

K954496

**510(k) SUMMARY - FRONTLINE® COCAINE**

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**Device Trade Name:** FRONTLINE® COCAINE

**Device Common Name:** Immunochromatographic test for cocaine and cocaine metabolite

**Classification Name:** Cocaine and cocaine metabolite test system (per 21 CFR §862.3250)

**Predicate Device:** TDx® Cocaine Metabolite

**Device Description:** FRONTLINE® COCAINE is a homogeneous immunochromatographic assay for use in the qualitative analysis of cocaine metabolite (benzoylecgonine) in human urine. The assay is based on Gold Labeled Optical-read Rapid Immuno Assay (GLORIA) technology. Each test strip contains monoclonal antibodies reactive to a benzoylecgonine derivative labeled with colloidal gold (conjugate) and benzoylecgonine polyhapten, bulking agents, stabilizers and preservatives (solid phase). When immersed in urine, the test strip absorbs the volume of fluid necessary for the chromatographic reaction to occur. By capillary action, the urine passes through a compartment containing soluble conjugate which specifically binds to the benzoylecgonine analyte. Excess conjugate is retained by the solid phase in a separate compartment. Only that conjugate with bound benzoylecgonine analyte passes to the detection pad where a red-colored conjugate-analyte complex is viewed. The color developed on the detection pad is compared visually with a scale provided on the test strip vial. The intensity of the color developed correlates with the concentration of the analyte in the sample and the user may classify the analyte sample as: negative or positive (≥300 ng/mL).

**Intended Use:** For use in the qualitative analysis of cocaine metabolite (benzoylecgonine) in human urine at a cutoff concentration of 300 ng/mL.

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**Device Technological  
Characteristics and  
Comparison to  
Predicate Devices:**

**FRONTLINE®** is based on Gold Labeled Optical-read Rapid Immuno Assay (GLORIA) technology. Each test strip contains monoclonal antibodies reactive to a benzoylecgonine derivative labeled with colloidal gold (conjugate) and benzoylecgonine polyhapten, bulking agents, stabilizers and preservatives (solid phase). When immersed in urine, the test strip absorbs the volume of fluid necessary for the chromatographic reaction to occur. By capillary action, the urine passes through a compartment containing soluble conjugate which specifically binds to the benzoylecgonine analyte. Excess conjugate is retained by the solid phase in a separate compartment. Only that conjugate with bound benzoylecgonine analyte passes to the detection pad where a red-colored conjugate-analyte complex is viewed. The color developed on the detection pad is compared visually with a scale provided on the test strip vial. **FRONTLINE® COCAINE** is a non-instrumented assay and requires no user calibration.

**TDx® Cocaine Metabolite** is a fluorescence polarization immunoassay (FPIA) in which the change in fluorescence polarization due to antibody binding correlates with the concentration of analyte in the sample. Results are measured with a suitable instrument and compared to those generated by defined calibrators.

**Performance Data:**

Comparison to FPIA: A total of 513 metabolized urine samples were evaluated at two sites. 58 samples were **FRONTLINE®** positive and 450 were **FRONTLINE®** negative when compared to FPIA and the confirmation method. Five samples were classified as false positive.

**Conclusion:**

**FRONTLINE® COCAINE** is substantially equivalent to other commercially available cocaine metabolite test systems.