

## DIAQUICK Multi-Drug Panels

for human urine samples

<b>Multi-3 Drug Panel</b> - REF Z06576CE	BZO,COC,MOP Cont.: 30 Panels, individually packed (30x REF Z06576B)
<b>Multi-3/1 Drug Panel</b> - REF Z09577CE	BUP, MOP, MTD Cont.: 30 Panels, individually packed (30x REF Z09577B)
<b>Multi-4 Drug Panel</b> - REF Z02575CE	AMP,COC,MOP,THC Cont.: 30 Panels, individually packed (30x REF Z02575B)
<b>Multi-5/3 Drug Panel</b> - REF Z06502CE	AMP,COC,MET,MOP,THC Cont.: 30 Panels, individually packed (30x REF Z06502B)
<b>Multi-5/4 Drug Panel</b> - REF Z11504CE	AMP,COC,MDMA,MOP,THC Cont.: 30 Panels, individually packed (30x REF Z11504B)
<b>Multi-5/6 Drug Panel</b> - REF Z06506CE	AMP,BZO,COC,MOP,THC Cont.: 30 Panels, individually packed (30x REF Z06506B)
<b>Multi-6 Drug Panel</b> - REF Z98907CE	BZO,COC,MET,MOP,MTD,THC Cont.: 30 Panels, individually packed (30x REF Z98907B)
<b>Multi-6/1 Drug Panel</b> - REF Z03220CE	AMP,BZO,COC,MET,MOP,THC Cont.: 30 Panels, individually packed (30x REF Z03220B)
<b>Multi-6/4 Drug Panel</b> - REF Z08940CE	AMP,BUP,BZO,MET,MOP,THC Cont.: 30 Panels, individually packed (30x REF Z08940B)
<b>Multi-6/7 Drug Panel</b> - REF Z09970CE	BUP,BZO,COC,MOP,MTD,THC Cont.: 30 Panels, individually packed (30x REF Z09970B)
<b>Multi-6/10 Drug Panel</b> - REF Z11911CE	AMP,BZO,COC,MOP,MTD,THC Cont.: 30 Panels, individually packed (30x REF Z11911B)
<b>Multi-7 Drug Panel</b> - REF Z12730CE	AMP,BUP,BZO,COC,MTD,MOP,THC Cont.: 30 Panels, individually packed (30x REF Z12730B)
<b>Multi-10 Drug Panel</b> - REF Z06230CE - REF Z04231CE	AMP,BAR,BZO,COC,MDMA,MET,MOP,MTD,TCA,THC Cont.: 30 Panels, individually packed (30x REF Z04230B) Cont.: 10 Panels, individually packed (10x REF Z04230B)
<b>Multi-10/1 Drug Panel</b> - REF Z06235CE - REF Z06236CE	AMP,BAR,BZO,BUP,COC,MDMA,MET,MOP,MTD,THC Cont.: 30 Panels, individually packed (30x REF Z06235B) Cont.: 10 Panels, individually packed (10x REF Z06236B)
<b>Multi-10/3 Drug Panel</b> - REF Z06103CE	AMP,BZO,COC,MDMA,MOP,MTD,OPI,PCP,TCA,THC Cont.: 30 Panels, individually packed (30x REF Z06103B)
<b>Multi-10/4 Drug Panel</b> - REF Z06104CE	AMP,BAR,BUP,BZO,COC,MDMA,MET,MTD,OPI,THC Cont.: 30 Panels, individually packed (30x REF Z06104B)
<b>Multi-10/6 Drug Panel</b> - REF Z06106CE	AMP,BAR,BZO,COC,MET,MOP,MTD,PCP,TCA,THC Cont.: 30 Panels, individually packed (30x REF Z06106B)
<b>Multi-10/7 Drug Panel</b> - REF Z06107CE	AMP,BAR,BZO,COC,MET,MTD,OPI,PCP,TCA,THC Cont.: 30 Panels, individually packed (30x REF Z06107B)

All products contain a package insert!

For in vitro diagnostic use only. For use by medical professionals only.  
 For diagnosis and therapeutic monitoring only.

### INTENDED USE

The DIAQUICK Multi-Drug Panels (urine) are rapid, lateral flow chromatographic immunoassays for the simultaneous, qualitative detection of the following drugs and their metabolites:

Parameter	Code	Calibrator Substance	Cut-off
Amphetamine	AMP	d-Amphetamine	1 000 ng/mL
Barbiturates	BAR	Secobarbital	300 ng/mL
Buprenorphine	BUP	Buprenorphine	10 ng/mL
Benzodiazepines	BZO	Oxazepam	300 ng/mL
Cocaine	COC	Benzoylcocaine	300 ng/mL
Ethylglucuronide	ETG	Ethyl-β-D-Glucuronide	500 ng/mL
Fentanyl	FYL	Norfentanyl	20 ng/mL
Ketamine	KET	Ketamine	1 000 ng/mL
Ecstasy	MDMA	(±) 3,4-Methylenedioxyamphetamine HCl	500 ng/mL
Methamphetamine	MET	d-Methamphetamine	1 000 ng/mL
Opiates, Morphine, Heroine	MOP	Morphine	300 ng/mL
Methadone	MTD	Methadone	300 ng/mL
Opiate, Morphine, Heroine	OPI	Morphine	2 000 ng/mL
Phencyclidine	PCP	Phencyclidine	25 ng/mL
Tricyclic Antidepressants	TCA	Nortriptyline	1 000 ng/mL
Marihuana/Cannabis	THC	11-nor-Δ9-THC-9-COOH	50 ng/mL
Tramadol	TRA	cis-Tramadol	100 ng/mL

This test will detect other related compounds, please refer to the Analytical Specificity table in this insert. 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 obtained. For in vitro diagnostic use only.

### TEST PRINCIPLE

The DIAQUICK Multi-Drug Panels (urine) are immunoassays based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a urine specimen migrates upward 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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### WARNINGS AND PRECAUTIONS

- For medical and other 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 panels should be discarded according to federal, state and local regulations.

### REAGENTS

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

### STORAGE

The DIAQUICK Multi-Drug Panels can be stored refrigerated or at room temperature (2-30°C). The test panel is stable through the expiration date printed on the sealed pouch. The test panel must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

### SAMPLE COLLECTION AND PREPARATION

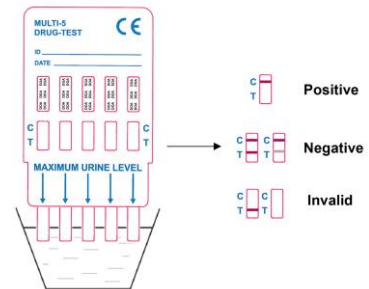
The urine must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitations should be centrifuged, filtered or allowed to settle to obtain a clear specimen for testing. Urine specimens may be stored at 2-8°C for up to 48 h prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### ASSAY PROCEDURE

Allow the test panel, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing

- Remove the test panel from the sealed pouch and use it as soon as possible.

- Take off the protective cap plugged on the test panel. With arrows pointing towards the urine specimen, immerse the test panel vertically into the urine specimen for 10-15 seconds. Do not allow the urine sample to touch the plastic cassette when immersing the test device into the urine sample. Avoid immersion of the cassette deeper than the mark indicated with the arrows on the device and avoid any direct contact of the sample with the test region.



- Put the protective cap back onto the test panel. Place the test panel on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. Read the results at 5 minutes. Do not interpret results after 10 minutes.

### INTERPRETATION OF RESULTS

**NEGATIVE:** A colored line in the control region (C) and a colored line in the test line region (T) for a specific drug indicate a negative results. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

\*NOTE: The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

**POSITIVE:** A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive results. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off 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

### QUALITY CONTROL

A procedural control is included in the test. A red 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

- The DIAQUICK Multi-Drug Panels (urine) provide only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleaching agents 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate the level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained if a drug is present but below the cut-off level of the test.
- The DIAQUICK Multi-Drug Panels (urine) do not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

### PERFORMANCE CHARACTERISTICS

#### ACCURACY

A side-by-side comparison of the DIAQUICK Multi-Drug Panels and a commercially available rapid drug test was conducted. Testing was performed on approx. 100 specimens previously collected from subjects present for drug screen testing. The agreement was > 99.9 % for all tests.

A side-by-side comparison of the DIAQUICK DOA Dipsticks and GC/MS at the cut-off level of the tests was conducted. Testing was performed on 250 specimens previously collected from subjects present for drug screen testing. The following results were tabulated.

#### % Agreement with GC/MS

	Positive Agreement	Negative Agreement	Total Results
AMP	98,1 %	97,9 %	98,0 %
BAR	96,1 %	98,6 %	97,6 %
BUP	99,1 %	> 99,9 %	99,6 %
BZO	98,4 %	99,2 %	98,8 %
COC	98,2 %	97,8 %	98,0 %
ETG	97,6 %	99,4 %	98,8 %
FYL	98,8 %	99,4 %	99,2 %



<b>KET</b>	97,5 %	98,2 %	98,0 %
<b>MDMA</b>	98,1 %	99,3 %	98,8 %
<b>MET</b>	96,2 %	97,1 %	96,8 %
<b>MOP</b>	95,0 %	95,3 %	95,2 %
<b>MTD</b>	98,9 %	98,8 %	98,8 %
<b>OPI</b>	96,7 %	93,8 %	95,2 %
<b>PCP</b>	92,4 %	96,8 %	95,2 %
<b>TCA</b>	94,8 %	91,6 %	92,8 %
<b>THC</b>	97,9 %	98,1 %	98,0 %
<b>TRA</b>	88,2 %	92,4 %	90,8 %

#### ANALYTICAL SPECIFICITY

The following tables lists the concentration of compounds (ng/mL) that are detected positive in urine by the DIAQUICK Multi-Drug Panels (urine) at 5 minutes.

<b>AMPHETAMINE</b>	<b>AMP</b>	<b>BARBITURATES</b>	<b>BAR</b>
D,L-Amphetamine sulfate	300	Amobarbital	5 000
L-Amphetamine	25 000	5,5-Diphenylhydantoin	8 000
(±) 3,4-Methylenedioxyamphetamine	500	Allobarbitol	600
Phentermine	800	Barbital	8 000
Maprotiline	50 000	Talbutal	200
Methoxyphenamine	6 000	Butalbitol	8 000
<b>D-Amphetamine</b>	<b>1 000</b>	Phenobarbital	300
<b>BUPRENORPHINE</b>	<b>BUP</b>	Cyclopentobarbital	30 000
Buprenorphine	<b>10</b>	Pentobarbital	8 000
Norbuprenorphine	50	Alphenol	600
Buprenorphine 3-D-Glucuronide	50	Aprobarbital	500
Norbuprenorphine 3-D-Glucuronide	100	Butabarbitol	200
<b>BENZODIAZEPINES</b>	<b>BZO</b>	Butethal	500
Alprazolam	100	<b>Secobarbital</b>	<b>300</b>
a-hydroxyalprazolam	1 500	<b>COCAINE</b>	<b>COC</b>
Bromazepam	900	<b>Benzoylcegonine</b>	<b>300</b>
Chlordiazepoxide	900	Cocaine HCl	200
Clobazam	200	Cocaehtylene	20 000
Clonazepam	500	Ecgonine HCl	30 000
Clorazepate dipotassium	500	<b>ETHYLGLUCURONIDE</b>	<b>ETG</b>
Delorazepam	900	<b>Ethyl-β-D-Glucuronide</b>	<b>500</b>
Desalkylflurazepam	200	Propyl-β-D-Glucuronide	50 000
Diazepam	300	Morphine-3-β-Glucuronide	100 000
Estazolam	6 000	Morphine-6-β-Glucuronide	100 000
Flunitrazepam	200	Glucuronic Acid	100 000
(±) Lorazepam	3 000	Ethanol	100 000
RS-Lorazepam glucuronide	200	Methanol	100 000
Midazolam	6 000	<b>FENTANYL</b>	<b>FYL</b>
Nitrazepam	200	Alfentanyl	600 000
Norchlordiazepoxide	100	Fenfluramine	50 000
Nordiazepam	900	<b>Norfentanyl</b>	<b>20</b>
<b>Oxazepam</b>	<b>300</b>	Busporine	15 000
Temazepam	100	Fentanyl	100
Triazolam	3 000	Sufentanyl	50 000
<b>KETAMINE</b>	<b>KET</b>	<b>ECSTASY</b>	<b>MDMA</b>
Ketamine	<b>1 000</b>	(±) 3,4-Methylenedioxyamphetamine HCl	<b>500</b>
Benzphetamine	25 000	(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3 000
(+) Chlorpheniramine	25 000	3,4-Methylenedioxyethyl-amphetamine (MDE)	300
Clonidine	100 000	<b>METHAMPHETAMINE</b>	<b>MET</b>
Dextromethorphan	2 000	p-Hydroxymethamphetamine	25 000
Disopyramide	25 000	<b>D-Methamphetamine</b>	<b>1 000</b>
EDDP	50 000	L-Methamphetamine	20 000
Mephentermine	25 000	(±)-3,4-Methylenedioxyamphetamine	12 500
(1R, 2S) - (-)-Ephedrine	100 000	Mephentermine	50 000
4-Hydroxyphencyclidine	50 000	<b>MORPHINE</b>	<b>MOP</b>
Levorphanol	50 000	Codeine	200
MDE	50 000	Ethylmorphine	6 000
Tetrahydrozoline	500	Hydrocodone	50 000
d-Methamphetamine	50 000	Hydromorphone	3 000
l-Methamphetamine	50 000	Levorphanol	1 500
Methoxyphenamine	25 000	6-Monoacetylmorphine	300
(+)-3,4-Methylenedioxyamphetamine	100 000	Morphine 3-β-D-glucuronide	800
d-Norpropoxyphene	25 000	<b>Morphine</b>	<b>300</b>
Pentazocine	25 000	Norcodeine	6 000
Phencyclidine	25 000	Normorphine	50 000
Promazine	25 000	Oxycodone	30 000
Promethazine	25 000	Oxymorphone	50 000
Thioridazine	50 000	Procaine	15 000
Meperidine	25 000	Thebaine	6 000
<b>METHADONE</b>	<b>MTD</b>	<b>TRICYCLIC ANTIDEPRESSANTS</b>	<b>TCA</b>
Methadone	<b>300</b>	<b>Nortriptyline</b>	<b>1 000</b>
Doxylamine	100 000	Nordoxepine	500
Cis-tramadol	300 000	Trimipramine	3 000
<b>OPIATES</b>	<b>OPI</b>	Amitriptyline	1 500
Codeine	2 000	Promazine	3 000
Ethylmorphine	3 000	Desipramine	200
Hydrocodone	50 000	Cyclobenzaprine	2 000
Hydromorphone	15 000	Imipramine	400
Levorphanol	25 000	Clomipramine	50 000
6-Monoacetylmorphine	3 000	Doxepine	2 000
Morphine 3-β-D-glucuronide	2 000	Maprotiline	2 000
<b>Morphine</b>	<b>2 000</b>	Promethazine	50 000
Norcodeine	25 000	Perphenazine	50 000
Normorphine	50 000	Dithiaden	10 000
Oxycodone	25 000	<b>TRAMADOL</b>	<b>TRA</b>
Oxymorphone	25 000	n-Desmethyl-cis-tramadol	200
Procaine	50 000	<b>Cis-tramadol</b>	<b>100</b>
Thebaine	25 000	Procyclidine	100 000
<b>CANNABIS</b>	<b>THC</b>	o-Desmethyl-cis-tramadol	10 000
Cannabinol	35 000	Phencyclidine	100 000
11-nor-Δ <sup>8</sup> -THC-9 COOH	30	d,l-O-Desmethyl venlafaxine	50 000
<b>11-nor-Δ<sup>8</sup>-THC-9 COOH</b>	<b>50</b>	<b>PHENCYCLIDINE</b>	<b>PCP</b>
Δ <sup>8</sup> -THC	17 000	4-Hydroxyphencyclidine	12 500
Δ <sup>9</sup> -THC	17 000	<b>Phencyclidine</b>	<b>25</b>

#### 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. The following compounds did not show a cross-reactivity when tested with the DIAQUICK Multi-Drug Panels (urine) at a concentration of 100 µg/mL.

#### Non Cross-Reacting Compounds:

Acetophenetidin	Cortisone	Zomepirac	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labelalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diffunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Atropine	β-Estradiol	Niacinamide	3-acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethidrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Genitic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Cyclochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine	Isosuprine	d,l-Propranolol	

#### REFERENCES

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- Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

