Package Insert

OneSecond Multi-Dip Test

Cat.-No.: 0270020 - 0272099 **IVD**

Intended Use

The OneSecond Multi-Dip Test is a rapid and qualitative immunoassay for the qualitative detection of drugs and drug metabolites as well as for the semi-quantitative detection of adulteration parameters in human urine.
Up to 16 parameters can be detected simultaneously.
The test is intended for screening in professional institutions, clinical laboratories, drug clinics, correctional facilities and for occupational health services. It should not be performed without close observation and is to be used only for professional in vitro diagnostics.

Summary

The following parameters can be determined simultaneously in various combinations:

Parameters (Drugs)	Abbreviation	Cut-off
Amphetamine	AMP	1000 ng/ml
Amphetamine 500	AMP 500	500 ng/ml
Amphetamine 300	AMP 300	300 ng/ml
Barbiturate	BAR	300 ng/ml
Benzodiazepine	BZD	300 ng/ml
Buprenorphine	BUP	10 ng/ml
Cannabinoids	THC	50 ng/ml
Cannabinoids 25	THC 25	25 ng/ml
Cotinine	COT	200 ng/ml
Ecstasy	MDMA	500 ng/ml
EDDP	EDDP	100 ng/ml
ETG	ETG	500 ng/ml
Fentanyl	FYL	20 ng/ml
Ketamine	KET	1000 ng/ml
Cocaine 300	COC	300 ng/ml
Cocaine 150	COC 150	1500 ng/ml
Methadone	MTD	300 ng/ml
Methamphetamine	MET	1000 ng/ml
Methamphetamine 500	MET 500	500 ng/ml
Methaqualon	MQL	300 ng/ml
Methylphendiate	MPD	1000 ng/ml
Morphine	MOR(MOP)	300 ng/ml
Opiate 2000	OPI 2000	2000 ng/ml
Oxycodone	OXY	100 ng/ml
Phencyclidine	PCP	25 ng/ml
Pregabalin	PFG	2000 ng/ml
Propoxyphene	PPX	300 ng/ml
Spice	K2	50 ng/ml
Tramadol	TRA	100 ng/ml
Tricyclic Antidepressant	TCA	1000 ng/ml
Zopiclone	ZOP	50 ng/ml

Parameters (Adulteration)	Abbreviation
Creatinin	CR
Gluteraldehyde	GL
Nitrite	NIT
Oxidants	OX
pH	PH
Specific Weight	SG

Other parameters on request.

Materials

10 OneSecond Multi-Dip Tests
10 Urine Cups
1 Documentation Pad
1 Colorchart for evaluation of adulteration parameters (if integrated)
1 Package Insert

Additionally recommended material

1. Timer
2. Disposable Gloves

Storage and stability

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Specimen collection

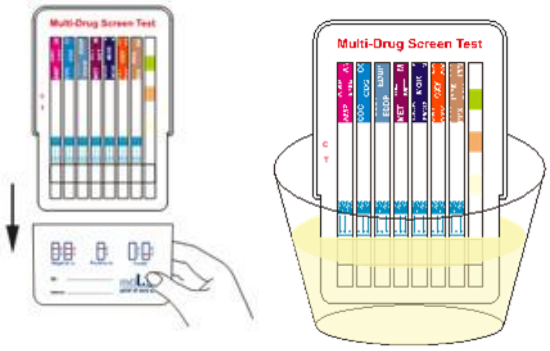
The OneSecond Multi-Dip Test is used for the examination of urine samples. The urine sample does not require any pretreatment. Bleach and other additives can produce false results. If additives are suspected, the semi-quantitative determination of adulteration parameters can provide confirmation of contamination.

Storage and stability of the urine sample

The urine specimen should be tested promptly (1 - 1½ h after collection), preferably on the day of collection.
Urine specimens can be stored at 2 - 8 °C for up to 48 hours.
For longer storage, freeze the specimens (-20 °C).
Before use, bring the urine specimen to room temperature (15 - 30 °C) and mix well.

Directions for use

1. Bring cooled sample and materials to room temperature.
2. Open the pouch and remove the Multi-Dip Test.
   Use the test immediately.
3. Label the protective cap with the ID number and date.

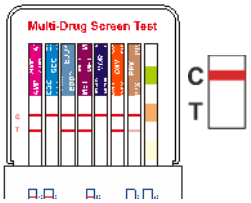


4. Remove the protective cap. Immerse the test cassette vertically in the direction of the arrow in the urine for at least 1 second. The specimen collection window should be completely immersed.
   If there is not enough sample material for this, leave the test cassette in the sample for approx. 20 seconds. Alternatively, the test cassette can remain in the urine sample until the results are read.
5. Replace the protective cap and place the OneSecond Multi-Dip Test on a clean flat surface.
6. Read the result of the **adulteration parameters** (if integrated in the test) after **3 - 5 minutes**. Compare the color change of the adulteration parameters with the enclosed color scale.
   Read the result of the **drug parameters** after **5 minutes**.
   The result remains stable for 10 minutes. After this time, a change in the lines is possible. The test should no longer be read or evaluated.

Interpretation of results

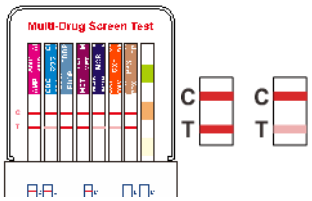
The identification of the parameters is indicated by the label in the result window. The arrangement of the parameters can be different for the different configurations.

Positive



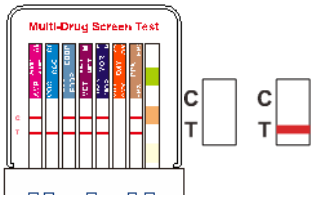
If only one colored line appears in the control zone "C" and none in the test zone "T", the test result is positive. A positive result means that the drug concentration in the urine sample is higher than the designated cut-off of the specific drug parameter.
In our example image, these are the parameters: COC/MOR

Negative



If two colored lines appear, one in the control zone "C" and another in the test zone "T", the test result is negative. The intensity of the test line "T" can vary. Any sign of a line should be considered a negative result.

Invalid



If no line appears in control zone "C", the test is invalid in any case.
The test must be repeated with a new test. The control line indicates the correct execution and function of the test.
In our example image, these are the parameters: COC/OXY

Adulteration parameters
The semi-quantitative result is determined by comparing the color change of the adulteration parameters with the enclosed color scale.

Limitations drug parameters

1. The OneSecond Multi-Dip Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, 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 does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

Limitations adulteration parameters

The included adulteration parameters are to be used as an aid in identifying abnormal urine specimens.

Creatinine: Normal creatinine levels range from 20 to 350 mg/dl. Under rare conditions, such as certain kidney diseases, dilute urine shows up.
Nitrite: Nitrite is not a normal component of human urine. If nitrite is detected in urine, it may indicate a urinary tract or bacterial infection. Nitrite levels > 20 mg/dl can cause false positive glutaraldehyde results.
Glutaraldehyde: Glutaraldehyde is not normally found in urine. Some metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets), may affect test results.
Specific weight : Elevated levels of protein in the urine may be the cause of abnormally high specific weight values.
Oxidants / PCC: Normal human urine should not contain oxidants or PCC. High antioxidant concentrations, such as ascorbic acid, can lead to false negative results.

Expected values

A negative result indicates that the drug concentration in urine is below the detection limit of the corresponding parameter.
A positive result indicates that the drug concentration in urine is above the detection limit of the corresponding parameter.

Precaution

1. For professional use in in-vitro diagnostics only.
2. Avoid cross-contamination by using a new urine collection cup for each urine specimen.
3. Do not use the test if the pouch is torn or perforated.
4. Do not use the test after the expiration date.
5. Do not open the pouch until immediately before using the test.
6. Prolonged contact with high humidity may affect test performance.
7. Materials that have come in contact with specimens may be infectious. Handle and dispose of all specimens and materials properly. Avoid skin contact.
8. Dispose of the specimen material and all used test components as potentially infectious material. Observe the local official regulations for disposal.

Test principle drug parameters

The OneSecond Multi-Dip Test is a rapid chromatographic immunoassay based on the principle of antibody-antigen binding. Drugs or drugs present in the urine sample compete against the drug conjugates for binding sites on the antibodies. During testing, a urine sample flows through the test membrane by capillary action. If the concentration of the drug in the urine sample is below the cut-off concentration, the binding sites of the antibody-coated particles on the test membrane are not saturated. The antibody-coated particles are then bound by immobilized conjugates forming a visible red line in the test area. If the drugs bind to the anti-drug antibody binding sites, no red line is formed in the test area. A positive urine specimen will not produce a red line in the test area, while a negative urine specimen will produce a red line in the test area. For procedural control, a red line always appears in the control area if the test was performed correctly

Test principle adulteration parameters

The test is based on the chemical reaction between the chemical reagent on the test pad and the urine sample, which results in a color change on the test pad.
3 - 5 minutes after activation of the reagent test pads by the urine sample, the color that appears on the pad can be compared with the enclosed color scale. The color comparison provides a semi-quantitative value which can help in the evaluation of the urine sample.

Active ingredients

The OneSecond Multi-Dip Test contains mouse monoclonal anti-drug antibody particles and drug protein conjugates applied to the membrane. A goat antibody is used to establish the control line. All reagents necessary for the test are included on the test membrane. No additional reagents are required.

Performance characteristics

Sensitivity, Specificity and Accuracy

Further notes in comparison to GC/MS are available on request.

Notes on urine adulteration

Please note that it may be in the patient's interest to manipulate the urine, e.g. by adding chemical substance ends. Adulteration tests can be used as a control for this purpose. The safest way to check for adulteration is to collect the specimen under supervision.

Quality control

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms adequate membrane wicking. 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.

Quality assurance

This product is manufactured for möLab according to the rules of GMP with quality management DIN EN ISO 9001 and DIN EN ISO 13485. möLab monitors this product with its own quality management DIN EN ISO 13485. It is subject to the EDMA classification and monitoring system and is placed on the market in accordance with Directive 98/79/EC..

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Index of symbols

	Consult instruction for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use of package is damaged				

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