

CDIA™ Barbiturates Colloidal Gold Test Cassette (Saliva)

Cat. No.: DTSJYJ053

Pkg. Size: 25T

Intended Use

The CDIA™ Barbiturates Colloidal Gold Test Cassette (Saliva) is a lateral flow chromatographic immunoassay for the detection of barbiturates and its metabolites in human saliva.

General Description

Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Barbiturate could develop tolerance and physiological dependency and lead to its abuse. The CDIA™ Barbiturates Colloidal Gold Test Cassette (Saliva) is a rapid saliva-screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of barbiturates in saliva. The CDIA™ Barbiturates Colloidal Gold Test Cassette (Saliva) yields a positive result when the barbiturates in saliva exceeds 50 ng/mL.

Principle of the Test

Barbiturates antigen is coated on the test region of the nitrocellulose membrane of the strips, and barbiturates antibody is labeled with colloid gold. During a test, the colloid gold labeled antibody coated in the strip move forward along the membrane, and a red line will show up when the antibody gathers with the antigen in the test line; if barbiturates in the sample is over the detection limit, line T is blank; on the other wise, if barbiturates in the sample is less than the detection limit, line T is red.

Materials Provides

1. Drug Test Tube
2. Product insert
3. Procedure Card
4. Saliva Collector
5. Color chart for alcohol test (optional)
6. One instruction.

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Materials Required but Not Provided

1. Specimen collection container
2. Timer

Specimen Collection and Preparation

The saliva specimen should be collected. Follow the detailed Directions for Use below. No other collection devices should be used with this assay. saliva collected at any time of the day may be used.

Assay Operation

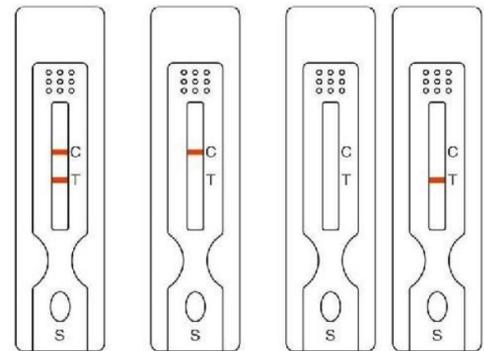
1. Specimen collection and shake the sample collection device several times.
2. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
3. Squeeze 3 drops (~75uL) of the sample solution in the sample well of the cassette.
4. Read the test results in 5 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes.

Results

Negative: Two lines appear. One colored line should be in the control region (C) and another apparent colored line should be in the test line region (T).

Positive: One colored line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Line C has no color, which indicates the strips are invalid. In this case, please read the instructions again, and redo the assay with new cassette device.



Positive

Negative

Invalid

Quality Control

A procedural control is included in the test. A red 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.

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Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

Limitation

1. The CDIA™ Barbiturates Colloidal Gold Test Cassette (Saliva) 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) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.
4. There is a possibility that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.

Detection Limit (LOD)

50 ng/mL

Storage

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Notice for Operations

1. Please do the assay following the instruction. Do not touch the membrane of the strip.
2. This cassette device is used for only once; please do not use it repeatedly.