MULTI DRUGS TEST 10 parameters

For *in Vitro* diagnostic use only

Immunochromatographic test for the qualitative detection of drugs and its major metabolites in human urine

INTENDED USE

The Multi Drugs Test Mascia Brunelli is a lateral flow, one-step panel immunoassay for the qualitative detection of multiple drug metabolites in human urine at the following cut-off concentrations.

DRUGS	TYPE	CUT-OFF
BZD	- Benzodiazepines	300 ng/ml
COC	- Benzoilecgonine / Cocaine	300 ng/ml
MET	- Methamphetamines	1000 ng/ml
MTD	- Methadone	300 ng/ml
MOR	- Morfine	300 ng/ml
THC	- 11-nor-Δ9-THC-9-COOH/ Tetrahydrocannabinol	50 ng/ml
AMP	- Amphetamine	1000 ng/ml
MDMA	- Ectasy	500 ng/ml
BAR	- Barbitrurate	300 ng/ml
TCA	- Tricyclic Antidepressants / Nortriptiline	1000 ng/ml

This product is used to obtain a visual, qualitative result and is intended for use by drug testing professionals in drug testing programs. The assay should not be used without proper supervision and is not intended for over the counter sale to lay persons.

This assay provides 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) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

Urine based screened tests for drugs of abuse of abuse range from simple immunoassay tests to complex analytical procedures. The speed of immunoassays has made them the most widely accepted method for screening urine for drugs of abuse.

The Multi Drug Screen Panel is based on the principle of highly specific immunochemical reactions of antibodies which are used for the analysis of specific compounds in biological fluids. The drug screen panel is rapid, visual, competitive panel immunoassays that can be used for the simultaneous, qualitative detection of multiple drug metabolites in human urine

PRINCIPLE OF THE METHOD

The Multi Drugs Test Mascia Brunelli is a one-step Test immunoassay in which a chemically labeled drug (drug conjugate) competes with the drug which may be present in urine for limited antibody binding sites. The test device contains a membrane strip which was pre-coated with drug-protein conjugate on the test line. A colored monoclonal antibody colloidal gold conjugate pad is placed at the end closing to the sample pad of the membrane.The colored antibody-colloidal gold conjugate moves along with urine, chromatographically by the capillary action, across the membrane, in the absence of drug in the urine, the colored antibody colloidal gold conjugate attaches to the drug conjugate on the test region to form a visible line as the antibody/drug conjugate complexes. Therefore, the formation of a visible precipitant in the test region occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with the drug conjugate on the test region for the limited antibody sites. When a sufficient amount of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug conjugate zone on the test region. Therefore, absence of the color line on the test region indicates a positive result.

A control or reference line with a different antigen/antibody reaction is also added to the immunoassay membrane strip to indicate that the test is performed properly. This control line should always appear regardless of the presence of drug or metabolite. This means that negative urine will produce two colored lines, and positive urine will produce only one line. The presence of this colored line in the control region also serves as verification that 1) sufficient volume has been added, and 2) that proper flow was obtained.

STORAGE AND STABILITY

The test kit is to be stored refrigerated or at room temperature (*+4*°C - +30°C) in the sealed pouch for the duration of the shelf life. If test kit is refrigerated, it should be brought to room temperature before use.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Avoid cross contamination of urine samples by using a new urine specimen container.
3. Urine specimens are potentially infectious. Proper handling and disposal methods should be established according to good laboratory practices.
4. Do not eat or drink or smoke while handling specimen in the laboratory.
5. The device should remain in its original sealed pouch until ready for use.
6. Do not use the test if the pouch is damaged or the seal is broken.
7. Do not use the test kit after the expiration date.

MATERIALS PROVIDED

Multi DrugsTest kit contains the following items to perform the assay:

1. Individually wrapped test devices which include one disposable pipette each. Each test device contains 10 membranes cards coated with drug conjugates and a colloidal gold conjugate pads coated with different monoclonal antibodies
2. Instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Clock or timer

LIMITATIONS

- The test is designed for use with unadulterated human urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine samples may interfere with the test and cause erroneous results.

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- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, the test should be repeated with a new sample.
- A positive test result does not provide any indication of the level of intoxication or urinary concentration.
- The test result read after 10 minutes may not be consistent with the original reading obtained within the 10-minute reading period..

QUALITY CONTROL

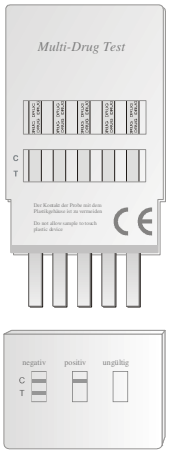
Good laboratory practice recommends the use of control materials to ensure proper kit performance. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

SPECIMEN COLLECTION AND HANDLING

1. The Drug Multi Test Card is formulated for use with urine specimens.
2. Fresh urine does not require any special handling or pretreatment.
3. Specimens should be collected in a clean glass or plastic container.
4. If testing will not be performed immediately, specimens should be refrigerated.
5. Specimens should be brought to room temperature before testing
6. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying

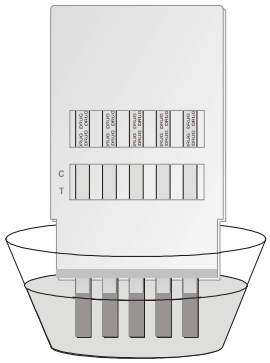
PROCEURE OF THE TEST

Test device, patient's samples, and controls should be brought to room temperature (+20℃ - +30℃) prior to testing. Do not open pouches until ready to perform the assay.



1. Remove the test device from its protective pouch and label the device with patient identification.
2. Dip the test device into the urine sample for at least 10 seconds or dispense 3 / 4 drops into the sample well with the dropper enclosed. Be aware that the urine does not go beyond the part of the test that is marked with MAX. If the urine comes into direct contact with the open test window, the test gets invalid.

1. Please read the result after **5minutes** as follow



INTERPRETATION OF RESULTS

1. As the test kit begins to work, a purple band will appear at the result window to show that the Control Line (indicated as letter "C" on the cassette) is working properly.
2. The lower section of the result window indicates the test results. If another purple band appears at the result window, this band is Test Band (indicated as letter "T" on the cassette).**Negative**

The appearance of two purple bands within the result window indicates a negative test result. No drug above the cut-off level has been detected. The color of the Test band may be lighter or darker than that of the Control Band.

Note: A purple band in the T row of the result window (no matter a faint or obvious band), visible at 10 minutes, indicates that the test result is negative.

Positive

Only one colored line appears in the control region (C). The absence of a test line indicates a positive result.

Important Note

Not all parameters have to be positive at the same time in one test. Please look at every parameter individually and mark the results of every single parameter (e.g. MTD-neg & BZD-pos).

Invalid

No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and should be repeated. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Control the procedure and repeat the test with a new device, if the problem persists, contact the producer for the technical attendance.

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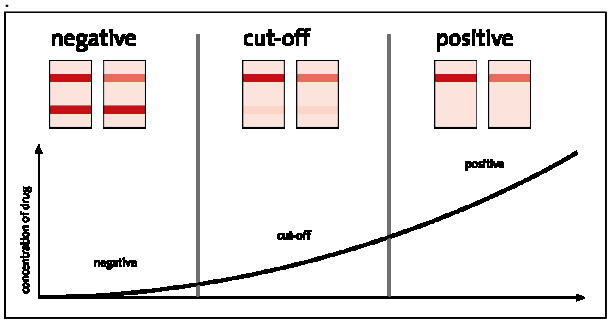

EXPECTED VAI.UES

Droghe-Multi Test Card is a qualitative assay. The amount of drugs and metabolites present in the urine cannot be estimated by the assay. The assay results distinguish positive from negative samples.

PERFORMANCE CHARACTERISTICS

Accuracy

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The **Multi Drugs Test Mascia Brunelli** was evaluated in comparison to a commercially available immunoassay. Fifty (50) urine samples, collected from presumed non-user volunteers, have been tested by both procedures with 100% agreement.

Precision
The precision of the ***Multi Drugs Test Mascia Brunelli*** was determined by conducting the test with spiked blind controls. The control at a concentration of 50% below the cut-off level will give a negative result and the control at a concentration of 200% above the cut-off level will give a positive result.

Specificity
The specificity for the drug screen assays with each other Drug Screen Test was tested by adding various drugs and drug metabolites and other compounds that are likely to be present in urine to the testing sample. All compounds were prepared in drug-free normal human urine.

The following structurally related compounds produced positive results with the specified drug screen assays when tested at levels equal to or greater than the concentrations listed below.

Compound	Concentration (ng/ml)
Amphetamine	
D-Amfetamina	1000
L-Amfetamina	>50000
D-Metamfetamina	>20000
L- Metamfetamina	>20000
3,4- Metilendiossiamfetamina (MDA)	2400
3,4-Metilendiossi-metamfetamina (MDMA)	>20000
3,4-Metilendiossietilamfetamina (MDEA)	>100000
Para-metossiamfetamina (PMA)	1000
Bar	
Alfenal	1000
Benzodiazepines	
Oxazepam	300
Alprazolam	125
Bromazepam	500
Clordiazeposside	6250
Clobazam	150
Clonazepam	16000
Clorazepato	4000
Delorazepam	1200
Desalchilflurazepam	625
Diazepam	600
Estazolam	4000
Fentanyl	>100000
Flunitrazepam	600
Flurazepam	>10000
α-Idrossialprazolam	100000
Lorazepam	800
Lormetazepam	1000
Medazepam	>100000
Midazolam	6250
Nitrazepam	50000
Nordiazepam	300
Prazepam	12500
Temazepam	2500
Tetrazepam	1000
Cocaine	
Benzoilecgonina	300
Cocaina	1000
Ecgonina	>40000
Ecgonina Metil Estere	>100000
MDMA (Ectasy)	
3,4-Metilendiossi-metamfetamina (MDMA)	1000
3,4-Metilendiossiamfetamina (MDA)	2000
3,4-Metilendiossietilamfetamina (MDEA)	600
d-Amfetamina	>100000
d-Metamfetamina	100000
l-Metamfetamina	>100000
Metadon and Derivates	
Metadone	300
Metadolo	1000

Compound	Concentration (ng/ml)
Metamfphtamine	
D-Metamfetamina	1000
D-Amfetamina	>40000
Clorochina	10000
(+/-)-Efedrina	>100000
L-Metamfetamina	15000
3,4-Metilendiossiamfetamina(MDA)	>10000
3,4-Metilendiossimetamfetamina(MDMA)	2000
3,4-Metilendiossietilamfetamina(MDEA)	20000
Procaina	100000
Morfine	
Morfine	300
Codeine	300
Diacetilmorfina (Eroina)	300
Etilmorfina	300
Idromorfone	1500
Idrocodone	1500
Merperidina	>100000
6-Monoacetilmorfina	300
Morfina-3- β-d-glucuronide	6000
Ossicodone	>20000
Ossimorfone	>20000
Prometazina	>250000
Rifampicina	25000
Tebaina	25000
Trimipramina	>20000
TCA	
Nortriptilina	1000
Amitriptilina	1000
Clorpromazina	3500
Clomipramina	10000
Ciclobenzaprina	1500
Desipramina	500
Difenildramina	20000
Dossepina	1000
Imipramina	800
Nordossepina	1000
Opipramolo	4000
Protriptilina	3000
Dossepina	1000
Perfenazina	25000
Promazina	200
Prometazina	40000
Protriptilina	3000
Trimipramina	2500
THC and Derivates	
11-nor-Δ8-THC-9-COOH	50
11-nor-Δ9-THC-9-COOH	50
11-idrossi-Δ9-Tetraidrocannabinolo	>100000
Δ8- Tetraidrocannabinolo	15000
Δ9- Tetraidrocannabinolo	15000

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2-Etilidene-1,5-Dimetil-3,3-Difenilpirolidina (EDDP)	>40000	Cannabinolo	20000
Dossilamina	>40000	Cannabidiolo	>100000
		L-Metamfetamina	15000

REFERENCES

1. Urine Testing for Drugs of Abuse, National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Ambre, J.J. Anal. Toxicol. 9: 241-5, 1985.
3. Norbert W. Tietz, Textbook of Clinical Chemistry, W.B. Saunders Company, p. 1735,1986.
4. R.C. Baselt, Disposition of Toxic Drugs and Chemicals in Man, 2 and ED, Biomedical Publ, Davis, CA., p. 488,1982.

IVD	In Vitro Diagnostic Medical Device	LOT	Batch code (EXXX)
	Consult Instructions for Use	REF	Catalogue number
	Keep dry	NON STERILE	Non-sterile
	Temperature limitation		Manufacturer
	Use By (year/month)		Do not reuse
	Fragile, handle with care		Keep away from heat

CONTENTS

10 x 10 Tests	**Cod. VU85010**
Multi DrugsTest Device (10 test)	10 items
Instruction for use	1 item

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