APAC Multi Panel Test Cup
Package Insert

[INTENDED USE]
The APAC Multi Panel Test Cup is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations (Table 1):

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Buprenorphine(BUP)	Buprenorphine	10
Benzodiazepines (BZO)	Oxazepam	200
Cocaine (COC)	Benzoylecgonine	300
Methamphetamine (MET)	D-Methamphetamine	300
Morphine (MOP 300 or OPI 300)	Morphine	300
EtG	Ethyl Glucuronide	300
Methadone (MTD)	Methadone	300
Methaqualone (MQL)	Methaqualone	300
Oxycodone(OXY)	Oxycodone	100
Tricyclic Antidepressants(TCA)	Nortriptyline	1,000
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Synthetic Cannabinoid (K2)	JWH-073/JWH-018	200
Tramadol (TRA)	Tramadol	200
Cotinine (COT)	Cotinine	200
Ketamine (KET)	Ketamine	500
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Fentanyl(FYL)	Fentanyl	200

Note: The number of test strips in the Cup i.e. number of detectable drugs will vary, depending on configuration that the customer choses. Each strip is labelled with an abbreviation e.g. AMP, which relates to the detectable drug listed in Table 1. Each abbreviation is listed in Table 1.
This immunoassay only provides a preliminary analytical screening result. A more specific analytical method must be used in order to obtain a confirmation result. Gas or Liquid chromatography/mass spectrometry (GC/MS or LC/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 used.

[PRINCIPLE]
The APAC Multi Panel Test Cup is an immunoassay urine screening test based on competitive binding of monoclonal antibodies that specifically targets drugs.
During testing, the urine sample migrates upwards by capillary action. A drug, if present in the urine specimen 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 coloured line will show up in the test line region of the specific drug strip. The presence of a drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the line will not form in the test line region (T).
A drug-positive urine specimen will not generate a line in the specific test line region (T) of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.
To serve as a procedural control, a coloured line will always appear at the control line region (C), indicating that proper volume of specimen has been added and membrane wicking has occurred.

[REAGENTS]
The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to the individual drug strips mounted in the cup.

[PRECAUTIONS]
- The cup should not be used for therapeutic use, nor point of care and should be handled by trained laboratory professionals only.
- Always use protective gear including but not limited to medical gloves, eye protection and facial mask
- For in vitro diagnostic use only. Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

[STORAGE AND STABILITY]
Store as packaged in the sealed pouch at 4-30°C. The test cup is stable through to the expiration date printed on the sealed pouch. The test cup must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

[SPECIMEN COLLECTION AND PREPARATION]
For instant analysis, the APAC Multi Panel Test Cup may be used for urine collection. If another specimen container is used, make sure the container is clean and dry. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

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

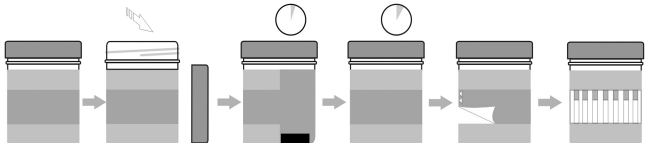
Materials Provided
- Test Cup
- Package insert
- Colour chart

Materials Required But Not Provided
- Timer
- Security Seals
- Chain of custody

Adulterant Reagents

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
pH	0.06%	99.94%
Creatinine	0.04%	99.96%

[DIRECTIONS FOR USE]
Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing. Always use protective gear included but not limited to gloves, facial mask and specs.
1. Tear the foil bag open and remove test cup. Label the device with donor information.
2. Remove the lid of the cup and collect urine specimen. Fill to a minimum of 30 ml as marked on the cup. Do not fill above 2/3 of the cup.
3. Once urine specimen has been collected, close the lid securely, put the cup on a stable horizontal surface and start the timer.
4. Use the temperature strip to verify the temperature of the freshly collected urine. Green dot showing up on the temperature strip shows the temperature detected.
5. Peel off the label on the cup to view the results.
6. Read **adulteration test result at 3-5 minutes.** Refer to supplied colour chart for the level of each index to be tested and check if it is in the normal range.
7. Read **drugs of abuse test result at 5 minutes.**
8. Do not interpret results after 10 minutes.



[INTERPRETATION OF RESULTS]

Negative Positive Invalid
(Please refer to the illustration above)

NEGATIVE: Two lines appear. A line in the control region (C) and a line in the test region (T) indicate a negative result for the specific drug. This means that the drug concentration of the sample is below the indicated cut off value for the specific drug.
The strength of the test line will vary due to the concentration of the drug e.g. complete absence of a drug will result in a strong test line while a concentration bordering the cut off level will result in a faint line. Appearance of a faint line should therefore be interpreted as a negative screening.

POSITIVE: One line appears in the control region. No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

ADULTERANT INTERPRETATION (Please refer to the colour chart)
Semi-quantitative results are obtained by visually comparing the reacted colour blocks on the strip to the printed colour blocks on the colour chart. No instrumentation is required.

[QUALITY CONTROL]
A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]
1. The APAC Multi Panel Test Cup provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS) are the preferred confirmatory methods. [3,4,7]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result indicates presence of a drug but does not indicate level or 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 positive test result may be obtained from certain foods or food supplements.

[ADULTERATION LIMITATIONS]
1. The adulteration tests, if included with this product, are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.
2. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

Analytical Specificity
The following table lists the concentration of compounds (ng/mL) that are detected positive in urine at 3-5 minutes.

AMPHETAMINE (AMP300)	**ng/mL**
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
p-Hydroxyamphetamine	1,560
p-Hydroxynorephedrine	100,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine (d,l-Norephedrine)	100,000
Tyramine	100,000
BARBITURATES (BAR300)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100

Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BUPRENORPHINE (BUP10)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
BENZODIAZEPINES (BZO200)	
Alprazolam	195
7-aminoclonazepam	＞100,000
7-aminoflunitrazepam	200
7-aminonitrazepam	390
Bromazepam	1,562
Chlordiazepoxide	780
Clobazam	390
Clorazepate	1,562
Desalkylflurazepam	1,000
Diazepam	200
Estazolam	780
Flunitrazepam	12,500
a –Hydroxyalprazolam	1,562
(+) Lorazepam	100,000
Midazolam	6,250
Nitrazepam	100
Norchlordiazepoxide	3,125
Nordiazepam	780
Oxazepam	200
Sertraline	12,500
Temazepam	100
Triazolam	50,000
COCAINE (COC300)	
Benzoylecgonine	300
Cocaine HCl	780
Cocaethylene	12,500
Ecgonine HCl	32,000
METHAMPHETAMINE (MET300)	
d-Methamphetamine	300
d,l-Amphetamine	100,000
Chloroquine	25,000
Ephedrine	100,000
(1R,2S)-(-)-Ephedrine	100,000
l-Epinephrine	50,000
Fenfluramine	12,500
p-Hydroxymethamphetamine	25,000
Mephentermine	50,000
l-Methamphetamine	3,125
3,4–Methylenedioxymethamphetamine	780
Trimethobenzamide	25,000
MORPHINE (MOP 300 or OPI 300)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levophanol	1500
6-Monoacetylmorphine	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250

Ethyl Glucuronide (EtG300)	
Ethyl Glucuronide	300
METHADONE (MTD300)	
Methadone	300
Doxylamine	50,000
Methaqualone (MQL300)	
Methaqualone	300
OXYCODONE (OXY100)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1,562
Hydromorphone	12,500
Oxymorphone	1,562
Thebaine	50,000
TRICYCLIC ANTIDEPRESSANTS (TCA1000)	
Notriptyline	1,000
Nordoxepine	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000
MARIJUANA (THC50)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
SYNTHETIC CANNABINOID (K2 200)	
JWH-073	200
JWH-018	200
Tramadol (TRA200)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000
Cotinine (COT200)	
Cotinine	200
Nicotine	6,250
Ketamine (KET500)	
Methoxy-amphetamine	6,250
D-Methamphetamine	6,250
Promethazine	12,500
4 - hydroxyphenylcyclohexylpiperidine	25,000
Phencyclidine (PCP25)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX300)	
D-Propoxyphene	300
D-Norpropoxyphene	300
Fentanyl (FYL200)	
Fentanyl	200
Norfentanyl	375

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the APAC Multi Panel Test Cup. The results demonstrate that varying ranges of pH does 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 drug positive urine containing Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Methamphetamine, Morphine, Ethyl Glucuronide, Methadone, Methaqualone, Oxycodone, Tricyclic Antidepressants, Marijuana, Synthetic Cannabinoid, Tramadol, Cotinine, Ketamine, Phencyclidine, Propoxyphene, Fentanyl. The following compounds show no cross-reactivity when tested with the APAC Multi Panel Test Cup at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Diclofenac	Maprotiline	D-Pseudoephedrine
Acetophenetidin	Diflunisal	MDE	Quinacrine
N-Acetylprocainamide	Digoxin	Meperidine	Quinidine
Acetylsalicylic acid	Diphenhydramine	Meprobamate	Quinine
Aminopyrine	Doxylamine	Methoxyphenamine	Ranitidine
Amitryptyline	Ecgonine methylester	Methyphenidate	Salicylic acid
Amoxicillin	(-) -Ψ-Ephedrine	Nalidixic acid	Serotonin
Ampicillin	β-Estradiol	Naloxone	Sulfamethazine
L-Ascorbic acid	Estrone-3-sulfate	Naltrexone	Sulindac
Apomorphine	Ethyl-p-aminobenzoate	Naproxen	Tetracycline
Aspartame	[1R,2S] (-) Ephedrine	Niacinamide	Tetrahydrocortisone 3-acetate
Atropine	(L) – Epinephrine	Nifedipine	
Benzilic acid	Erythromycin	Norethindrone	Tetrahydrocortisone 3-(β-D-glucuronide)
Benzoic acid	Fenoprofen	D-Norpropoxyphene	
Benzphetamine	Furosemide	Noscapine	Tetrahydrozoline
Bilirubin	Gentisic acid	DL-Octopamine	Thiamine
(±) – Brompheniramine	Hemoglobin	Oxalic acid	Thioridazine
Caffeine	Hydralazine	Oxolinic acid	Trans-2-phenylcyclo-propylamine hydrochloride
Cannabidiol	Hydrochlorothiazide	Oxymetazoline	
Chloralhydrate	Hydrocortisone	Papaverine	
Chloramphenicol	O-Hydroxyhippuric acid	Penicillin-G	DL-Tyrosine
Chlorothiazide	p-Hydroxyamphetamine	Pentazocine hydrochloride	Tolbutamide
(±) – Chlorpheniramine	3-Hydroxytyramine		Triamterene
Chlorpromazine	Ibuprofen	Perphenazine	Trifluoperazine
Chlorquine	Imipramine	Phenelzine	Trimethoprim
Cholesterol	Iproniazid	β-Phenylethylamine	Trimipramine
Clomipramine	(±) – Isoproterenol	Phenylpropanolamine	Tryptamine
Clonidine	Isoxsuprine	Prednisolone	DL-Tryptophan
Cortisone	Ketamine	Prednisone	Tyramine
(-) Cotinine	Ketoprofen	Promazine	Uric acid
Creatinine	Labetalol	Promethazine	Verapamil
Deoxycorticosterone	Loperamide	DL-Propranolol	Zomepirac
Dextromethorphan	L-Phenylephrine	D-Propoxyphene	

Cross Reacting compounds

Sertraline: May cause False Positive reading on the BENZODIAZEPINES strip.

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