

LSD Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of Lysergic Acid Diethylamide in human whole blood or serum or plasma.
For medical and other professional *in vitro* diagnostic use only.

INTENDED USE

The LSD Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Lysergic Acid Diethylamide in whole blood or serum or plasma at a cut-off concentration of 20ng/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) 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 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 2A receptors 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 2.54 hours. Metabolites of LSD include N-desmethyl-LSD, hydroxy-LSD, 2-oxo-LSD, and 2-oxo-3-hydroxy-LSD. These metabolites are all inactive.

The LSD Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid whole blood/serum/plasma 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 whole blood/serum/plasma. The LSD Rapid Test Cassette (Whole Blood/Serum/Plasma) yields a positive result when Lysergic Acid Diethylamide in whole blood/serum/plasma exceeds 20ng/mL.

PRINCIPLE

The LSD Rapid Test Cassette (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody. During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Lysergic Acid Diethylamide, if present in the specimen below 20ng/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 20ng/mL because it will saturate all the binding sites of anti-Lysergic Acid Diethylamide antibodies.

A drug-positive specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative 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 professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch 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

- The LSD Rapid Test Cassette can be performed using whole blood (from venipuncture or

fingerstick) or serum or plasma.

- To collect **Fingerstick Whole blood specimens**:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
 - Add the Fingerstick Whole blood specimen to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 40 μ L. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

- Materials Provided
 - Test cassettes
 - Droppers
 - Buffer
 - Package insert
- Materials Required But Not Provided
 - Specimen collection containers
 - Lancets (for fingerstick whole blood only)
 - Centrifuge
 - Timer
 - Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the cassette from the sealed pouch and use it within one hour.
- Place the cassette on a clean and level surface.

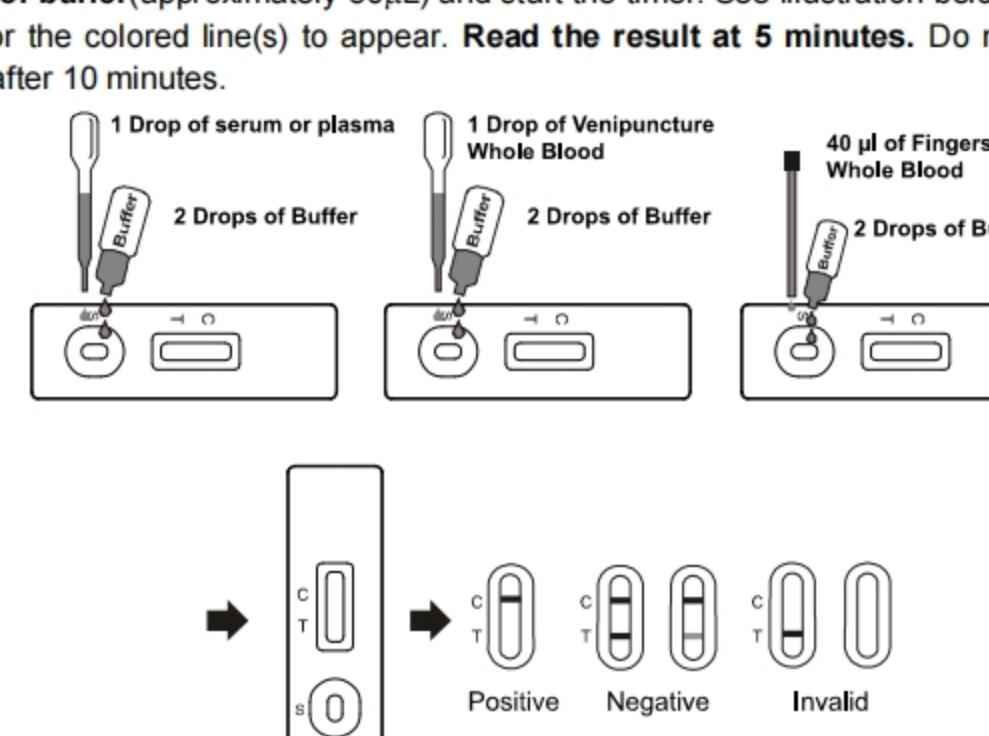
For serum or plasma specimen:

- Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40 μ L), then **add 2 drops of buffer** (approximately 80 μ L) to the specimen well(S) of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

For Venipuncture Whole blood specimen:

- Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40 μ L) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 μ L), and start the timer. See illustration below.

- Wait for the colored line(s) to appear. **Read the result 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 cut-off level.

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Lysergic acid diethylamide concentration exceeds the detectable 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 with a new test. If the problem persists, discontinue using the test kit 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 the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The LSD Rapid Test Cassette (Whole Blood/Serum/Plasma) 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

- It is possible that technical or procedural errors, as well as other interfering substances in the whole blood or serum or plasma specimen may cause erroneous results.

- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood or serum or plasma.

- A negative result may not necessarily indicate drug-free Whole blood/serum/plasma. Negative results can be obtained when drug is present but below the cut-off level of the test.

- 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 20ng/mL. Testing was performed on 91 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method	GC/MS		Total Results
	Results	Positive	
LSD Rapid Test Cassette	Positive	20	1
	Negative	1	69
	Total Results	21	70
	% Agreement	95.2%	98.6%
			97.8%

Clinic Result of Serum or Plasma

Method	GC/MS		Total Results
	Results	Positive	
LSD Rapid Test Cassette	Positive	20	1
	Negative	1	69
	Total Results	21	70
	% Agreement	95.2%	98.6%
			97.8%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Lysergic acid diethylamide at the following concentrations of \pm 50% cutoff and 3x cutoff, the data are summarized below:

For whole blood:

LSD Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
20	Cut-off	30	15	15
30	+50%	30	0	30
60	3X	30	0	30

For serum or plasma:

LSD Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
20	Cut-off	30	15	15
30	+50%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the LSD Rapid Test Cassette (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
Lysergic Acid Diethylamide	20

Precision

A study was conducted at three hospitals using three 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, and 50% Lysergic acid diethylamide above and below the 20ng/mL cut-off was provided to each site. The following results were tabulated:

LSD Concentration (ng/mL)	n per Site	Site A		Site B		Site C	