DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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DIAQUICK Multi-Drug Panels

for human urine samples

Multi-3 Drug Panel	BZO,COC,MOP
- REF Z06576CE	Cont.: 30 Panels, individually packed (30x REF Z06576B)
Multi-3/1 Drug Panel	BUP, MOP, MTD
- REF Z09577CE	Cont.: 30 Panels, individually packed (30x REF Z09577B)
Multi-4 Drug Panel	AMP,COC,MOP,THC
- REF Z02575CE	Cont.: 30 Panels, individually packed (30x REF Z02575B)
Multi-5/3 Drug Panel	AMP,COC,MET,MOP,THC
- REF Z06502CE	Cont.: 30 Panels, individually packed (30x REF Z06502B)
Multi-5/4 Drug Panel	AMP,COC,MDMA,MOP,THC
- REF Z11504CE	Cont.: 30 Panels, individually packed (30x REF Z11504B)
Multi-5/6 Drug Panel	AMP,BZO,COC,MOP,THC
- REF Z06506CE	Cont.: 30 Panels, individually packed (30x REF Z06506B)
Multi-6 Drug Panel	BZO,COC,MET,MOP,MTD,THC
- REF Z98907CE	Cont.: 30 Panels, individually packed (30x REF Z98907B)
Multi-6/1 Drug Panel	AMP,BZO,COC,MET,MOP,THC
- REF Z03220CE	Cont.: 30 Panels, individually packed (30x REF Z03220B)
Multi-6/4 Drug Panel	AMP,BUP,BZO,MET,MOP,THC
- REF Z08940CE	Cont.: 30 Panels, individually packed (30x REF Z08940B)
Multi-6/7 Drug Panel	BUP,BZO,COC,MOP,MTD,THC
- REF Z09970CE	Cont.: 30 Panels, individually packed (30x REF Z09970B)
Multi-6/10 Drug Panel	AMP,BZO,COC,MOP,MTD,THC
- REF Z11911CE	Cont.: 30 Panels, individually packed (30x REF Z11911B)
Multi-7 Drug Panel	AMP,BUP,BZO,COC,MTD,MOP,THC
- REF Z12730CE	Cont.: 30 Panels, individually packed (30x REF Z12730B)
Multi-10 Drug Panel	AMP,BAR,BZO,COC,MDMA,MET,MOP,MTD,TCA,THC
- REF Z06230CE	Cont.: 30 Panels, individually packed (30x REF Z04230B)
- REF Z04231CE	Cont.: 10 Panels, individually packed (10x REF Z04230B)
Multi-10/1 Drug Panel	AMP,BAR,BZO,BUP,COC,MDMA,MET,MOP,MTD,THC
- REF Z06235CE	Cont.: 30 Panels, individually packed (30x REF Z05235B)
- REF Z06236CE	Cont.: 10 Panels, individually packed (10x REF Z05235B)
Multi-10/3 Drug Panel	AMP, BZO,COC,MDMA,MOP,MTD,OPI,PCP,TCA,THC
- REF Z06103CE	Cont.: 30 Panels, individually packed (30x REF Z06103B)
Multi-10/4 Drug Panel	AMP,BAR,BUP,BZO,COC,MDMA,MET,MTD,OPI,THC
- REF Z06104CE	Cont.: 30 Panels, individually packed (30x REF Z06104B)
Multi-10/6 Drug Panel	AMP,BAR,BZO,COC,MET,MOP,MTD,PCP,TCA,THC
- REF Z06106CE	Cont.: 30 Panels, individually packed (30x REF Z06106B)
Multi-10/7 Drug Panel	AMP,BAR,BZO,COC,MET,MTD,OPI,PCP,TCA,THC
- REF Z06107CE	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	Benzoylecgonine	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-Methylenedioxymethamphetamine 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.

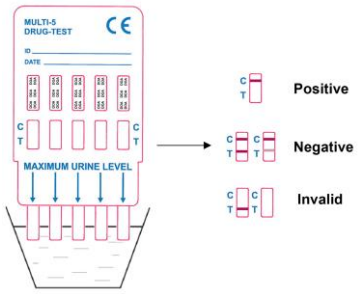
SAMPLE COLLECTION AND PREPARATION

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

1. Remove the test panel from the sealed pouch and use it as soon as possible.
2. 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.



3. 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

1. 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.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. 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.
5. 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.
6. The DIAQUICK Multi-Drug Panels (urine) do not distinguish between drugs of abuse and certain medications.
7. 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 %

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

AMPHETAMINE	**AMP**
D,L-Amphetamine sulfate	300
L-Amphetamine	25 000
(±) 3,4-Methylenedioxyamphetamine	500
Phentermine	800
Maprotiline	50 000
Methoxyphenamine	6 000
D-Amphetamine	**1 000**
BUPRENORPHINE	**BUP**
Buprenorphine	**10**
Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50
Norbuprenorphine 3-D-Glucuronide	100
BENZODIAZEPINES	**BZO**
Alprazolam	100
a-hydroxyalprazolam	1 500
Bromazepam	900
Chlordiazepoxide	900
Clobazam	200
Clonazepam	500
Clorazepate dipotassium	500
Delorazepam	900
Desalkylflurazepam	200
Diazepam	300
Estazolam	6 000
Flunitrazepam	200
(±) Lorazepam	3 000
RS-Lorazepam glucuronide	200
Midazolam	6 000
Nitrazepam	200
Norchlordiazepoxide	100
Nordiazepam	900
Oxazepam	**300**
Temazepam	100
Triazolam	3 000
KETAMINE	**KET**
Ketamine	**1 000**
Benzphetamine	25 000
(+) Chlorpheniramine	25 000
Clonidine	100 000
Dextromethorphan	2 000
Disopyramide	25 000
EDDP	50 000
Mephentermine	25 000
(1R, 2S) - (-)-Ephedrine	100 000
4-Hydroxyphencyclidine	50 000
Levorphanol	50 000
MDE	50 000
Tetrahydrozoline	500
d-Methamphetamine	50 000
l-Methamphetamine	50 000
Methoxyphenamine	25 000
(+)3,4-Methylendioxymethamphetamine	100 000
d-Norpropoxyphene	25 000
Pentazocine	25 000
Phencyclidine	25 000
Promazine	25 000
Promethazine	25 000
Thioridazine	50 000
Meperidine	25 000
METHADONE	**MTD**
Methadone	**300**
Doxylamine	100 000
Cis-tramadol	300 000
OPIATES	**OPI**
Codeine	2 000
Ethylmorphine	3 000
Hydrocodone	50 000
Hydromorphone	15 000
Levorphanol	25 000
6-Monoacetylmorphine	3 000
Morphine 3-β-D-glucuronide	2 000
Morphine	**2 000**
Norcodeine	25 000
Normorphone	50 000
Oxycodone	25 000
Oxymorphone	25 000
Procaine	50 000
Thebaine	25 000
CANNABIS	**THC**
Cannabinol	35 000
11-nor-Δ^8-THC-9 COOH	30
11-nor-Δ^9-THC-9 COOH	**50**
Δ^8-THC	17 000
Δ^9-THC	17 000

BARBITURATES	**BAR**
Amobarbital	5 000
5,5-Diphenylhydantoin	8 000
Allobarbital	600
Barbital	8 000
Talbutal	200
Butalbital	8 000
Phenobarbital	300
Cyclopentobarbital	30 000
Pentobarbital	8 000
Alphenol	600
Aprobarbital	500
Butabarbital	200
Butethal	500
Secobarbital	**300**
COCAINE	**COC**
Benzoylecgonine	**300**
Cocaine HCl	200
Cocaethylene	20 000
Ecgonine HCl	30 000
ETHYLGLUCURONIDE	**ETG**
Ethyl-β-D-Glucuronide	**500**
Propyl-β-D-Glucuronide	50 000
Morphine-3-β-Glucuronide	100 000
Morphine-6-β-Glucuronide	100 000
Glucuronic Acid	100 000
Ethanol	100 000
Methanol	100 000
FENTANYL	**FYL**
Alfentanyl	600 000
Fenfluramine	50 000
Norfentanyl	**20**
Busporine	15 000
Fentanyl	100
Sufentanyl	50 000
ECSTASY	**MDMA**
(±) 3,4-Methylenedioxymethamphetamine HCl	**500**
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)	300
METHAMPHETAMINE	**MET**
ρ-Hydroxymethamphetamine	25 000
D-Methamphetamine	**1 000**
L-Methamphetamine	20 000
(±)-3,4-Methylenedioxymethamphetamine	12 500
Mephentermine	50 000
MORPHINE	**MOP**
Codeine	200
Ethylmorphine	6 000
Hydrocodone	50 000
Hydromorphone	3 000
Levorphanol	1 500
6-Monoacethylmorphine	300
Morphine 3-β-D-glucuronide	800
Morphine	**300**
Norcodeine	6 000
Normorphone	50 000
Oxycodone	30 000
Oxymorphone	50,000
Procaine	15,000
Thebaine	6,000
TRICYCLIC ANTIDEPRESSANTS	**TCA**
Nortriptyline	**1 000**
Nordoxepine	500
Trimipramine	3 000
Amitriptyline	1 500
Promazine	3 000
Desipramine	200
Cyclobenzaprine	2 000
Imipramine	400
Clomipramine	50 000
Doxepine	2 000
Maprotiline	2 000
Promethazine	50 000
Perphenazine	50 000
Dithiaden	10 000
TRAMADOL	**TRA**
n-Desmethyl-cis-tramadol	200
Cis-tramadol	**100**
Procyclidine	100 000
o-Desmethyl-cis-tramadol	10 000
Phencyclidine	100 000
d,l-O-Desmethyl venlafaxine	50 000
PHENCYCLCIDINE	**PCP**
4-Hydroxyphencyclidine	12 500
Phencyclidine	**25**

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	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	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	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	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	Isoxsuprine	d,l-Propanolol	

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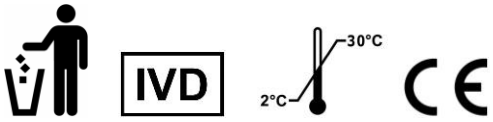

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