Know Drug Test Card™

When you need to know

# K2 Combo Test

***For Forensic Use Only***

The K2 Combo Test detects multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

| Abbreviation | Drug | Cutoff (ng/ml) |
|---|---|---|
| K2 25 | Synthetic Marijuana | 25 |
| K2+ | AB-PINACA | 10 |

## WARNINGS AND PRECAUTIONS

- Treat all urine specimens and materials as if capable of transmitting infection. Wear gloves and proper laboratory attire to avoid skin contact with urine specimens. Proper handling and disposal methods should be established.
- Use a new specimen collection container for each urine sample to avoid cross-contamination of urine samples.
- Collect a fresh urine sample in the container provided or a clean, dry plastic or glass container. Fresh urine does not require any special pretreatment. If the specimen is not tested immediately, it may be refrigerated at 2-8°C up to 2 days.
- Do not use the test kit after the expiration date.

## MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container
- External positive and negative controls

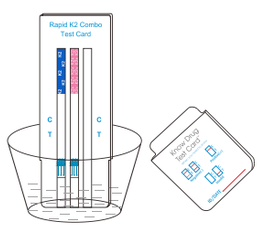
## PROCEDURE

**Preparation:**

1. Allow the test device, controls, and/or specimens to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

**Dip Card:**

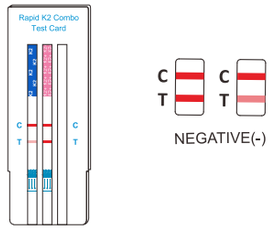
1. Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
2. With the arrows pointing toward the urine specimen, immerse the sample tips vertically in the urine specimen for at least 20 seconds. Replace the cap back onto the dip card and place the dip card on a flat surface. Alternatively, the dip card can be left in the urine specimen throughout the testing process.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. If included on test card read specimen validity test (SVT) results by comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.
   Position of SVT pads may vary based on the drug strip configuration.




## RESULT INTERPRETATION

Read results after 5 minutes. Do not read results past 60 minutes.
A red or pink line must appear next to the “C” (control) on all of the test strips. The appearance of a red or pink line next to the “C” on each test strip indicates that the test has worked properly.

**Negative Result:**
**A red or pink line next to the “T” (drug test line) under the drug name indicates a negative result for that drug.** If a test line appears next to the “T” for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.

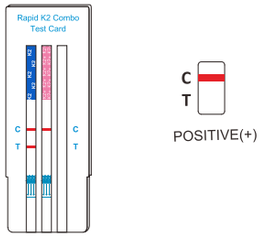






NEGATIVE(-)

**Preliminary Positive Result:**
**If NO red or pink line appears next to the “T” under the drug name, the sample may contain that drug.** It is recommended to send the sample to a laboratory for confirmation testing.
***The illustration on the right shows preliminary positive results for K2+, but negative for K2.***

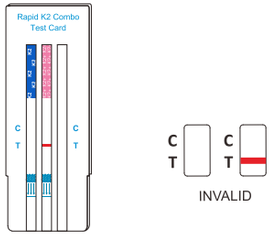






POSITIVE(+)

**Invalid Result:**
A colored line should always appear next to the letter “C” on every test strip. If no control line appears on any of test strips, the result is invalid.
***The illustration at right shows no line next to the letter “C” on the first strip (K2) and second strip (k2+). The test results for those two test strips are invalid.***







INVALID

## STORAGE

The K2 Combo test should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and/or expose reagent kits to temperatures greater than 30°C.

## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.
To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators.
Quality control testing should be performed with each new lot, with each new shipment, and every thirty days to check storage conditions. External controls can be purchased from the following vendor:
CLIAwaived,Inc, 1-888-882-7739,
www.cliawaived.com

## PERFORMANCE CHARACTERISTICS

**A. ACCURACY**

The accuracy of the K2 Combo test was evaluated in comparison to GC/MS and LC/MS. Drug-free urine samples collected from presumed non-user volunteers were tested with K2 combo test. Of these negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 30 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS. A summary of the accuracy results on the K2 combo test are shown in the following table.

**Summary of Accuracy Results on the K2 Combo Test**

| Drug Test/ Cutoff (ng/ml) | Result | Range of GC/MS Data | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Drug -free | -50% - <-25% C/O | -25% C/O - C/O | C/O - +25% C/O | >+25% - +50% C/O | >+50/% C/O | % Agreement |
| K2/25 | Neg | 40 | 2 | 1 | 0 | 0 | 0 | 93.5% |
| | Pos | 0 | 0 | 3 | 2 | 3 | 21 | 100% |
| K2+/10 | Neg | 40 | 0 | 0 | 0 | 0 | 0 | 100% |
| | Pos | 0 | 0 | 0 | 0 | 4 | 0 | 100% |

**B. ANALYTICAL SENSITIVITY/PRECISION**

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days or by in-house personnel at the manufacturing site. Results showed over 99% agreement at +/-50% cutoff levels with the K2 combo test.

**C. ANALYTICAL SPECIFICITY**

The following compounds are detected positive in urine by the K2 combo test. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

| Compound | Conc. (%) | Compound | Conc. (%) |
|---|---|---|---|
| **K2 25** | | | |
| JWH-073 5-Butanoic acid metabolite | 40 (62%) | JWH-018 4N-(4-Hydroxypentyl) metabolite | 2000 (1%) |
| JWH-018 5-Pentanoic acid (calibrator) | 25 (100%) | JWH-018 5-Hydroxypentyl metabolite | 1250 (2%) |
| **K2+ 10** | | | |
| AB-PINACA pentanoic acid metabolite | 10 (100%) | AB-PINACA N-(4-hydroxypentyl) metabolite | 10 (100%) |
| ADB-PINACA N-(4-hydroxypentyl) metabolite | 15 (66.7%) | ADB-PINACA N-(5-hydroxypentyl) metabolite | 20 (50%) |
| 5-fluoro AB-PINACA N-(4-hydroxypentyl) metabolite | 20 (50%) | AB-PINACA N-(5-hydroxypentyl) metabolite | 30 (33.3%) |
| ADB-PINACA pentanoic acid metabolite | 20 (50%) | AB-PINACA | 100 (10%) |
| 5-fluoro AB-PINACA | 50 (20%) | 5-fluoro ADB-PINACA | 250 (40%) |
| AB-FUBINACA | 150 (6.67%) | APINACA(AKB-48) | >10,000 (<0.1%) |
| 5-chloro AB-PINACA | 1,000 (1%) | CUMPY-THPINACA | >100,000 (<0.01%) |
| APINACA(AKB-48) 5-Hydroxypentyl metabolite | >10,000 (<0.1%) | AB-CHMINACA metabolite M2 | >100,000 (<0.01%) |
| 5-fluoro AEB | >100,000 (<0.01%) | 5-fluoro ADB(5-fluoro MDMB-PINACA) | >100,000 (<0.01%) |
| PX 1(5-fluoro APP-PICA) | >100,000 (<0.01%) | MMB-FUBINACA | >100,000 (<0.01%) |
| PX 2(5-fluoro APP-PINACA) | >100,000 (<0.01%) | 5-fluoro MN-18 | >100,000 (<0.01%) |
| 4-cyano CUMYL-BUTINACA | >100,000 (<0.01%) | 5-fluoro PB-22 3-carboxyindole metabolite | >100,000 (<0.01%) |
| CUMYL-PICA | >100,000 (<0.01%) | AM2201 N-(4-hydroxypentyl) metabolite | >100,000 (<0.01%) |
| MN-18 | >100,000 (<0.01%) | | |
| BB-22 3-carboxyindole metabolite | >100,000 (<0.01%) | | |

**D. INTERFERENCE**

The following compounds were evaluated for potential positive or negative interference with the K2 combo test. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the K2 combo test cup and dip. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL.

| | | |
|---|---|---|
| Acetaminophen | 4-Dimethylaminoantipyrine | Niacinamide |
| Acetone | Diphenhydramine | (+/-)-Norephedrine |
| Albumin | Dopamine | Oxalic acid |
| Ampicillin | (+/-)-Isoproterenol | Penicillin-G |
| Ascorbic acid | (+)-Naproxen | Pheniramine |
| Aspartame | Erythromycin | Phenothiazine |
| Aspirin | Ethanol (except EtG) | L-Phenylephrine |
| Atropine | Furosemide | B-Phenylethylamine |
| Benzocaine | Glucose | Procaine |
| Bilirubin | Guaiacolglyceryl ether | Quinidine |
| Caffeine | Hemoglobin | Ranitidine |
| Chloroquine | Ibuprofen | Riboflavin |
| (+)-Chlorpheniramine | (+/-)-Isoproterenol | Sodium chloride |
| (+/-)-Chlorpheniramine | Levorphanol | Sulindac |
| Creatine | Lidocaine | Theophylline |
| Dexbrompheniramine | (1R,2S)-(-)-n-Methylephedrine | Tyramine |
| Dextromethorphan | | |

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