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)
- REF Z06576B	Cont.: 1 panel, individually packed
Multi-3/1 Drug Panel	BUP, MOP, MTD
- REF Z09577CE	Cont.: 30 panels, individually packed (30x REF Z09577B)
- REF Z09577B	Cont.: 1 panel, individually packed
Multi-4 Drug Panel	AMP,COC,MOP,THC
- REF Z02575CE	Cont.: 30 panels, individually packed (30x REF Z02575B)
- REF Z02575B	Cont.: 1 panel, individually packed
Multi-5 Drug Panel	BZO,COC,MET,MOP,THC
- REF Z05236CE	Cont.: 30 panels, individually packed (30x REF Z05236B)
- REF Z05236B	Cont.: 1 panel, individually packed
Multi-5/3 Drug Panel	AMP,COC,MET,MOP,THC
- REF Z06502CE	Cont.: 30 panels, individually packed (30x REF Z06502B)
- REF Z06502B	Cont.: 1 panel, individually packed
Multi-5/4 Drug Panel	AMP,COC,MDMA,MOP,THC
- REF Z11504CE	Cont.: 30 panels, individually packed (30x REF Z11504B)
- REF Z11504B	Cont.: 1 panel, individually packed
Multi-5/6 Drug Panel	AMP,BZO,COC,MOP,THC
- REF Z06506CE	Cont.: 30 panels, individually packed (30x REF Z06506B)
- REF Z06506B	Cont.: 1 panel, individually packed
Multi-6 Drug Panel	BZO,COC,MET,MOP,MTD,THC
- REF Z98907CE	Cont.: 30 panels, individually packed (30x REF Z98907B)
- REF Z98907B	Cont.: 1 panel, individually packed
Multi-6/1 Drug Panel	AMP,BZO,COC,MET,MOP,THC
- REF Z03220CE	Cont.: 30 panels, individually packed (30x REF Z03220B)
- REF Z03220B	Cont.: 1 panel, individually packed
Multi-6/3 Drug Panel	BUP, BZO, COC, MTD, OPI, THC
- REF Z08930CE	Cont.: 30 panels, individually packed (30x REF Z08930B)
- REF Z08930B	Cont.: 1 panel, individually packed
Multi-6/4 Drug Panel	AMP,BUP,BZO,MET,MOP,THC
- REF Z08940CE	Cont.: 30 panels, individually packed (30x REF Z08940B)
- REF Z08940B	Cont.: 1 panel, individually packed
Multi-6/6 Drug Panel	BUP,COC,MET,MOP,MTD,THC
- REF Z13960CE	Cont.: 30 panels, individually packed (30x REF Z13960B)
- REF Z13960B	Cont.: 1 panel, individually packed
Multi-6/7 Drug Panel	BUP,BZO,COC,MOP,MTD,THC
- REF Z09970CE	Cont.: 30 panels, individually packed (30x REF Z09970B)
- REF Z09970B	Cont.: 1 panel, individually packed
Multi-6/10 Drug Panel	AMP,BZO,COC,MOP,MTD,THC
- REF Z11911CE	Cont.: 30 panels, individually packed (30x REF Z11911B)
- REF Z11911B	Cont.: 1 panel, individually packed
Multi-7 Drug Panel	AMP,BUP,BZO,COC,MTD,MOP,THC
- REF Z12730CE	Cont.: 30 panels, individually packed (30x REF Z12730B)
- REF Z12730B	Cont.: 1 panel, individually packed
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)
- REF Z04230B	Cont.: 1 panel, individually packed
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)
- REF Z05235B	Cont.: 1 panel, individually packed
Multi-10/2 Drug Panel	AMP,BAR,BZO,COC,MDMA,MOP,MTD,OPI,TCA,THC
- REF Z06102CE	Cont.: 30 panels, individually packed (30x REF Z06102B)
- REF Z06102B	Cont.: 1 panel, individually packed
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)
- REF Z06103B	Cont.: 1 panel, individually packed
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)
- REF Z06104B	Cont.: 1 panel, individually packed
Multi-10/5 Drug Panel	AMP,BAR,BZO,BUP,COC,MET,MOP,MTD,TCA,THC
- REF Z06105CE	Cont.: 30 panels, individually packed (30x REF Z06105B)
- REF Z06105B	Cont.: 1 panel, individually packed
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)
- REF Z06106B	Cont.: 1 panel, individually packed
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)
- REF Z06107B	Cont.: 1 panel, individually packed

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	Short	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
Ecstasy	MDMA	d,l Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine	MET	d-Methamphetamine	1,000 ng/mL
Methadone	MTD	Methadone	300 ng/mL
Opiate, Morphine, Heroine	MOP	Morphine	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

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.

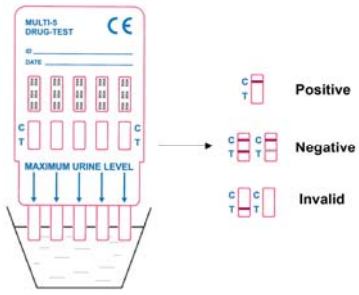
SAMPLE COLLECTION AND PREPARATION

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

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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 was conducted using the "DIAQUICK" Multi-Drug Panels (urine) and commercially available drug rapid tests. Testing was performed on approximately 250 specimens. Presumptive positive results were confirmed by GC/MS. The following results were tabulated.

% Agreement with Commercial Kit

	Positive Agreement	Negative Agreement	Total Results
AMP	> 99.9 %	> 99.9 %	> 99.9 %
BAR	> 99.9 %	> 99.9 %	> 99.9 %
BUP	> 99.9 %	> 99.9 %	> 99.9 %
BZO	> 99.9 %	> 99.9 %	> 99.9 %
COC	> 99.9 %	> 99.9 %	> 99.9 %
THC	> 99.9 %	> 99.9 %	> 99.9 %
MTD	> 99.9 %	> 99.9 %	> 99.9 %
MET	> 99.9 %	> 99.9 %	> 99.9 %
MDMA	> 99.9 %	> 99.9 %	> 99.9 %
MOP	> 99.9 %	> 99.9 %	> 99.9 %
OPI	*	*	*
PCP	> 99.9 %	> 99.9 %	> 99.9 %
TCA	*	*	*

* NOTE: Based on GC/MS instead of Commerical Kit.

% Agreement with GC/MS

	Positive Agreement	Negative Agreement	Total Results
AMP	98.4 %	98.4 %	98.4 %
BAR	97.3 %	99.3 %	98.4 %
BUP	99.2 %	> 99.9 %	99.6 %
BZO	98.4 %	99.2 %	98.8 %
COC	98.0 %	99.3 %	98.8 %
THC	> 99.9 %	99.1 %	99.6 %
MTD	99.1 %	98.6 %	98.8 %
MET	98.9 %	93.6 %	95.6 %
MDMA	96.2 %	97.5 %	96.8 %
MOP	96.3 %	95.7 %	96.0 %
OPI	94.3 %	91.3 %	92.8 %
PCP	95.1 %	94.6 %	94.8 %
TCA	94.8 %	89.6 %	92.0 %

ANALYTICAL SENSITIVITY

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below:

Drug Conc.	n	AMP		BAR		BUP		BZO		COC	
		-	+	-	+	-	+	-	+	-	+
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	27	3	26	4	27	3	26	4
Cut-off	30	14	16	16	14	14	16	15	15	15	15
+25% Cut-off	30	3	27	4	26	3	27	4	26	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.	n	MTD		MET		MDMA		MOP		OPI	
		-	+	-	+	-	+	-	+	-	+
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	26	4	25	5	26	4	27	3
Cut-off	30	15	15	14	16	14	16	15	15	15	15
+25% Cut-off	30	3	27	3	27	4	26	3	27	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.	n	PCP		TCA		THC					
		-	+	-	+	-	+				
-50% Cut-off	30	30	0	30	0	30	0				
-25% Cut-off	30	26	4	25	5	26	4				
Cut-off	30	14	16	15	15	14	16				
+25% Cut-off	30	3	27	3	27	3	27				
+50% Cut-off	30	0	30	0	30	0	30				

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

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.

AMPHETAMINES (AMP)	AMP
d,l-Amphetamine sulfate	200
l-Amphetamine	25,000
d-Amphetamine	1,000
(±) 3,4-Methylenedioxyamphetamine	400
Maprotiline	50,000
Methoxyphenamine	6,000
Phentermine	800
BARBITURATES	**BAR**
Allobarbital	450
Amobarbital	3,000
Alphenol	300
Aprobarbital	450
Barbital	6,000
Butabarbital	150
Butalbital	6,000
Butethal	450
Cyclopentobarbital	25,000
5,5-Diphenylhydantoin	6,000
Pentobarbital	6,000
Phenobarbital	300
Secobarbital	300
Talbutal	30
BENZODIAZEPINES	**BZO**
Alprazolam	100
a-hydroxyalprazolam	1,500
Bromazepam	780
Chlordiazepoxide	780
Clobazam	200
Clonazepam	390
Clorazepate dipotassium	390
Delorazepam	780
Desalkylflurazepam	200
Diazepam	1,500
Estazolam	6,250
Flunitrazepam	200
(±) Lorazepam	3,100
RS-Lorazepam glucuronide	200
Midazolam	6,250
Nitrazepam	200
Norchlordiazepoxide	100
Nordiazepam	780
Oxazepam	300
Temazepam	100
Triazolam	3,100
BUPRENORPHINE	**BUP**
Buprenorphine	10
Buprenorphine 3-d-Glucuronide	50
Norbuprenorphine	50
3-d-Glucuronide	100
COCAINE	**COC**
Benzoylecgonine	300
Cocain HCl	200
Cocaethylene	12,500
Ecgonine HCl	30,000
METHADONE	**MTD**
Methadone	300
Doxylamine	100,000
METHAMPHETAMINE	**MET**
p-Hydroxymethamphetamine	25,000
d-Methamphetamine	1,000
l-Methamphetamine	12,500
(±) 3,4-Methylenedioxymethamphetamine	6,250
Mephentermine	50,000

ECSTASY	MDMA
(±) 3,4-Methylenedioxymethamphetamine HCl	500
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDE)	300
OPIATE, MORPHINE, HEROINE	**MOP**
Codeine	200
Ethylmorphine	6,000
Hydrocodone	50,000
Hydromorphone	3,000
Levorphanol	1,500
6-Monoacethylmorphine	400
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
MARIHUANA/CANNABIS	**THC**
Cannabinol	20,000
11-nor-Δ8- THC-9 COOH	30
11-nor-Δ9- THC-9 COOH	50
Δ8- THC	15,000
Δ9- THC	15,000
OPIATE, MORPHINE, HEROINE	**OPI**
Codeine	2,000
Ethylmorphine	3,000
Hydrocodone	50,000
Hydromorphone	12,500
Levorphanol	25,000
6-Monoacethylmorphine	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
PHENCYCLIDINE	**PCP**
Phencyclidine	25
4-Hydroxyphencyclidine	6,250
TRICYCLIC ANTIDEPRESSANTS	**TCA**
Amitriptyline	1,500
Clomipramine	50,000
Cyclobenzaprine	1,500
Desipramine	200
Doxepine	1,500
Imipramine	400
Maprotiline	1,500
Nordoxepine	400
Nortriptyline	1,000
Perphenazine	25,000
Promazine	3,000
Promethazine	25,000
Trimipramine	3,000

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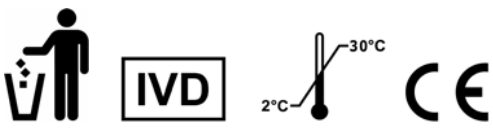

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for humane urinprøver

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Multi-5/3 Drug Panel	AMP,COC,MET,MOP,THC
- REF Z06502CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z06502B)
- REF Z06502B	Innhold: 1 Panel, individuelt pakket
Multi-5/4 Drug Panel	AMP,COC,MDMA,MOP,THC
- REF Z11504CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z11504B)
- REF Z11504B	Innhold: 1 Panel, individuelt pakket
Multi-5/6 Drug Panel	AMP,BZO,COC,MOP,THC
- REF Z06506CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z06506B)
- REF Z06506B	Innhold: 1 Panel, individuelt pakket
Multi-6 Drug Panel	BZO,COC,MET,MOP,MTD,THC
- REF Z98907CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z98907B)
- REF Z98907B	Innhold: 1 Panel, individuelt pakket
Multi-6/1 Drug Panel	AMP,BZO,COC,MET,MOP,THC
- REF Z03220CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z03220B)
- REF Z03220B	Innhold: 1 Panel, individuelt pakket
Multi-6/3 Drug Panel	BUP, BZO, COC, MTD, OPI, THC
- REF Z08930CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z08930B)
- REF Z08930B	Innhold: 1 Panel, individuelt pakket
Multi-6/4 Drug Panel	AMP,BUP,BZO,MET,MOP,THC
- REF Z08940CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z08940B)
- REF Z08940B	Innhold: 1 Panel, individuelt pakket
Multi-6/6 Drug Panel	BUP,COC,MET,MOP,MTD,THC
- REF Z13960CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z13960B)
- REF Z13960B	Innhold: 1 Panel, individuelt pakket
Multi-6/7 Drug Panel	BUP,BZO,COC,MOP,MTD,THC
- REF Z09970CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z09970B)
- REF Z09970B	Innhold: 1 Panel, individuelt pakket
Multi-6/10 Drug Panel	AMP,BZO,COC,MOP,MTD,THC
- REF Z11911CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z11911B)
- REF Z11911B	Innhold: 1 Panel, individuelt pakket
Multi-7 Drug Panel	AMP,BUP,BZO,COC,MTD,MOP,THC
- REF Z12730CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z12730B)
- REF Z12730B	Innhold: 1 Panel, individuelt pakket
Multi-10 Drug Panel	AMP,BAR,BZO,COC,MDMA,MET,MOP,MTD,TCA,THC
- REF Z06230CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z04230B)
- REF Z04231CE	Innhold: 10 Paneler, individuelt pakket (10x REF Z04230B)
- REF Z04230B	Innhold: 1 Panel, individuelt pakket
Multi-10/1 Drug Panel	AMP,BAR,BZO,BUP,COC,MDMA,MET,MOP,MTD,THC
- REF Z06235CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z05235B)
- REF Z06236CE	Innhold: 10 Paneler, individuelt pakket (10x REF Z05235B)
- REF Z05235B	Innhold: 1 panel, individually packed
Multi-10/2 Drug Panel	AMP,BAR,BZO,COC,MDMA,MOP,MTD,OPI,TCA,THC
- REF Z06102CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z06102B)
- REF Z06102B	Innhold: 1 Panel, individuelt pakket
Multi-10/3 Drug Panel	AMP, BZO,COC,MDMA,MOP,MTD,OPI,PCP,TCA,THC
- REF Z06103CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z06103B)
- REF Z06103B	Innhold: 1 Panel, individuelt pakket
Multi-10/4 Drug Panel	AMP,BAR,BUP,BZO,COC,MDMA,MET,MTD,OPI,THC
- REF Z06104CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z06104B)
- REF Z06104B	Innhold: 1 Panel, individuelt pakket
Multi-10/5 Drug Panel	AMP,BAR,BZO,BUP,COC,MET,MOP,MTD,TCA,THC
- REF Z06105CE	Innhold: 30 panels, individually packed (30x REF Z06105B)
- REF Z06105B	Innhold: 1 Panel, individuelt pakket
Multi-10/6 Drug Panel	AMP,BAR,BZO,COC,MET,MOP,MTD,PCP,TCA,THC
- REF Z06106CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z06106B)
- REF Z06106B	Innhold: 1 Panel, individuelt pakket
Multi-10/7 Drug Panel	AMP,BAR,BZO,COC,MET,MTD,OPI,PCP,TCA,THC
- REF Z06107CE	Innhold: 30 Paneler, individuelt pakket (30x REF Z06107B)
- REF Z06107B	Innhold: 1 Panel, individuelt pakket

Alle produktene inneholder et pakningsvedlegg!

Kun til in vitro diagnostisk bruk. Skal kun brukes av medisinsk fagpersonell. Kun til diagnostikk og terapeutisk overvåkning.

TILTENKT BRUK

"DIAQUICK" Multi-Drug Paneler (urin) er raske, lateral flytkromatografiske immunanalyser for samtidig, kvalitativ påvisning av følgende narkotiske stoffer og deres metabolitter:

Parameter	Kort	Kalibrator	Cut-off
Amfetamin	AMP	d-Amphetamin	1,000 ng/mL
Barbiturater	BAR	Secobarbital	300 ng/mL
Buprenorfin	BUP	Buprenorfin	10 ng/mL
Benzodiazepiner	BZO	Oxazepam	300 ng/mL
Kokain	COC	Benzoylecgonin	300 ng/mL
Ecstasy	MDMA	d,l Metylenedioxymetamfetamin	500 ng/mL
Metamfetamin	MET	d-Metamfetamin	1,000 ng/mL
Metadon	MTD	Metadon	300 ng/mL
Opiat, Morfin, Heroin	MOP	Morfin	300 ng/mL
Opiat, Morfin, Heroin	OPI	Morfin	2.000 ng/mL
Fensyklidin	PCP	Fensyklidin	25 ng/mL
Trisykliske antidepressiva	TCA	Nortriptylin	1,000 ng/mL
Marihuana/Cannabis	THC	11-nor-Δ9-THC-9-COOH	50 ng/mL

Denne testen vil oppdage andre beslektede forbindelser, vennligst se tabellen Analytisk spesifisitet i dette pakningsvedlegget. Denne analysen gir kun et foreløpig analytisk resultat. En mer spesifikk alternativ kjemisk fremgangsmåte må brukes for å få et bekreftet analytisk resultat. Gasskromatografi/massespektrometri (GC/MS) er den foretrukne bekreftende metode. Klinisk vurdering og profesjonelt skjønn skal anvendes for alle testresultater relatert til misbruksanalyser, særlig når de foreløpige resultatene er positive. Kun til in vitro diagnostisk bruk.

TEST PRINSIPP

"DIAQUICK" Multi-Drug Panels (urin) er immunanalyser basert på prinsippet om konkurrerende binding. Narkotika som kan være tilstede i urinprøven konkurrerer mot deres respektive narkotiske konjugat for bindingssteder på deres spesifikke antistoff. Under testing, vandrer urinprøven oppover med kapillæreffekt. Narkotika, hvis tilstede i urinprøven under cut-off konsentrasjon, vil det ikke mette bindingsstedene for sitt spesifikke antistoff belag på partiklene. Antistoffbelagte partikler vil da bli fanget opp av det immobiliserte stoffkonjugatet og en synlig farget linje vil dukke opp i testlinjeområdet på teststrimmelen for det spesifikke stoffet. Det dannes ingen farget linje i testlinjeområdet hvis stoffnivået er over cut-off konsentrasjonen, fordi de metter alle bindingsstedene til antistoffet belagt på partiklene. En urinprøve som tester positivt for narkotika, vil ikke generere en farget linje i det spesifikke testlinjeområdet på teststrimmelen på grunn av konkurrerende stoffer, men en urinprøve som tester negativt for narkotika eller en prøve som inneholder en stoffkonsentrasjon som er lavere enn cut-off verdien, vil generere en linje i testlinjeområdet. For å fungere som en prosedyrekontroll, vil det alltid vises en farget linje i kontrollinjeområdet, som indikerer at riktig prøvevolum er tilsatt og at fukttransport på membranen har foregått.

ADVARSLER OG FORHOLDSREGLER

- Kun for medisinsk og annen in vitro diagnostisk bruk. Ikke bruk etter utløpsdatoen.
- Testpanelet må oppbevares i den forseglede posen til det skal brukes.
- Alle prøver skal betraktes som potensielt farlige og håndteres på samme måte som smittefarlige materialer.
- Brukte testpaneler skal kasseres i henhold til statlige og lokale forskrifter

REAGENSER

Hver testlinje inneholder anti-narkotika monoklonalt antistoff fra mus og tilhørende protein-konjugater fra denne narkotikaen. Kontrollinjen inneholder geit anti-kanin-IgG polyklonale antistoffer og kanin IgG.

OPPBEVARING

"DIAQUICK" Multi-Drug Panelene kan oppbevares i kjøleskap eller ved romtemperatur (2-30 °C). Testpanelet er stabilt til og med utløpsdatoen som er trykt på den forseglede posen. Testpanelet må oppbevares i den forseglede posen til det skal brukes. MÅ IKKE FRYSES. Ikke bruk etter utløpsdatoen.

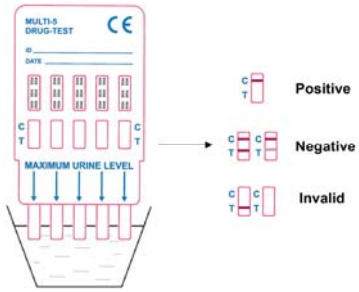
PRØVETAKING OG KLARGJØRING

Urinprøven må innhentes i en ren og tørr beholder. Urin samlet inn når som helst på dagen kan anvendes. Urinprøver med synlig utfelling bør sentrifugeres, filtreres eller få bunnfalle seg for å få klar prøve for testing. Urinprøver kan lagres ved 2-8°C i opptil 48 timer før analysering. For langvarig lagring, kan prøvene fryses og lagres under -20 °C. Frosne prøver må tines og blandes før testing.

ANALYSEPROSEDYRE

La testpanelet, urinprøven, og/eller kontrollene oppnå romtemperatur (15-30 °C) før testing.

1. Ta testpanelet ut av den forseglede posen og bruk det så snart som mulig.
2. Ta av beskyttelseshetten som er plugget på testpanelet. Med pilene pekende mot urinprøven, dypp testpanelet vertikalt i urinprøven for 10-15 sekunder. Ikke la urinprøven komme i kontakt med plastkassetten mens testenheten dyppes i urinprøven. Unngå nedsenkning av kassetten dypere enn merket med pilene på enheten, og unngå at testområdet kommer direkte i kontakt med prøven.
3. Sett beskyttelseshetten tilbake på testpanelet. Plasser testpanelet på et ikke-absorberende flatt underlag, start tidtakeren og vent på at den (de) røde linjen(e) skal vises. Avles resultatene etter 5 minutter. Ikke tolk resultater etter 10 minutter.



TOLKNING AV RESULTATER

NEGATIV: En farget linje i kontrollinjeområdet (C) og en farget linje i testlinjeområdet (T) for et bestemt narkotisk stoff indikerer et negativt resultat. Dette indikerer at konsentrasjonen for narkotiske stoffet i urinprøven er under angitt cut- off nivå for dette bestemte narkotika.

*MERK: Fargenyansen i testlinjeområdet (T) kan variere, men resultatet skal anses som negativet selv om det bare vises en svak rosa linje.

POSITIV: En farget linje i kontrollinjeområdet (C), men ingen linje i testlinjeområdet (T) for et bestemt narkotika indikerer et positivt resultat. Dette indikerer at konsentrasjonen av narkotikaen i urinprøven overstiger det angitte cut-off nivået.

UGYLDIG: Kontrollinjen vises ikke. Utilstrekkelig prøvevolum eller feil prosedyreteknikk er de mest sannsynlige årsakene til manglende kontrollinje. Gå gjennom prosedyren og gjenta testen med et nytt testpanel. Hvis problemet vedvarer, slutt å bruke loten umiddelbart og kontakt din lokale leverandør.

KVALITETSKONTROLL

En intern prosedyrekontroll er inkludert i testen. Den røde linjen som vises i kontrollinjeområdet (C), er en intern prosedyrekontroll. Det bekrefter tilstrekkelig prøvevolum, tilstrekkelig fukttransportering på membranen og riktig prosedyreteknikk. Kontroller følger ikke med dette kitet. Det anbefales imidlertid at positive og negative kontroller testes for god laboratoriepraksis, for å bekrefte testprosedyren og til å verifisere riktig testytelse.

BEGRENSNINGER

1. "DIAQUICK" Multi-Drug Paneler (urin) gir kun et foreløpig analytisk resultat. En mer spesifikk kjemisk metode må brukes for å få bekreftet resultatet. Gasskromatografi/massespektrometri (GC/GS) en den foretrukne bekreftende metode.
2. Det er mulig at tekniske eller prosedyrefeil, samt andre forstyrrende stoffer i urinprøven kan gi feilaktige resultater.
3. Forfalskningsmidler, slik som blekemiddel i urinprøver, kan gi feilaktige resultater uavhengig av den analytiske metoden som brukes. Hvis forfalskning mistenkes, bør testen gjentas med en annen urinprøve.
4. Et positivt resultat indikerer tilstedeværelse av det narkotiske stoffet eller dets metabolitter, men angir ikke nivået på rus, administrasjonsvei eller konsentrasjon i urin.

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5. Et negativt resultat indikerer nødvendigvis at urinen ikke inneholder narkotika. Negative resultater kan oppnås dersom narkotika er tilstede, men under cut-off nivået av testen.
6. "DIAQUICK" Multi-Drug Panels (urin) skiller ikke mellom narkotika misbruk og enkelte medisiner.
7. Et positivt resultat kan oppnås fra visse matvarer eller kosttilskudd.

YTELSE OG EGENSKAPER

NØYAKTIGHET

En side-ved-side-sammenligning ble gjennomført ved hjelp av "DIAQUICK" Multi-Drug Paneler (urin) og kommersielt tilgjengelige hurtigtester for påvisning av narkotika. Testene ble utført på 250 prøver. Presumptive positive resultater ble bekreftet ved GC/MS. Følgende resultater ble tabulert:

% samsvar med kommersielt kit

	Positivt samsvar	Negativt samsvar	Totalt samsvar
AMP	> 99.9 %	> 99.9 %	> 99.9 %
BAR	> 99.9 %	> 99.9 %	> 99.9 %
BUP	> 99.9 %	> 99.9 %	> 99.9 %
BZO	> 99.9 %	> 99.9 %	> 99.9 %
COC	> 99.9 %	> 99.9 %	> 99.9 %
THC	> 99.9 %	> 99.9 %	> 99.9 %
MTD	> 99.9 %	> 99.9 %	> 99.9 %
MET	> 99.9 %	> 99.9 %	> 99.9 %
MDMA	> 99.9 %	> 99.9 %	> 99.9 %
MOP	> 99.9 %	> 99.9 %	> 99.9 %
OPI	*	*	*
PCP	> 99.9 %	> 99.9 %	> 99.9 %
TCA	*	*	*

* MERK: Basert på GC/MS i stedet for kommersielt kit.

% Übereinstimmung mit GC/MS

	Positivt samsvar	Negativt samsvar	Totalt samsvar
AMP	98.4 %	98.4 %	98.4 %
BAR	97.3 %	99.3 %	98.4 %
BUP	99.2 %	> 99.9 %	99.6 %
BZO	98.4 %	99.2 %	98.8 %
COC	98.0 %	99.3 %	98.8 %
THC	> 99.9 %	99.1 %	99.6 %
MTD	99.1 %	98.6 %	98.8 %
MET	98.9 %	93.6 %	95.6 %
MDMA	96.2 %	97.5 %	96.8 %
MOP	96.3 %	95.7 %	96.0 %
OPI	94.3 %	91.3 %	92.8 %
PCP	95.1 %	94.6 %	94.8 %
TCA	94.8 %	89.6 %	92.0 %

ANALYTISK SENSITIVITET

En urinpool fri for narkotika ble tilsatt narkotikum med cut off verdier på ± 50% og ± 25% . Resultatene oppsummeres nedenfor:

% Cut-off	n	AMP		BAR		BUP		BZO		COC	
		-	+	-	+	-	+	-	+	-	+
- 50	30	30	0	30	0	30	0	30	0	30	0
- 25	30	27	3	27	3	26	4	27	3	26	4
Cut-off	30	14	16	16	14	14	16	15	15	15	15
+ 25	30	3	27	4	26	3	27	4	26	3	27
+ 50	30	0	30	0	30	0	30	0	30	0	30

% Cut-off	n	MTD		MET		MDMA		MOP		OPI	
		-	+	-	+	-	+	-	+	-	+
- 50	30	30	0	30	0	30	0	30	0	30	0
- 25	30	27	3	26	4	25	5	26	4	27	3
Cut-off	30	15	15	14	16	14	16	15	15	15	15
+ 25	30	3	27	3	27	4	26	3	27	4	26
+ 50	30	0	30	0	30	0	30	0	30	0	30

% Cut-off	n	PCP		TCA		THC					
		-	+	-	+	-	+				
- 50	30	30	0	30	0	30	0				
- 25	30	26	4	25	5	26	4				
Cut-off	30	14	16	15	15	14	16				
+ 25	30	3	27	3	27	3	27				
+ 50	30	0	30	0	30	0	30				

KRYSSREAKTIVITET

Det ble gjennomført en studie for å bestemme testens kryssreaktivitet med forbindelse i enten narkotikafri urin eller narkotikapositiv urin. Følgende forbindelser viste ingen kryssreaktivitet når testet med "DIAQUICK" Multi-Drug Paneler (urin) i en konsentrasjon på 100 µg/mL.

Forbindelser uten kryssreaktivitet:

Acetophenetidin	Cortison	Ketamin	d-Pseudoephedrin
N-Acetylprocainamid	Creatinin	Ketoprofen	Quinidin
Acetylsalicylsäure	Deoxycorticosteron	Labetalol	Quinin
Aminopyrin	Dextromethorphan	Loperamid	Salicylsäure
Amoxicillin	Diclofenac	Meprobamat	Serotonin
Ampicillin	Diflunisal	Methoxyphenamin	Sulfamethazin
l-Ascorbinsäure	Digoxin	Methylphenidat	Sulindac
Apomorphin	Diphenhydramin	Nalidixinsäure	Tetracyclin
Aspartam	Ethyl-p-aminobenzoat	Naproxen	Tetrahydrocortison
Atropin	β-Estradiol	Niacinamid	3-acetat
Benzilinäsure	Estron-3-sulfat	Nifedipin	Tetrahydrocortison
Benzoesäure	Erythromycin	Norethindron	Tetrahydrozolin
Bilirubin	Fenoprofen	Noscapin	Thiamin
d,l-Brompheniramin	Furosemid	d,l-Octopamin	Thioridazin
Koffein	Gentisinsäure	Oxalsäure	d,l-Tyrosin
Cannabidiol	Hämoglobin	Oxolinsäure	Tolbutamid
Chloralhydrat	Hydralazin	Oxymetazolin	Triamteren
Chloramphenicol	Hydrochlorothiazid	Papaverin	Trifluoperazin
Chlorothiazid	Hydrocortison	Penicillin-G	Trimethoprim
d,l-Chlorpheniramin	o-Hydroxyhippursäure	Perphenazin	d,l-Tryptophan
Chlorpromazin	3-Hydroxytyramin	Phenelzin	Urinsäure
Cholesterol	d,l-Isoproterenol	Prednison	Verapamil
Clonidin	Isoxsuprin	d,l-Propanolol	Zomepirac

ANALYTISK SPESIFISITET

Tabellene nedenfor viser konsentrasjonen av stoffer (ng/mL) som blir funnet positive i urin av "DIAQUICK" Multi-Drug Panels (urin) på 5 minutter.

AMFETAMIN (AMP)	AMP	ECSTASY	MDMA
d,l-Amfetaminsulfat	200	(±) 3,4-Metylendioxymetamfetamin HCl	500
l-Amfetamin	25 000	(±) 3,4-Metylendioxyamfetamin HCl	3 000
d- Amfetamin	1 000	(±) 3,4-Metylendioxyetylmetamftamin	300
(±) 3,4-Metylendioxyamfetamin	400	**OPIAT, MORFIN, HEROIN**	**MOP**
Matprotilin	50 000	Kodein	200
Metoxyfenamin	6 000	Etylmorfin	6 000
Fentermin	800	Hydrokodon	50 000
BARBITURATER	**BAR**	Hydromorfon	3 000
Allobarbital	450	Levorfanol	1 500
Amobarbital	3 000	6-Monacetylmorfin	400
Alfenol	300	Morfin 3-β-d-glukuronid	800
Aprobarbital	450	Morfin	300
Barbital	6 000	Norkodein	6 000
Butabarbital	150	Normorfon	50 000
Butalbital	6 000	Oksykodon	30 000
Butetal	450	Oksymorfon	50 000
Syklopentobarbital	25 000	Prokain	15 000
5,5-Difenylhydantoin	6 000	Tebain	6 000
Pentobarbital	6 000	**MARIHUANA/CANNABIS**	**THC**
Fenobarbital	300	Cannabinol	20 000
Secobarbital	300	11-nor-Δ8- THC-9 COOH	30
Talbutal	30	11-nor-Δ9- THC-9 COOH	50
BENZODIAZEPINER	**BZO**	Δ8- THC	15 000
Alprazolam	100	Δ9- THC	15 000
a-hydroxyalprazolam	1 500	**OPIAT, MORFIN, HEROIN**	**OPI**
Bromazepam	780	Kodein	2 000
Norklordiazepokside	780	Etylmorfin	3 000
Klobazam	200	Hydrokodon	50 000
Klonazepam	390	Hydromorfon	12 500
Klorazepatdekalium	390	Levorfanol	25 000
Delorazepam	780	6-Monacetylmorfin	3 000
Desalkylflurazepam	200	Morfin 3-β-d-glukuronid	2 000
Diazepam	1 500	Morfin	2 000
Estazolam	6 250	Norkodein	25 000
Flunitrazepam	200	Normorfon	50 000
(±) Lorazepam	3 100	Oksykodon	25 000
RS-Lorazepamglukuronid	200	Oksymorfon	25 000
Midazolam	6 250	Prokain	50 000
Nitrazepam	200	Tebain	25 000
Norklordiazepoksid	100	**FENSYKLIDIN (PCP)**	**PCP**
Nordiazepam	780	Fensyklidin	25
Oxazepam	300	4-Hydroxyfensyklidin	6 250
Temazepam	100	**TRISYKLISKE ANTIDEPRESSIVA**	**TCA**
Triazolam	3 100	Amitriptylin	1 500
BUPRENORFIN	**BUP**	Klomipramin	50 000
Buprenorfin	10	Sykobenzaprin	1 500
Buprenorfin 3-d-Glukuronid	50	Desipramin	200
Norbuprenorfin	50	Doksepin	1 500
3-d-Glukuronid	100	Imipramin	400
KOKAIN	**COC**	Matprotilin	1 500
Benzoylekgonin	300	Nordoxepin	400
Kokain HCl	200	Nortriptylin	1 000
Kokaetylen	12 500	Perfenazin	25 000
Ekgonin HCl	30 000	Promazin	3 000
METADON	**MTD**	Prometazin	25 000
Metadon	300	Trimipramin	3 000
Doxylamin	100 000		
METAMFETAMIN	**MET**		
p-Hydroksymetamfetamin	25 000		
d-Metamfetamin	1 000		
l-Metamfetamin	12 500		
(±) 3,4-Metylendioxymetamfetamin	6 250		
Mefentermin	50 000		

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