The fluorometric enzyme immunoassays that can be run on the automated Stratus analyzer (American Dade, Miami, FL) are based on monoclonal antibodies coated to glass-fiber paper tabs. The available assays are specifically designed for quantification of analytes in plasma and serum, but not in urine. For example, eight urine samples with hCG concentrations <2.5 int. units/L according to the Tandem-E immunoenzymometric assay for urinary intact hCG (Hybridgetch Europe SA, Liége, Belgium) had apparent hCG concentrations ranging between 9.3 and 16 int. units/L when measured with the Stratus. To further investigate this observation, we processed 35 urine samples for intact hCG with the Stratus (y) and compared these with results with the Tandem-E (x). Regression analysis between the two "sandwich"-type assays revealed the following equation: 

\[ y = 1.45x + 9.20 \text{ int. units/L}, \quad S_{yx} = 7.0, \quad \bar{x} = 55 \text{ int. units/L}, \quad r = 0.987 \] (Figure 1A).

Apart from possible differences in specificities between the two hCG assays compared, we suspected a matrix effect with the Stratus. To test this, we treated the glass-fiber paper tabs of the hCG assay with 50 µL of Stratus sample diluent (i.e., processed human serum included in the kit), then assayed 38 urine samples for hCG content with these pretreated tabs on the Stratus [Stratus(+)]. Regression analysis of these results yielded the following: Stratus(+)

\[ y = 1.06x + 0.58 \text{ int. units/L}, \quad S_{yx} = 7.7, \quad \bar{x} = 93 \text{ int. units/L}, \quad r = 0.993 \] (Figure 1B). Use of 25, 50, or 100 µL of Stratus "serum sample diluent" did not change the results. Also, the apparently false-positive hCG results obtained for the above-mentioned eight urine samples with the unmodified Stratus became concordant with the Tandem-E results (i.e., <2.5 int. units/L) if we followed this modification procedure with the Stratus tabs.

We conclude that (a) the Stratus hCG assay is suitable for urine samples if the glass-fiber paper tabs are pretreated with Stratus "serum sample diluent" in amounts between 25 and 100 µL; (b) the "Stratus urine hCG assay" compares well with the Tandem-E immunoenzymometric assay of urinary hCG; and (c) this modification provides an automatable quantitative and probably more sensitive alternative to conventional pregnancy-testing kits, which are designed to measure hCG only semi-quantitatively in urine specimens.


This nonisotopic assay for follitropin (FSH; follicle-stimulating hormone) for use with the Abbott IMX "(I) is based on microparticle enzyme immunoassay technology involving the "sandwich" principle. FSH in serum or plasma is bound by mouse monoclonal antibody to β-FSH covalently coupled to carboxylate-modified polystyrene microparticles. After a 7.5-min incubation at 34 °C and a separation step on the glass fiber matrix of the IMX disposable reaction cell, an antibody–alkaline phosphatase (EC 3.1.3.1) conjugate prepared from affinity-purified goat antibody to FSH α subunit is added and the mixture is incubated an additional 7.5 min. Specifically bound conjugate is quantitated by determining the rate of conversion of 4-methylumbelliferyl phosphate to fluorescein 4-methylumbelliferone. The sample FSH concentration is calculated from a stored calibration curve.

The IMX FSH assay detects as little as 0.2 int. unit/L (the lowest concentration exceeding the 95% confidence limit for the zero calibrator). The assay range, standardized against the WHO Second International Reference Preparation (IRP) 78/549, is 0 to 150 int. units/L. Cross-reactivity with lutropin (1000 int. units/L) was 0.066%, with thyrotropin (2 int. units/L) 0.045%, and with a supraphysiological concentration of choriogonadotropin (500 000 int. units/L) 0.00024%. There was <5% interference from cholesterol (10.9 g/L), triglycerides (40 g/L), bilirubin (500 mg/L), or hemoglobin (7.5 g/L). Analytical recovery of 2nd IRP 78/549 FSH added to normal human serum was 96% to 102.2%. Intra-, inter-, and total assay CVs for 60 assays done in each of 10 IMX instruments averaged <4.8%, <7.5%, and <8.3%, respectively, over the range 3.8 to 60 int. units/L.

FSH ranges were determined for 30 normal men (mean 5 int. units/L, range 1 to 12 int. units/L), 57 postmenopausal women (mean 74 int. units/L, range 18 to 153 int. units/L), and 23 women with normal menstrual cycles. Cycle days were synchronized to the mid-cycle lutropin peak, with follicular phase defined as the time from 10 days to four...