always mean a person did not take illegal drugs. There are a number of factors that can affect results. Certain drugs of abuse tests are more accurate than others.

**Preliminary Positive:** One pink band shows in the C region and no band in the T region. The sample must be tested by a laboratory to confirm if a drug of abuse is actually present.

**Invalid:** No band shows in the C region. The test is invalid, and the sample should be tested again with a new device.

Note: The test band color may be lighter or darker than the control band.

## LIMITATIONS OF THE TEST

1. Certain food or medicine may interfere with the test and yield false results.
2. A false positive result is when the test result is positive, even though the target drug is not present in the sample. Certain food and medicines, diet plan drugs and nutritional supplements may cause a false positive result with this device.
3. A false negative result is when the target drug is present but is not detected by the device. If the sample is diluted, or the sample is tainted or contaminated with certain substances, this could cause a false negative result.

4. The test does not distinguish between drugs of abuse and certain medications.
5. A preliminary positive result does not mean a person took illegal drugs. A negative result does not mean a person did not take illegal drugs. There are many factors that affect the test. Certain drug tests are more accurate than others.
6. There is a possibility that interfering substances such as bleach in the urine specimen may cause erroneous results.

## QUALITY CONTROL

If you work in a laboratory, quality control testing should be performed. Good laboratory practice recommends the use of control materials to ensure proper device performance. When testing quality control standards, use the same assay procedure as with a urine sample. The SAMHSA guidelines for drug of abuse screening state that controls should contain the analyte at levels at least 25% above the cut-off values. Quality control testing should be performed with each new lot, each new shipment and every thirty days. Follow local, state and federal regulations.

## PERFORMANCE CHARACTERISTICS

### Precision and Sensitivity

The test was performed by 3 people over 6 days.

Test Cutoff concentration	AMP		MET		MOP		COC		THC	
	+	-	+	-	+	-	+	-	+	-
Neg.	0	30	0	30	0	30	0	30	0	30
-50%	0	30	0	30	0	30	0	30	0	30
-25%	0	30	0	30	0	30	1	29	0	30
cutoff	24	6	20	10	23	7	9	21	6	24
+25%	30	0	30	0	30	0	29	1	28	2
+50%	30	0	30	0	30	0	30	0	30	0

## Specificity and Cross-reactivity

The following compounds showed positive results:

Amphetamine (AMP)	ng/ml
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
d-Methamphetamine	>100,000
l-Methamphetamine	>100,000
d-Ephedrine	>100,000
l-Ephedrine	>100,000
d-Pseudoephedrine	>100,000
l-Pseudoephedrine	>100,000
(+/-)3,4-methylenedioxy-amphetamine (MDA)	2,500
3,4-Methylenedioxythyl-amphetamine (MDEA)	>100,000
(+/-)3,4-Methylenedioxy-methamphetamine (MDMA)	>100,000
Phentermine	25,000

Methamphetamine (MET)	ng/ml
d-Methamphetamine	1,000
l-Methamphetamine	100,000
d-Amphetamine	>100,000
l-Amphetamine	>100,000
d-Ephedrine	>100,000
l-Ephedrine	>100,000
d-Pseudoephedrine	>100,000
l-Pseudoephedrine	>100,000
(+/-)3,4-methylenedioxy-amphetamine (MDA)	>100,000
3,4-Methylenedioxythyl-amphetamine (MDEA)	50,000
(+/-)3,4-Methylenedioxy-methamphetamine (MDMA)	25,000
Chloroquine	50,000
β-Phenylethylamine	50,000
Trimethobenzamide	10,000

Morphine (MOP)	ng/ml
Morphine	300
Codeine	300
Ethylmorphine	300
Heroin	300
6-Monoacetylmorphine	300
Hydrocodone	5,000
Hydromorphone	5,000
Morphine-3-β-glucuronide	1,000
Oxycodone	>100,000

Cocaine (COC)	ng/ml
Benzoylcegonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000
Norcocaine	>100,000

Marijuana (THC)	ng/ml
11-Nor-Δ9-Tetrahydro-cannabinol carboxylic acid	50
11-Hydroxy-Δ9-Tetrahydro-cannabinol	2,500
Δ8-Tetrahydrocannabinol	7,500
Δ9-Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000

## Interference

The compounds below were tested and did not influence the test results.

Acetylsalicylic Acid	Ethyl-p-aminobenzoate	Oxymetazoline
Aminopyrine	Erythromycin	Papaverine
Amoxicillin	β-Estradiol	Penicillin-G
Ampicillin	Fenoprofen	Perphenazine
Apomorphine	Furosemide	Phenacetin
Aspartame	Gentisic acid	Phenelzine
Atropine	Hemoglobin	L-Phenylephrine
Benzilic acid	Hydralazine	β-Phenylethylamine
Benzoic acid	Hydrochlorothiazide	Phenylpropanolamine
Bilirubin	Hydrocortisone	Prednisone
Caffeine	3-Hydroxytyramine	D,L-Propranolol

Chloral hydrate	D,L-Isoproterenol	D-Pseudoephedrine
Chloramphenicol	Isoxsuprine	Quinidine
Chlorothiazide	Ketoprofen	Quinine
D,L-Chlorpheniramine	Labetalol	Ranitidine
Chlorpromazine	Loperamide	Salicylic acid
Chloroquine	Meprobamate	Serotonin
Cholesterol	Nalidixic acid	Sulfamethazine
Clonidine	Naloxone	Tetrahydrozoline
Cortisone	Naltrexone	Thiamine
L-Cotinine	Methoxyphenamine	Thioridazine
Creatinine	Naproxen	D,L-Tyrosine
Deoxycorticosterone	Niacinamide	Triamterene
Dextromethorphan	Nifedipine	Trifluoperazine
Diclofenac	Norethindrone	Trimethoprim
Diffunisal	D-Norpropoxyphene	Tyramine
Digoxin	Noscapine	D,L-Tryptophan
Diphenhydramine	D,L-Octopamine	Uric acid
Ecgonine methyl ester	Oxalic acid	Verapamil
L-ψ-Ephedrine	Oxolinic acid	Zomepirac

Urine samples with different pH and urine density were tested. The tests showed that pH and urine density did not affect results.

## Lay-User Accuracy Study

A study was done at three sites with 300 people. They had different educations and skills. Their ages were from 18 to over 50. Samples had different drug concentrations. The results are shown below:

Test	Drug Concentration						% Accuracy	
	Negative	-50%	-25%	+25%	+50%	+100%		
AMP	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
MET	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
MOP	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
COC	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
THC	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	

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