ACM Medical Laboratory

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Technical Bulletin

Detailed information concerning methodology, specimen requirements, and reference ranges on new and specialized tests

- Test Name: Buprenorphine Confirmation
- Test Order Number: Reflex test from 1424, Linked to Urine Creatinine (2144)
- Department: Toxicology (700)
- Testing Schedule: Monday – Friday, 3-5 days for results.
- Specimen Requirement: Urine at ambient temperature
- Methodology: Liquid Chromatography / Mass Spectrometry

Background Information:

Buprenorphine is prescribed for either pain relief, where it is normally given by transdermal patch or injection, or as an opiate replacement therapy for patients in drug rehabilitation. The buprenorphine used in opiate replacement therapy is normally prescribed as a sublingual preparation, and may be given to patients who take it at home, unsupervised. Buprenorphine is metabolized via N-dealkylation to norbuprenorphine, and then both buprenorphine and norbuprenorphine are conjugated to a glucuronic acid molecule; this makes them more easily excreted in urine. One key factor in the treatment of opiate addiction is tracking whether patients are actually taking their medications as prescribed; prescribed buprenorphine could be used recreationally or diverted (sold to other users).

The Buprenorphine confirmation test is performed using Liquid Chromatography, Tandem Mass Spectrometry. This test is intended to detect all four metabolites (buprenorphine, buprenorphine glucuronide, norbuprenorphine, and norbuprenorphine glucuronide), and when the creatinine test is ordered, a calculation is automatically performed to normalize the result to the creatinine. Creatinine normalized results allow the clinician to track the stability of buprenorphine results over time. Because this confirmation test reports the parent drug and all three major metabolites, it gives a clearer picture of the patients behavior. Patients who attempt to obfuscate the test by shaving a tablet into the urine will certainly return a positive initial test. However, upon confirmation, no metabolic products will be found, demonstrating that the patient is not taking their prescription as directed.

Test Information:

This confirmation test is reflexed following a positive enzyme immunoassay test (test #1424). The initial test shows the potential presence of buprenorphine in the sample, and the confirmation shows each component as follows:

Component	Limit of Detection	Upper Limit of Linearity
Buprenorphine	5 ng/mL	1,000 ng/mL
Buprenorphine Glucuronide	5 ng/mL	5,000 ng/mL
Norbuprenorphine	5 ng/mL	10,000 ng/mL
Norbuprenorphine Glucuronide	5 ng/mL	10,000 ng/mL
Total Buprenorphine	5 ng/mL	1,000 ng/mL
Total Norbuprenorphine	5 ng/mL	10,000 ng/mL
Total Buprenorphine / Creatinine Ratio	Reported as ng (of drug) / mg (of Creatinine)	
Total Norbuprenorphine / Creatinine Ratio	Reported as ng (of drug) / mg (of Creatinine)	

The total buprenorphine is a calculated value, where the buprenorphine content of buprenorphine glucuronide is calculated and added to the buprenorphine result, giving the total buprenorphine result.

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This total buprenorphine result is then normalized to the creatinine result, giving a result of ng of buprenorphine per mg of creatinine.

The total norbuprenorphine is a calculated value, where the norbuprenorphine content of norbuprenorphine glucuronide is calculated and added to the norbuprenorphine result, giving the total norbuprenorphine result. This total norbuprenorphine result is then normalized to the creatinine result, giving a result of ng of buprenorphine per mg of creatinine.

Creatinine normalized results are calculated by dividing the drug result by the creatinine result and multiplying by 100. This converts ng/mL of drug and mg/dL of creatinine into ng (of drug) per mg (of creatinine).

Specimen Collection: Urine is collected and shipped to the lab at ambient temperature. Preserved urine is not acceptable.

Testing Schedule: Testing performed on Monday – Friday, results within 3-5 days.

References:

1. **The metabolism and excretion of buprenorphine in humans**. Cone EJ, Gorodetzky CW, Yousefnejad D, Buchwald WF, Johnson RE. Drug Metab Dispos. 1984 Sep-Oct;12(5):577-81.
2. **Urinary Buprenorphine Concentrations in Patients Treated with Suboxone® as Determined by Liquid Chromatography–Mass Spectrometry and CEDIA Immunoassay.** Mindy J. Hull, Michael F. Bierer, David A. Griggs, William H. Long, Andrea L. Nixon, and James G. Flood*, Journal of Analytical Toxicology, Vol. 32, September 2008, Pg 516-521

Questions? Call 249-2300 (Client Services) and ask for Toxicology (Michael Peterson, Toxicology Manager (585) 429-2380.