Chapter 16

Visualine II™ Drugs-of-Abuse Test Kits

Scott A. Kuzdzal and James H. Nichols

1. INTRODUCTION

Visualine II™ drug-abuse, test kits are one-step, rapid immunoassay kits developed by Sun Biomedical Laboratories (Cherry Hill, NJ) for the quantitative analysis of drugs-of-abuse in human urine. The test kits are marketed for use by professional laboratories, physician offices, clinics, institutions, law-enforcement agencies, and pre-employment testing laboratories.

2. PRINCIPLE

The Visualine II drug abuse test kits (Fig. 1) are homogeneous immunochromatographic assays based on the principle of antigen/antibody complexation. The assay is based on the competition for limited antibody sites between the drug or drug metabolite in the specimen and a drug conjugate immobilized on a porous membrane support. An aliquot of a urine specimen is placed into the window in the device that holds the porous membrane. The urine is automatically wicked along the chromatographic membrane to mobilize the microspheres coated with antibody specific to the particular drug. These microspheres then move along the membrane by capillary action to the probe area on the membrane. If the drug is absent, the colored microspheres are attached to the drug conjugate probe, forming a visible line as the antibody complexes with the drug conjugate. Therefore, the formation of a visible red precipitin at the probe line occurs when the urine is negative for the drug. Results are read after a five-minute incubation period.

When the drug is present in the urine specimen, the drug or drug metabolite competes for the limited antibody sites on the microspheres. When an
adequate amount of drug is present, it will fill the limited antibody binding sites. This prevents attachment of the colored microspheres to the probe site on the membrane. Therefore, a positive urine specimen will not form a line at the probe area. The testing procedure is illustrated in Fig. 2.

A reference or control line with a different antigen/antibody reaction is also added to the immunochromatographic membrane strip to indicate that the test result is valid. The control line should always be visible. A negative urine specimen will produce two colored lines, and a positive specimen will produce only one line. The test kits are also available with simultaneous testing for multiple drugs (Fig. 3).

3. DESCRIPTION OF TEST KITS

Each Visualine II test kit is housed in a single plastic device. The device contains a membrane strip with a defined amount of microspheres coated with an anti-drug monoclonal antibody (mouse) in a pH 7.4 buffer. The kits contain mouse monoclonal antibody directed against benzoylecgonine (cocaine), morphine glucuronide (opiates), 11-nor-Δ-9-tetrahydrocannabinol-9-carboxylic acid (cannabinoids, THC), oxazepam glucuronide (benzodiazepines), amphetamine, and methamphetamine.

A second antibody (goat antimouse IgG) is incorporated to form the aforementioned reference line. Antigenic probe and animal serum are also absorbed onto the membrane. The membrane is treated with stabilizer and preservative and is then dried before assembly and use. All necessary reagents for performing the test are included in the individual test device; no additional reagents are required.