

K954497

510(k) SUMMARY - FRONTLINE® CANNABIS

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Device Trade Name: FRONTLINE® CANNABIS

Device Common Name: Immunochromatographic test for cannabinoids

Classification Name: Cannabinoids test system
(per 21 CFR §862.3870)

Predicate Devices: Emit® d.a.u. Cannabinoid 100 ng Assay;
TDx® Cannabinoids

Device Description: FRONTLINE® CANNABIS is a homogeneous immunochromatographic assay for use in the qualitative analysis of cannabinoids 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 11-nor- Δ^9 -THC-carboxylic acid derivative labeled with colloidal gold (conjugate) and 11-nor- Δ^9 -THC-carboxylic acid 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 cannabinoid analyte. Excess conjugate is retained by the solid phase in a separate compartment. Only that conjugate with bound cannabinoid 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 (≥ 50 ng/mL).

Intended Use: For use in the qualitative analysis of cannabinoids in human urine at a cutoff concentration of 50 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 11-nor- Δ^9 -THC-carboxylic acid derivative labeled with colloidal gold (conjugate) and 11-nor- Δ^9 -THC-carboxylic acid 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 cannabinoid analyte. Excess conjugate is retained by the solid phase in a separate compartment. Only that conjugate with bound cannabinoid 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® CANNABIS** is a non-instrumented assay and requires no user calibration.

Emit® d.a.u. Cannabinoid 100 ng Assay is an enzyme immunoassay (EIA) based on the competition between analyte in the sample and analyte labeled with an enzyme for antibody binding sites. Results are measured with a suitable instrument based on absorbance changes compared to those generated by defined calibrators.

TDx® Cannabinoids 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 EIA: A total of 761 metabolized urine samples were evaluated at three sites. 243 samples were **FRONTLINE®** positive and 500 were **FRONTLINE®** negative when compared to EIA and the confirmation method. Fourteen samples were classified as false positive and four samples were unavailable for confirmation analysis.

Comparison to FPIA: A total of 399 metabolized urine samples were evaluated at two sites. 153 samples were **FRONTLINE®** positive and 240 were **FRONTLINE®** negative when compared to FPIA and the confirmation method. Three samples were classified as false positive, two samples were classified as false negative, and one sample was unavailable for confirmation analysis.

Conclusion:

FRONTLINE® CANNABIS is substantially equivalent to other commercially available cannabinoid test systems.