PRECAUTIONS
STORAGE AND STABILITY

For goat anti-rabbit IgG antibody.

INTENDED USE
In Vitro Diagnostic Use

This colored band should always appear on the control line zone if the test is read properly.

A control line is present in the test window to work as a procedural control.

A positive urine specimen will not show a colored band on the test strip.

A negative result indicates that the concentrations of metabolites in the specimen is above the cut-off level.

LIMITATION OF PROCEDURE
The specificity for K2/Spice Test test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in the urine specimen to the assay. The specificity study was performed by three individuals observing the test results.

The precision study was performed by three individuals observing the test results. The negative result indicates that the concentrations of metabolites in the specimen is above the cut-off level.

The K2/Spice Test is a qualitative assay. It identifies JWH-018, JWH-073, JWH-200, and CP-47,497 in human urine at a concentration of 25 ng/mL or higher and other K2 compounds at the indicated level.

The cut-off concentration of the synthetic cannabis cannot be determined by this assay. The test is intended to distinguish a negative result from a presumptive positive result. If a positive result must be confirmed using an alternate method, preferably GC/MS. NOT: This test has been determined to cross react with the drug Lamictal (Lamotrigine). Specimen from individuals taking this medication drug will likely register a false positive result. All presumptive positive screens should be sent for a confirmation lab for analysis.

SPECIMEN COLLECTION AND PREPARATION

The K2/Spice Test provides a built-in process control with a different control line for the K2/Spice Test. The laboratory then processed and tested each specimen following the guidelines.

A. Sensitivity

The K2/Spice Test was evaluated to K2 spiked urine specimens. Forty K2 urine specimens were spiked with JWH-018 pentanoic acid or JWH-073 butanoic acid at concentrations between 10 and 1,000 ng/mL. Each specimen was tested with the K2/Spice Test.

The precision study was performed by three individuals observing the test results to determine the random error of visual interpretation. The results were found to have no significant differences between the three observers.

B. Accuracy

The K2/Spice Test was evaluated in K2 spiked urine specimens. Forty K2 urine specimens were spiked with JWH-018 pentanoic acid or JWH-073 butanoic acid at concentrations between 10 and 1,000 ng/mL. Each specimen was tested with the K2/Spice Test.

The accuracy of the K2/Spice Test was evaluated by adding various drugs, drug metabolites, and other compounds that are likely to be present in the urine specimen to the assay. The accuracy of the K2/Spice Test was evaluated by adding various drugs, drug metabolites, and other compounds that are likely to be present in the urine specimen to the assay.

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