

INTEX[®]-Drug test

Instructions for use

Rapid test for the detection of drugs of abuse in urine

Amphetamine	Methadone
Barbiturates	Methamphetamine
Benzodiazepines	Opiates (Morphine, Heroine, Codeine)
Buprenorphine	TCA (Tricyclic Antidepressants)
Cocaine	THC (Cannabinoids)
MDMA (Ecstasy)	

1 INTENDED USE

The INTEX[®]-Drug test Device is a lateral flow, one-step immunoassay for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepine, Cocaine, MDMA, Methadone, Methamphetamine, Opiates, TCA or THC in human urine.

2 TEST PRINCIPLE

The INTEX[®]-Drug test Device is a competitive immunoassay for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, MDMA, Methadone, Methamphetamine, Opiates, TCA or THC. The detection limits of the test are 300 ng/ml or 1000 ng/ml.

The INTEX[®]-Drug test Device uses highly-specific antigen-antibody reactions for the detection of drugs in human urine.

The test is interpreted visually and provides a qualitative result. In case there is no drug in the urine (non-consumer) two red lines (test- and control-line) appear at the reaction zone of the device. If there is the according drug in the urine sample (consumer) only one control-line appears at the reaction zone.

Drug type	Drug metabolites	Detection limit (cut-off)
Amphetamine	Amphetamine	1000 ng/ml
Barbiturates	Secobarbital	300 ng/ml
Benzodiazepines	Oxazepam	300 ng/ml
Buprenorphine		10 ng/ml
Cocaine/-metabolites	Benzoyllecgonin	300 ng/ml
MDMA (Ecstasy)	(+/-) 3,4 Metylen-dioxy-methamphetamin	1000 ng/ml
Methadone	Methadone	300 ng/ml
Methamphetamine	Methamphetamine	1000 ng/ml
Opiates	Morphine, Heroine, Codeine	300 ng/ml
TCA (Tricyclic Antidepressants)	Nortriptylin	1000 ng/ml
THC	11-nor- Δ -9-Tetrahydrocannabinol	50 ng/ml

The cut-off describes the sensitivity of the drug test. It describes the drug concentration at which the test line starts to disappear and is thus the limit to decide whether a drug is regarded as being detected and tested positive. Depending on the application it is useful to have a high or low detection limit (cut-off) to enable an easier interpretation of the result. This is explained by the following example: If the test is very sensitive it might appear that harmless opioids of poppy-pastries are detected. Common abuse of opium would lead to a much higher concentration in the urine. Thus, the tests should be more insensitive to detect the drug consume on the one hand and to avoid the false positive results on the other hand.

3 RELEVANT INFORMATION

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 Substance Abuse and Mental Services Administration (SAMSHA). Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

This product can be used as an aid to initiate or attend therapeutic treatments by physicians. Each device is designed for professional and in-vitro-diagnostic use. The assay should not be used without proper supervision and is not intended for over the counter sale to lay persons.

4 BASICS

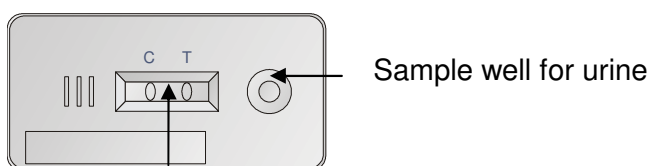
Methods of Examination of specimens range from simple immune-chemical to complex analytical methods. The INTEX[®]-Drug test immunoassays are acknowledged for these examinations because of their short reaction-time and high sensitivity.

CUT-OFF

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SET-UP FOR THE TEST DEVICE

The plastic case of the test cassette encloses one test strip. At the right end of the strip there is the sample well and at the left part there is the opening of the reaction zone. At the reaction zone you find the test (T) and the control (C) zone. The labelling next to the reaction zone marks the test and control zone. Because the strip encloses in a plastic case you can only imagine its position by the openings in the case.



Reaction zone with the test- (T) and the control- (C) zone (with ellipses marked)

5 PACKAGE CONTENT

- 10 Individually wrapped test devices
- 1 Disposable pipette
- 1 Instruction sheet

6 ADDITIONALLY NEEDED MATERIAL

- Specimen collection container
- Timer

7 STORAGE AND STABILITY

The INTEX[®]-Drug test is to be stored refrigerated or at room temperature (2-30 °C) in the sealed pouch for the duration of the shelf life.

8 PRECAUTIONS

- *For professional In Vitro use only!*
- *Use only once!*
- *Do not use more than the required amount of liquid.*
- *Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.*
- *Do not touch the reaction zone of the device to avoid contamination.*
- *Do not spill the samples into the reaction zone.*
- *Use only urine as liquid and no other one instead.*
- *Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.*
- *Do not use the cassette after expiration date.*
- *Use test right after unwrapping because it is humidity-sensitive!*
- *Therefore do not use the test after damage of the packaging foil!*
- *Please be aware of the developing time of the test before evaluation.*
- *Please take the specificity and the cross reactivity into account for evaluation.*
- *Store and transport the test device always at the stated temperature.*
- *The used test should be discarded according to local regulations.*

9 SPECIMEN COLLECTION AND HANDLING

Collect the urine specimen in a clean and dry collection container. Ensure that a sufficient quantity of the specimen is collected.

The INTEX[®]-Drug test devices are formulated for use with urine specimens. Fresh urine does not require any special handling or pre-treatment. The test of the urine specimens should be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may be refrigerated at 2-8 °C for two days, or frozen at -20 °C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed, equilibrated to room temperature, and mixed thoroughly prior to testing.

NOTE: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

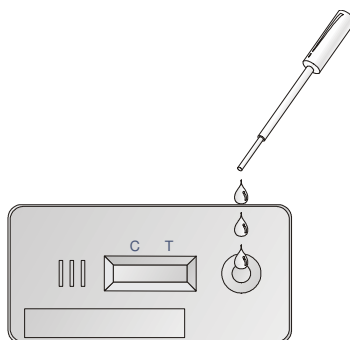
10 LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only. Due to too low specific weight (e.g. absence of ions) in other mediums it might be possible, that false results occur.
- A positive result with any of the tests indicates the presence of a drug/metabolite in urine only, and does not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances and factors not listed may interfere with the test and cause false results. See chapter "Specificity" for lists of substances that will produce positive results, or that do not interfere with test performance.
- If it is suspected that the samples have been mislabelled or tampered with, a new specimen should be collected and the test should be repeated.

11 TEST PROCEDURE

The test should be performed immediately after opening the protective pouch, because the test is humidity-sensitive. Refrigerated cassettes should be brought to room temperature (15-30°C) before opening to avoid condensation of moisture on the test. Refrigerated Patient's samples and controls should be brought to room temperature (15-30°C) prior to testing. Ensure that a sufficient quantity of the specimen has been collected.

1. Open the pouch and remove the cassette. Once opened, the cassette must be used immediately.
2. Draw the urine sample to the line marked on the pipette.
3. Dispense 3 drops (120-150 µl) into the sample well. Use a separate pipette and device for each sample or control. Start the timer.
4. **Caution:** If the urine directly touches the reaction zone, the test gets invalid!



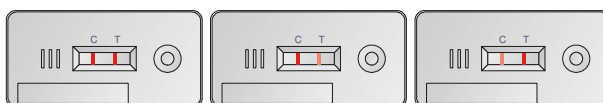
5. At the end of five to eight minutes read the result. Do not interpret the result later than 8 minutes after starting the assay.

12 INTERPRETATION OF RESULTS

For interpretation the reaction zone is regarded. One or two red lines will appear there.

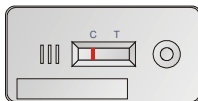
Negative Result:

Two coloured lines appear. The line in the test zone (T) is the drug line; the line in the control zone (C) is the control line, which is used to indicate proper performance of the strip. The colour intensity of the test line may be weaker or stronger than that of the control line.



Positive Result:

Only one red coloured line appears in the control zone (C). The absence of a red test line indicates a positive result. Keep the sample for further confirmation of the result.



NOTE:

A very faint line in the test zone indicates that the drug in the sample is near the cut-off level of the test. These samples should be re-tested or confirmed with a more specific method before a positive determination is made.

Invalid Result:

No line appears in the control zone (C). Under no circumstances should a positive sample be identified until the control line forms. Repeat the assay with a new test device. Pay special attention to the required amount of liquid and reaction time. If problems persist, contact your manufacturer.



13 QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. For testing the positive and negative controls are used in the same way as urine specimen.

14 ANALYTICAL CHARACTERISTICS

The accuracy and the sensitivity of the INTEX[®]-Drug tests were analyzed and compared to other commercially available drug tests. Thereby each INTEX[®]-Drug was proven to have a very high accuracy and sensitivity. The cut-off of each test was chosen according the recommendation of the NIDA (National Institute of Drug Abuse) and was confirmed by several test runs. The cut-off values are listed below.

The specificity of the INTEX[®]-Drug test Device was tested with the substances listed below, all of which can be found in a normal urine specimen. These substances were added to normal drug free urine.

The following compounds with a similar chemical structure yield a positive result at the specified concentration:

INTEX[®]-Drug test Amphetamine

Substance	Concentration (ng/ml)
D-Amphetamine	1'000
L-Amphetamine	10'000
(+/-)-3,4-Methylen-dioxyamphetamine (MDA)	5'000

INTEX[®]-Drug test Barbiturates

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
Secobarbital	300	Butabarbital	300
Allobarbital	1'000	Butalbital	2'000
Alphenal	300	Butethal	300
Amobarbital	1'000	Pentobarbital	300
Aprobarbital	300	Phenobarbital	300
Barbital	300		

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INTEX[®]-Drug test Benzodiazepines

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
Oxazepam	300	Flunitrazepam	1'000
Alprazolam	150	Flurazepam	300
Bromazepam	800	Lorazepam	1'500
Chlordiazepoxid	300	Lormetazepam	1'000
Clobazam	200	Medazepam	2'000
Clonazepam	25'000	Nitrazepam	1'000
Clorazepam	100	Nordiazepam	100
Delorazepam	6'000	Prazepam	1'000
Diazepam	150	Temazepam	150
Estazolam	300	Triazolam	1'500

INTEX[®]-Drug test Cocaine

Substance	Concentration (ng/ml)
Benzoylcegonin	300
Cocain	300

INTEX[®]-Drug test MDMA (Ecstasy)

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
MDMA	1'000	MDA	3'000
L-Amphetamine	20'000	Methamphetamine	1'500

INTEX[®]-Drug test Methadone

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
Methadone	300	2-Ethyliden-1,5-dimethyl-3,3-diphenylpyrolidin	50'000
Methadol	1'000		

INTEX[®]-Drug test Methamphetamine

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
D-Methamphetamine	1'000	(+/-)3,4-Methylen-dioxy-methamphetamine (MDMA)	2'000
L-Methamphetamine	25'000	Procain	10'000
D-Amphetamine	50'000	β -Phenylethylamin	50'000
Chloroquine	50'000	Ranitidin	50'000
(+/-) Ephedrine	50'000		
Mephentermin	50'000		

INTEX[®]-Drug test Opiates (Morphine, Heroine, Codeine)

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
Morphine	300	Morphin-3-glucuronid	1'000
Ethylmorphine	300	Thebain	30'000
Hydrocodon	5'000		
Hydromorphon	5'000		
Codein	300		

INTEX[®]-Drug test TCA (Tricyclic Antidepressants)

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
Nortriptylin	1'000	Clomipramin	5.000
Amitriptylin	1'000	Doxepin	3.000
Desipramin	600	Protriptylin	2.000
Imipramin	600	Perphenazin	75.000
Nordoxepin	1'000	Promazin	15.000
Cyclobenzaprin	1'500	Trimipramin	2.000

INTEX[®]-Drug test THC/Cannabinoids

Substance	Concentration (ng/ml)	Substance	Concentration (ng/ml)
11-nor- Δ -9-Tetrahydro-cannabinol-9-carbonsäure	50	Δ -9-Tetrahydro-cannabinol	10'000
11-nor- Δ -8-Tetrahydro-cannabinol-9-carbonsäure	50	Cannabinol	10'000
11-Hydroxy- Δ -9-tetrahydrocannabinol	2'500	Cannabidiol	100'000









All following listed compounds reacted negative up to a concentration of 100 µg/ml:



Acetamidophen, Acetone, Albumin, Ampicillin, Aspartam, Aspirin, Atropine, Bilirubin, Chinidin, (±)-Chlorpheniramin, Dextromethorphan, 4-Dimethylaminoantipyrine, Erythromycin, Ethanol, Furosemide, Glucose, Guaiacol-glyceryl ether, Haemoglobin, (±)-Isoproterenol, Coffeine, Creatin, Lidocaine, Naproxen, Sodium chloride, Oxalic Acid, Penicillin-G, Phenothiazine, Sulindac, Vitamin C

15 LITERATURE

1. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, 1982
2. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986
3. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970, 1988
4. McBay, A.J. Clin. Chem. 33, 33B-40B, 1987
5. Gilman, A.G., & Goodman, L.S. The Pharmacological Basis of Therapeutics; 10th ed., 2001, The McGraw-Hill Companies, Inc.

16 SYMBOLS

	Article number		For single use only
	Lot number		Expiry date
	Storage		Content
	Only for in vitro diagnostics		Instruction sheet

INTEX[®]-Drug test		
	10 Test cassettes	DKAMP-10 (Amphetamine)
	10 Test cassettes	DKBAR-10 (Barbiturates)
	10 Test cassettes	DKBZO-10 (Benzodiazepines)
	10 Test cassettes	DKCOC-10 (Cocaine)
	10 Test cassettes	DKMDMA-10 (MDMA (Ecstasy))
	10 Test cassettes	DKMTD-10 (Methadone)
	10 Test cassettes	DKMAMP-10 (Metamphetamine)
	10 Test cassettes	DKOPI-10 (Opiates (Morphine, Heroine, Codeine))
	10 Test cassettes	DKTCA-10 TCA (Tricyclic Antidepressants)
10 Test cassettes	DKTHC-10 (THC (Cannabinoids))	



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