CDIA™ Fentanyl Colloidal Gold Test Cassette (Urine)

Cat. No.: DTS239

Pkg. Size: 25T

Intended Use

The CDIA™ Fentanyl Colloidal Gold Test Cassette (Urine) is a lateral flow chromatographic immunoassay for the detection of fentanyl and its metabolites in human urine.

General Description

Fentanyl is an extremely fast-acting synthetic narcotic analgesic, of high potency(approximately 100 to 200 times that of morphine) and short duration of action. Pharmaceutical fentanyl has been available since 1963 as an anaesthetic supplement, and is available as a citrate salt for I.V or I.M injection. Transdermal patches are also available for management of chronic pain or for breakthrough cancer pain. Due to the lipophilicity of the drug, fentanyl rapidly crosses the blood-brain barrier, producing fast and pronounced CNS effect, such as a heightened euphoria and respiratory depression, and possible toxic effects which include muscle rigidity, seizures, coma, and hypotension. Fentanyl also has similar tolerance and physical dependence properties to those of morphine.The CDIA™ Fentanyl Colloidal Gold 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 fentanyl in urine. The CDIA™ Fentanyl Colloidal Gold Test Cassette (Urine) yields a positive result when the fentanyl in urine exceeds 300/200 ng/mL.

Principle of the Test

Fentanyl antigen is coated on the test region of the nitrocellulose membrane of the strips, and fentanyl 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 fentanyl in the sample is over the detection limit, line T is blank; on the other wise, if fentanyl in the sample is less than the detection limit, line T is red.

Materials Provides

1. Cassette device, 25T.
2. One instruction.

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Tel: 631-624-4882 Fax: 1-631-938-8221
E-mail: info@creative-diagnostics.com
www.cdia-test.com

Materials Required but Not Provided

1.Specimen collection container

2.Timer

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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

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

Assay Operation

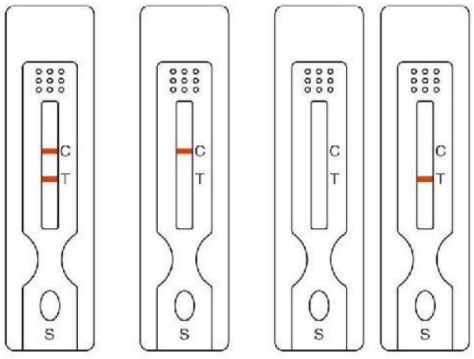
1. Specimen collection and shake the sample collection device several times.
2. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
3. Squeeze 3 drops (~75uL) of the sample solution in the sample well of the cassette.
4. Read the test results in 5 minutes. 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

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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.

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™ Fentanyl Colloidal Gold Test Cassette (Urine) 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. 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.

Detection Limit (LOD)

300/200 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.

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