Buprenorphine (BUP) Rapid Test Kit

The Buprenophine (BUP) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Buprenophine in human Urine specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PBUP 01
05 Tests	PBUP 05
10 Tests	PBUP 10
25 Tests	PBUP 25
50 Tests	PBUP 50

CLINICAL SIGNIFICANCE

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex, Buprenex, Temgesic, and Suboxone which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and nor buprenorphine in urine may be less than 1 ng/mL after therapeutic administration, but can range up to 20 ng/mL in abuse situations. The plasma half-life of Buprenorphine is 2-4 hours. While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

PRINCIPLE

The Paramcare Buprenophine (BUP) Rapid Test is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result. A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

KIT COMPONENTS

• Test Cassettes • Droppers • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

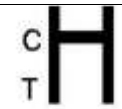
- Buprenorphine (BUP) Test kit is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Perform testing immediately after specimen collection.
- Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

DIRECTIONS FOR USE

Allow the test device and specimen to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. Once opened, the device must be used immediately.
4. Label the device with patient identity and place the testing device on a flat horizontal surface.
5. Dispense 2 drops urine sample into the each sample well (S) of the device using sample dropper. Avoid trapping air bubbles in the sample well, while dispensing the sample. Alternatively, carefully dispense 50 µl urine in each sample well using pipette.
6. Wait for the colored line(s) to appear. Read results after 5 minutes. **Note**: Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Positive Result	
Negative Result	

1) Positive
The control line is the only visible line on the test device. This is indicative of presence of BUP above 10 ng/ml

2) Negative
The control line and Test line is visible line on the test device. This no detected BUP below 10 ng/ml

3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control
Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test
1. The Buprenorphine (BUP) Rapid Test (Urine) is for in vitro diagnostic use only. This test should be used for detection of Buprenorphine in human urine at the cut off of 10 ng/ml. Neither the quantitative value nor the rate of increase in the concentration of Buprenorphine can be determined by this qualitative test.
2. A negative result can occur if the level of Buprenorphine present in the specimen is below the cut off value (10 ng/ml) present during the stage which a sample is collected. However, a negative test result does not preclude the possibility of BUP presence.
3. Human urine Samples suspecting BUP should be confirmed by other methods such as Gas chromatography/mass spectrometry.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician

Detection Limitation
The Buprenorphine (BUP) Rapid Test can detect BUP above as 10 ng/ml.

Sensitivity and Specificity
A total of 140 normal human urine specimens were collected from human subjects and 3 positive control samples tested by Buprenorphine (BUP) Rapid Test Kit. These specimens were confirmed by commercially available kit. Comparison for all subjects is showed in the following table.

Commercial BUP Rapid Test Results	Buprenorphine (BUP) Rapid Test		Total
	Positive	Negative	
Positive	3	0	3
Negative	2	138	140
Total	5	138	143

Relative Sensitivity: 100%, Relative Specificity: 98.57%, Overall Agreement: 98.60%

Specificity and cross-reactivity
The following substances were tested and confirmed did not interfere with by Buprenorphine (BUP) Rapid Test Kit at the listed concentrations.

Substances	Concentration
Glucose	2000 mg/dl
Human Albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/d

Drugs derivative	Concentration (ng/ml)
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. 2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. 3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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