

ACCU-TELL®
Multi-Drug Panel (Urine)
For in vitro diagnostic use only

For Urine Samples

This package insert is applied to the below products:

Catalog No.	Product Name
ABT-DOA-E320	Multi-12 Drug Panel (Urine)
ABT-DOA-E319	Multi-11 Drug Panel (Urine)
ABT-DOA-E53	Multi-10 Drug Panel (Urine) CE
ABT-DOA-E75	Multi-9 Drug Panel (Urine)
ABT-DOA-E74	Multi-8 Drug Panel (Urine)
ABT-DOA-E73	Multi-7 Drug Panel (Urine)
ABT-DOA-E32	Multi-6 Drug Panel (Urine) CE
ABT-DOA-E31	Multi-5 Drug Panel (Urine) CE
ABT-DOA-E45	Multi-4 Drug Panel (Urine)
ABT-DOA-E44	Multi-3 Drug Panel (Urine)
ABT-DOA-E51	Multi-2 Drug Panel (Urine)

INTENDED USE

ACCU-TELL® Multi-Drug Panel (Urine) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to seventeen of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Parameter	Calibrator	Cut-off(ng/mL)
AMP	d-Amphetamine	1000 ng/ml
AMP	d-Amphetamine	500 ng/ml
BAR	Secobarbital	200 ng/ml
BAR	Secobarbital	300 ng/ml
BUP	BUP-3-D-Glucuronide	10 ng/ml
BUP	BUP-3-D-Glucuronide	5ng/ml
BZO	Oxazepam	300 ng/ml
BZO	Oxazepam	200 ng/ml
COC	Benzoyllecgonine	300 ng/ml
EDDP	EDDP	100 ng/ml
KET	Ketamine	1,000ng/ml
MDMA	3,4-Methylenedioxy-MET	500 ng/ml
MET	d-Methamphetamine	1000 ng/ml
MET	d-Methamphetamine	500 ng/ml
MPD	Methylphenidate	500 ng/ml
MTD	Metadone	300 ng/ml
OPI	Morphine	2000 ng/ml
OPI/MOR	Morphine	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
TCA	Nortriptyline	1000 ng/ml
THC	11-nor-D9-THC-9-COOH	50 ng/ml
TML	Tramadol	100 ng/ml

The test is used to obtain visual qualitative result and is intended for health care professionals use including professionals at point of care sites to assist in the determination of drug compliance. It is not intended for over the counter sale to non-professionals.

This assay provided only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/ Mass Spectrometry (LC/MS) are 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.

PRINCIPLE

ACCU-TELL® Multi-Drug Panel (Urine) is one-step immunoassay in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs which may be present in urine. The test device contains membrane strips which are pre-coated with drug-protein conjugates on the test band(s). Each strip, the drug antibody-colloidal gold conjugate pad is placed at one end of the membrane. In the absence of drug in the urine, the solution of the colored antibody-colloidal gold conjugate move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugate then attach to the drug-protein conjugates to form visible lines as the antibody complex with the drug conjugate. Therefore, the formation of the

visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugate on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (drug-protein conjugate)-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test device should be discarded.

REAGENTS AND MATERIALS

Materials Provided

- Multi-Drug Rapid Test Panels
- Product Insert

Materials Required but Not provided

- Specimen collection container
- Timer
- Positive and negative urine controls

PRECAUTIONS

- For professional in vitro diagnostic use only.
- The pouch containing the test device should be sealed. Discard the test device if package is ripped or torn.
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

STORAGE AND STABILITY

The pouched DOA Panels should be stored at normal humidity and room temperature or refrigerated (2-30°C) until the expiration date stated on the pouch. The product is humidity-sensitive and should be used immediately after being opened. Any test in an improperly sealed pouch should be discarded.

SPECIMEN COLLECTION AND STORAGE

Urine Collection: ACCU-TELL® Multi-Drug Panel (Urine) is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. The urine specimen must be collected in a clean and dry container. 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 clear specimen for testing.

Urine Storage: It is recommended the collected fresh urine to be tested immediately. Fresh urine may be stored at room temperature (25°C) for up to 4 hours or to be refrigerated (2-8°C) for up to 48 hours prior to performing the test. For prolonged storage, specimens may be frozen and stored below -20°C. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

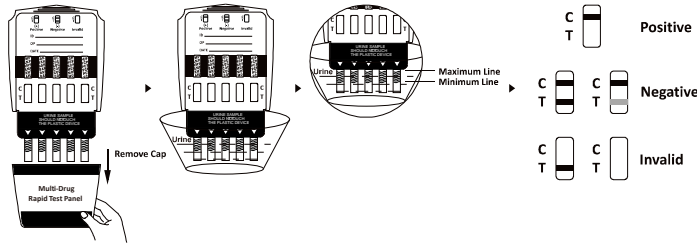
Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

IMPORTANT: Test dipstick, patient's sample, and controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test dipstick from the sealed pouch and use it as soon as possible.

2. Dip the sample pad area of the dipstick strip or dipstick card in the urine specimen submerging only up to the "MAX" mark of the dipstick strip or the edge of the dipstick card. Start the timer.
3. Place the dipstick on a clean and level surface.



Reading Result:

4. The result(s) should be read at 5 minutes. However, negative results may be read and reported as early as 3 minutes but positive results must be reported at 5 minutes only.
5. Do not interpret the result(s) after 10 minutes after the addition of sample.

INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources and are recommended to be used daily. Use the same assay procedure as with a urine specimen. Controls should be challenging to the assay cutoff concentration. If control values do not fall within established limits, assay results are invalid. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.
- ACCU-TELL® Multi-Drug Panel (Urine) provides built-in process control with a different antigen/antibody reaction at the control region (C) in each strip. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded. The presence of this control band in the control region serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

LIMITATIONS OF THE TEST

1. The assay is designed for use with human urine only.
2. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
3. There is a possibility that technical or procedural error as well as other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.
4. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

PERFORMANCE CHARACTERISTI

Accuracy

Accuracy of ACCU-TELL® Multi-Drug Panel (Urine) was established by running urine sample against GC/MS specification.

Specimen	AMP	AMP500	BAR	BUP*	BUP 5*	BZO	COC
Positive	95.8%	95.9%	97.8%	100%	100%	88.6%	98.2%
Negative	100%	100%	98.1%	100%	100%	98.2%	98.1%
Total	98.1%	98.1%	98%	100%	100%	94.9%	98.2%

Specimen	EDDP100	KET	MDMA	MET	MET500	MOP300	MTD
Positive	98.6%	98%	100%	96.8%	96.9%	96.8%	96.1%
Negative	100%	98.6%	100%	100%	100%	100%	100%
Total	99.1%	98.3%	100%	98.3%	98.3%	98.2%	98.1%

Specimen	MPD	OPI	OXY100	PCP	TCA	THC	TML
Positive	97.7%	97.6%	96.1%	97.8%	92.1%	96.8%	98.4%
Negative	98.4%	98.4%	100%	100%	100%	98.3%	100%
Total	98.1%	98.1%	98.1%	98.9%	96.8%	97.5%	99.1%

*NOTE: BUP was based on LC/MS data instead of GC/MS

Analytical Sensitivity

The sensitivity of ACCU-TELL® Multi-Drug Panel (Urine) was determined by tested GC/MS confirmed controls to the concentration at negative, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

Drug Conc.	n	AMP	AMP500	BAR	BUP	BUP5	BZO	COC
(Cut-off)	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50
50% Cut-off	50	50	0	50	0	50	0	50
75% Cutoff	50	50	0	50	0	50	0	50
Cutoff	50	16	34	14	36	11	39	25
125% Cutoff	50	0	50	0	50	0	50	0
150% Cutoff	50	0	50	0	50	0	50	0
3xCutoff	50	0	50	0	50	0	50	0

Drug	n	EDDP100	KET	MDMA	MET	MET500	MOP	MTD
(Cut-off)	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50
50%	50	50	0	50	0	50	0	50
75%	50	50	0	50	0	50	0	50
Cutoff	50	25	25	16	34	25	23	27
125%	50	0	50	0	50	0	50	0
150%	50	0	50	0	50	0	50	0
3xCutoff	50	0	50	0	50	0	50	0

Drug Conc.	n	MPD	OPI2000	OXY100	PCP	TCA	THC	TML
(Cut-off)	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50
50% Cut-off	50	50	0	50	0	50	0	50
75% Cutoff	50	50	0	50	0	50	0	50
Cutoff	50	22	28	13	37	19	31	9
125% Cutoff	50	0	50	0	50	0	50	0
150% Cutoff	50	0	50	0	50	0	50	0
3xCutoff	50	0	50	0	50	0	50	0

Specificity

The specificity for ACCU-TELL® Multi-Drug Panel (Urine) has been tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in drug-free normal human urine. ACCU-TELL® Multi-Drug Panel (Urine) performance at cutoff point are not affected when pH range of urine specimens is at 3.0 to 8.5 and specific gravity range of urine specimens is at near 1.005 to 1.03. The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/ml) listed below:

Amphetamine 1000 related compounds	
d-Amphetamine	1,000
l-Amphetamine	>100,000
d-methamphetamine	>100,000
l-methamphetamine	>100,000
3,4-Methylenedioxyamphetamine	1,250
3,4-Methylenedioxy-methamphetamine	>100,000

3,4-Methylenedioxyethylamphetamine	>100,000
Paramethoxyamphetamine	625
Phentermine	1,250
Tyramine	>100,000
Amphetamine 500 related compounds	
d-Amphetamine	500
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine	625
Phentermine	1,250
Paramethoxyamphetamine	625
Tyramine	>100,000
Barbiturates 300 related compounds	
Secobarbital	300
Allobarbital	1,250
Alphenal	625
Amobarbital	625
Aprobarbital	188
Butabarbital	94
Butalbital	2,500
Butethal	200
Cyclopentobarbital	400
Pentobarbital	1,000
Phenobarbital	300
Barbiturates 200 related compounds	
Secobarbital	200
Allobarbital	320
Alphenal	500
Amobarbital	500
Aprobarbital	130
Butabarbital	70
Butalbital	1,800
Butethal	150
Cyclopentobarbital	300
Pentobarbital	730
Phenobarbital	200
Buprenorphine 10 related compounds	
Buprenorphine	10
Buprenorphine-3-β-D-Glucuronide	10
Norbuprenorphine	50
Norbuprenorphine-3-β-D-Glucuronide	100
Buprenorphine 5 related compounds	
Buprenorphine	5
Buprenorphine-3-β-D-Glucuronide	5
Norbuprenorphine	25
Norbuprenorphine-3-β-D-Glucuronide	50
Benzodiazepines 300 related compounds	
Oxazepam	300
Alprazolam	125
Bromazepam	625
Chlordiazepoxide	2500
Clobazam	63
Clonazepam	2500
Clorazepate	3330
Desalkflurazepam	250
Diazepam	250
Estazolam	5000
Fentanyl	>100,000
Flunitrazepam	375
Flurazepam	>100,000
Lorazepam	1250
Lormetazepam	1250
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	25000
Norchlordiazepoxide	250
Nordiazepam	500
Prazepam	>100,000
Temazepam	63
Triazolam	5000
Benzodiazepines 200 related compounds	
Oxazepam	200
Alprazolam	30
Bromazepam	400
Chlordiazepoxide	1700
Clobazam	40
Clonazepam	1700
Clorazepate	2200
Desalkflurazepam	160
Diazepam	160
Estazolam	3300
Fentanyl	>100,000
Flunitrazepam	250
Flurazepam	>100,000
Lorazepam	300

Lormetazepam	800
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	16500
Norchlordiazepoxide	160
Nordiazepam	320
Prazepam	>100,000
Temazepam	40
Triazolam	3200
Cocaine 300 related compounds	
Benzoylcegonine	300
Cocaine	1,000
Ecgonine	100,000
Ecgonine Methyl Ester	>100,000
EDDP 100 related compounds	
EDDP	100
Meperidine	>100,000
Methadone	>100,000
Norfentanyl	>100,000
Phencyclidine	>100,000
Promazine	50,000
Promethazine	25,000
Prothipendyl	50,000
Prozine	12,500
Ketamine 1000 related compounds	
Ketamine	1,000
Norketamine	1,000
Dextromethorphan	>100000
Dextrorphan tartrate	>100000
D-Norpropoxyphene	31,250
EDDP	>100000
Meperidine	12,500
Mephentermine hemisulfate salt	50,000
Methadone	12,500
D-Methamphetamine	12,500
3,4-Methylenedioxyethylamphetamine	25,000
Nordoxepin hydrochloride	25,000
Phencyclidine	5,000
Promazine	8,000
Promethazine	25,000
Ecstasy 500 related compounds	
3,4-Methylenedioxy-methamphetamine	500
d-Amphetamine	>100,000
l-Amphetamine	>100,000
d-methamphetamine	>100,000
l-methamphetamine	>100,000
3,4-Methylenedioxyamphetamine	2,500
3,4-Methylenedioxyethylamphetamine	156
Paramethoxyamphetamine	50,000
Paramethoxymethamphetamine	>100,000
Methamphetamine 1000 related compounds	
d-Methamphetamine	1,000
Chloroquine	25,000
Fenfluramine	12,500
l-Methamphetamine	10,000
Mephentermine hemisulfate salt	31,250
3,4-Methylenedioxyethylamphetamine	50,000
3,4-Methylenedioxy-methamphetamine	313
Paramethoxymethamphetamine	625
(-)-Ephedrine	4,000
Methamphetamine 500 related compounds	
d-Methamphetamine	500
Chloroquine	12,500
Fenfluramine	12,500
l-Methamphetamine	3,125
Mephentermine hemisulfate salt	25,000
MDEA	12,500
MDMA	1,875
PMMA	625
(-)-Ephedrine	2,000
Morphine 300 related compounds	
Morphine	300
Acetylcodeine	150
Buprenorphine	3,125
Codeine	250
Diacetyl Morphin	250
Dihydrocodeine	586
Ethylmorphine	200
Hydrocodone	12,500
Hydromorphone	12,500
6-Monoacetylmorphine	250
Morphine-3-glucuronid	2,500
Nalorphine	25,000
Thebaine	25,000









Methadone 300 related compounds	
Methadone	300
(-)-alpha-methadol	2,000
MPD 500 related compounds	
Methylphenidate	500
Opiates 2000 related compounds	
Morphine	2,000
Acetylcodeine	1,563
Buprenorphine	25,000
Codeine	500
Diacetylmorphine (Heroin)	1,250
Dihydrocodeine	1,563
Ethylmorphine	300
Hydromorphone	25,000
Hydrocodone	50,000
Merperidine	>100,000
6-Monoacetylmorphine (6-MAM)	1,250
Morphine-3-β-d-glucuronide	12,500
Nalorphine Hydrochloride	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000
Rifampicine	>100,000
Thebaine	50,000
Oxycodone 100 related compounds	
Oxycodone	100
Hydrocodone	25,000
Hydromorphone	50,000
Naloxone	50,000
Oxymorphone	250
Phencyclidine 25 related compounds	
Phencyclidine	25
Hydrocodone	>100,000
Hydromorphone	>100,000
4-hydroxyphencyclidine	75
Tricyclic Antidepressants related compounds	
Nortriptyline HCl	1,000
Amitriptyline	1,500
Clomipramine	>100,000
Cyclobenzaprine	12,500
Desipramine	188
Doxepin	2,000
Imipramine	2,500
Maprotiline	750
Nordoxepin	500
Opipramol	1,563
Promazine	1,000
Promethazine	6,250
Prothipendyl	25,000
Protryptiline	6,250
Prozine	1,250
Trimipramine	>100,000
Marijuana 50 related compounds	
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	50
11-hydroxy-Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	15,000
Δ9-Tetrahydrocannabinol	15,000
Cannabinol	20,000
Cannabidiol	>100,000
Tramadol 100 related compounds	
Tramadol	100
(+/-)-Chlorpheniramine	50,000
Dimenhydrinate	50,000
Diphenhydramine	50,000
Phencyclidine	50,000
(+)-Chlorpheniramine	>100,000

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan	Pheniramine
4-Dimethylaminoantipyrine	Dextrophan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline (Except TCA)	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine (Except TCA)	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Ibuprofen
Chloroquine	Methadone (Except MTD)	

LITERATURE REFERENCES

- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
- Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
- Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
- McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
- Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

Non Cross-Reacting Compounds

The following compounds were found not to cross-react when tested at concentrations at 100 µg/ml.