The First Sign® Oral Fluid Drug Screen Device for AMPH/MAMP/COC/OPH/TBC/ZID/OXY/MTD/BAR/BUP/BAR/BAR/BUP is an immunoassay that yields a positive result when the oral fluid specimen competes against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen, will compete with its corresponding conjugate for binding sites on a specific antibody. A drug-positive oral fluid specimen will then react with the drug-protein conjugate and a stable colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

As a serve to procedural control, a colored line will always appear at the control line region, indicating that the oral specimen has been added and membrane is present as expected.

The test uses a combination of monoclonal antibodies to selectively detect elevated levels of specific drugs in oral fluid. The test utilizes monoclonal antibodies to selectively detect elevates levels of specific drugs in oral fluid. An immunoassay is the method used to test oral fluid specimens. The oral fluid specimen is collected in a polypropylene tube or other suitable container. The oral fluid specimen is collected in a polypropylene tube or other suitable container. The oral fluid specimen is collected in a polypropylene tube or other suitable container.
Step 2 persists, is even a faint distinguishable color line. Review the procedure and repeat the test using a new test device. If the problem is INVALID:

- **procedural control**. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. It is the negative result indicates that the drug concentration is below the detectable level.

- Two lines appear. One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

**3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the assay.**

**Secondary Analytical Method** must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is preferred confirmatory method.

**Cut-off and tested with the First Sign® Oral Fluid Drug Screen Device** when tested with concentrations up to 100 µg/mL.

**Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Benzodiazepines, Oxycodone, Methadone, Barbiturates and Buprenorphine Non-Cross-Reacting Compounds Are:**

- Parent compound only:
  - Chlorothiazide
  - DL-Chlorpheniramine
  - Chlorpropanol
  - Chlorpromazine
  - Chlorpheniramine
  - Chlordiazepoxide
  - Dextran
  - DL-Chlorpheniramine
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