LSD Rapid Test Cassette (Urine)
Package Insert

REF DLS-102 English

A rapid test for the qualitative detection of Lysergic Acid Diethylamide in human urine. For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The LSD Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Lysergic Acid Diethylamide in human urine at a cut-off concentration of 20 ng/mL.

This assay provides only a qualitative, preliminary 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) or Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

【SUMMARY】

Lysergic acid diethylamide (LSD) is a white powder or a clear, colorless liquid. LSD is manufactured from lysergic acid which occurs naturally in the ergot fungus that grows on wheat and rye. It is a Schedule I controlled substance, available in liquid, powder, tablet (microdots), and capsule form. LSD is recreationally used as a hallucinogen for its ability to alter human perception and mood. LSD is primarily used by oral administration, but can be inhaled, injected, and transdermally applied. LSD is a non-selective 5-HT agonist, may exert its hallucinogenic effect by interacting with 5-HT 2Areceptors as a partial agonist and modulating the NMDA receptor-mediated sensory, perceptual, affective and cognitive processes. LSD mimics 5-HT at 5-HT 1A receptors, producing a marked slowing of the firing rate of serotonergic neurons. LSD has a plasma half-life of 2.5-4 hours. Metabolites of LSD include N-desmethyl-LSD, hydroxy-LSD, 2-oxo-LSD, and 2-oxo-3-hydroxy-LSD. These metabolites are all inactive. LSD use can typically be detected in urine for periods of 2-5 days.

The LSD Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Lysergic Acid Diethylamide in urine. The LSD Rapid Test Cassette (Urine) yields a positive result when Lysergic Acid Diethylamide in urine exceeds 20 ng/mL.

【PRINCIPLE】

The LSD Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Lysergic Acid Diethylamide, if present in the urine specimen below 20 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized Lysergic Acid Diethylamide conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Lysergic Acid Diethylamide level exceeds 20 ng/mL because it will saturate all the binding sites of anti-Lysergic Acid Diethylamide antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration lower 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains mouse monoclonal anti-Lysergic Acid Diethylamide antibody-coupled particles and Lysergic Acid Diethylamide-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For medical and other professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test 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 should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (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 AND PREPARATION】

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed settle to obtain a clear specimen for testing.

Specimen Collection

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS】

Materials Provided

- Test cassettes
- Droppers
- Package insert

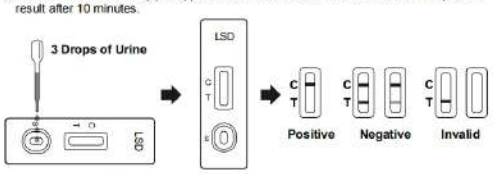
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). This negative result indicates that the Lysergic Acid Diethylamide concentration is below the detectable level (20 ng/mL).

***NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test line region (T). This positive result indicates that the Lysergic Acid Diethylamide concentration exceeds the detectable level (20 ng/mL).

INVALID: Control line (C) 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. 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 colored 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 LSD Rapid Test Cassette (Urine) provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.[2,3]
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 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 indicates presence of the drug or its metabolites but does not indicate 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 when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the LSD Rapid Test Cassette and GC/MS at the cut-off of 20 ng/mL. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
LSD Rapid Test Cassette	Results	Positive	Negative	
	Positive	33	1	34
	Negative	2	64	66
Total Results		35	65	100
% Agreement		94.3%	98.5%	97.0%

Analytical Sensitivity

A drug-free urine pool was spiked with Lysergic Acid Diethylamide at the following concentrations: 0 ng/mL, 10 ng/mL, 15 ng/mL, 20 ng/mL, 25 ng/mL, 30 ng/mL and 60 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Lysergic Acid Diethylamide Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
10	-50%	30	30	0
15	-25%	30	27	3
20	Cut-off	30	14	16
25	+25%	30	3	27
30	+50%	30	0	30
60	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the LSD Rapid Test Cassette (Urine) at 5 minutes.

Compound	Concentration(ng/mL)
Lysergic Acid Diethylamide	20

Precision

A study was conducted at 3 hospitals using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Lysergic Acid Diethylamide, 25% Lysergic Acid Diethylamide above and below the cutoff and 50% Lysergic Acid Diethylamide above and below the 20 ng/mL cutoff were provided to each site. The following results were tabulated:

Lysergic Acid Diethylamide Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities ranging from 1.004 to 1.034 were spiked with Lysergic Acid Diethylamide to the concentrations of 10 ng/mL and 30 ng/mL. The LSD Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Lysergic Acid Diethylamide to 10 ng/mL and 30 ng/mL. The spiked, pH-adjusted urine was tested with the LSD Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Lysergic Acid Diethylamide positive urine. The following compounds show no cross-reactivity when tested with the LSD Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic	Acid Ethanol	Phenothiazine
Aspartame	Furosemide	L-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Tyramine
Creatine	(+)-Naproxen	4-Dimethylaminoantipyrine
Dexbrompheniramine	Niacinamide	(1R,2S)-(-)-N-Methyl-Ephedrine
Dextromethorphan	Nicotine	
Diphenhydramine	(+/-)-Norephedrine	

【BIBLIOGRAPHY】

1. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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