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Evaluation of the TDx and ADx Methadone Immunoassays,

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We evaluated a new fluorescence polarization immunoassay (FPIA) for methadone in urine, using the TDx and ADx analyzers (Abbott Laboratories). After an initial calibration of each analyzer, we determined assay precision by analyzing three controls, designated low (L), medium (M), and high (H), with methadone concentrations of 0.3, 0.75, and 2.00 mg/L, respectively. The TDx-FPIA precision study included analysis of each control (n = 5) 10 times over 16 days. The ADx-FPIA precision study involved analysis of each control (n = 5) 10 times over 16 days, both in the batch mode (single assay per carousel) and in the combination mode (multiple assays per carousel). In addition, we used three multiconstituent controls to test assay precision in the panel mode (multiple sampling from a single cartridge). All within-run and between-run CVs were <5%, thus indicating good precision for the assay with either analyzer.

All FPIA calibrators were within 15% of their target concentrations when measured by gas chromatography/mass spectrometry (GC/MS). Further to study accuracy, we analyzed 100 urine specimens not containing methadone by TDx-FPIA, ADx-FPIA, and EMIT, and 100 urine specimens containing methadone (>0.15 mg/L) by TDx-FPIA, ADx-FPIA, EMIT, and GC/MS. All negative specimens produced TDx-FPIA and ADx-FPIA results <0.01 mg/L. Of the positive specimens 61 had FPIA concentrations >4.0 mg/L, thus producing a result of "high" on each instrument; 60 of these had methadone concentrations >4.0 mg/L when measured by GC/MS. Thirty-nine specimens had methadone concentrations by FPIA between 0.15 and 4.0 mg/L; 35 of these had methadone concentrations by GC/MS within 20% of the FPIA concentrations. Ninety-nine of the 100 positive specimens were positive by EMIT, the one negative specimen having a methadone concentration by FPIA and GC/MS <0.3 mg/L, the EMIT cutoff.

The TDx-FPIA and ADx-FPIA methadone assays are acceptable screening immunoassays for presumptive testing of urine specimens. In addition, good semiquantitative results can also be obtained by using these assays.

Unusual Band on Hemoglobin Electrophoresis Produced by a Monoclonal Immunoglobulin in Serum,

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We observed an unusual band on hemoglobin electrophoresis on cellulose acetate. This band migrated cathodically, in contrast to the anodic migration of hemoglobin bands, when electrophoresed at pH 8.6. The band disappeared when electrophoresed at pH 6.3 on citrate agar plates. The patient's other laboratory data included values for total serum protein, 116 g/L, and for albumin, 41 g/L. Serum protein electrophoresis showed the presence of a discrete band in the gamma region, which was IgG-kappa. The total IgG concentration in serum was 64.1 g/L. Bone-marrow biopsy confirmed the presence of plasma-cell myeloma. On electrophoresis of a washed erythrocyte hemolysate instead of a whole-blood hemolysate, the band was not seen. To demonstrate that this band was the monoclonal immunoglobulin, we did immunofixation of a whole-blood hemolysate and a washed erythrocyte hemolysate on agarose gel. The former showed a monoclonal IgG that was not present in the latter.

The manufacturer of the hemoglobin electrophoresis kit (Helena Laboratories, Beaumont, TX) suggests two alternative methods for preparing samples for hemoglobin electrophoresis on cellulose acetate. In one, whole-blood hemolysate is used, in the other, packed erythrocyte hemolysate.

The possible confusion in hemoglobin electrophoresis created by the presence of a monoclonal immunoglobulin may be avoided by preparing washed erythrocyte hemolysates. Also, the presence of an unusual band on hemoglobin electrophoresis should alert one to the possibility of a monoclonal immunoglobulin and warrant further investigation.