zone as much as 100-fold does not remove the interference supports this supposition.

The form of the interference is such that there is a lag phase during which no color develops. This lag phase is directly proportional to the concentration of ascorbate and inversely proportional to the glucose oxidase concentration in the reagent. Clearly, the degree of interference in the glucose measurement will depend upon the constitution of the reagent and the time course over which the reaction is monitored, with the greatest interference being where the reaction is monitored shortly after mixing and over a short interval of time. Thus, kinetic methods are potentially more susceptible to interference of this type.

The interference would appear to be due to preferential oxidation of the ascorbic acid. There appears to be no way in which this can be overcome without resorting to pre-incubation of each sample with ascorbate oxidase, because other alterations of the reaction conditions did not overcome the interference. One solution to this problem would be to use an end-point glucose oxidase/peroxidase method in which minimal interference is observed or to use a method based on the use of glucose dehydrogenase. Because the glucose dehydrogenase method does not appear to suffer from this interference, it therefore can be used with confidence in a formulation that meets the needs of the instrumentation available.

The interference of ascorbate in glucose measurements was confined solely to neonatal CSF samples. No interference was observed in any neonatal blood samples, adult CSF samples, or adult blood samples taken after an ascorbic acid load. The lack of interference in blood samples is explained by ascorbate being at a higher concentration in CSF than in plasma \( (10, 11) \). No CSF samples were obtained from adults known to have taken ascorbate; it is likely, however, that such samples would demonstrate the interference.

**References**


**Five Recent Urinary Tests for Early Pregnancy Evaluated**

**Kenneth W. Ryder, Robert A. Munsick, Tjien O. Oei, Peter C. Young, and H. Frances Blackford**

We evaluated five tests developed for the earlier detection of pregnancy, either in the clinical laboratory or by the patient in her home. These tests offer no advantage over other urinary pregnancy tests, and the results are distinctly inferior to those reported (Clin. Chem. 29: 561–563, 1983) for some serum tests for pregnancy.

**Additional Keyphrases:** chorionic gonadotropin · "kit" methods

Immunological tests for human chorionic gonadotropin (hCG) in urine have been the basis of laboratory tests of pregnancy for the past two decades. Evaluations of such tests have indicated that they perform this role reasonably well. Lewis

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pregnancy tests: the sensitivity of the test for the detection of hCG and the concentration of hCG in the specimen.

Recently, early diagnosis of pregnancy has been emphasized as a means of minimizing the problems associated with complications of pregnancy, particularly ectopic pregnancies (4–15). To assist in making this diagnosis, some new urinary pregnancy tests have been developed, which allegedly will detect lower concentrations of hCG. No evaluation of these tests has been reported. In addition, home tests for pregnancy have become available, which allow women to self-diagnose early pregnancy.

We have evaluated five urinary tests for pregnancy that were not included in the CAP Survey Report (3). One of these tests (e.p.t., see below) is intended for home pregnancy testing. The other four are intended as laboratory pregnancy tests, but the manufacturer of each claims a greater sensitivity (lower detection limit) than has been associated with other such tests, thus facilitating earlier diagnosis of pregnancy (at three weeks of gestation or less). Two of these tests are radioimmunoassays, one a slide-type flocculation test, and the other a tube-type flocculation test. In this study we used samples of urine from subjects known not to be pregnant and from patients with a wide range of gestational ages and serum hCG concentrations.

Materials and Methods

Pregnancy tests. The following urinary pregnancy tests were evaluated:

2. Betacept Pregnancy Assay, Monitor Science Corp., 1598 Monrovia Ave., Newport Beach, CA 92663.

Table 1 shows the principle of each test, as well as its claimed analytical sensitivity, performance time, stability, and cost.

All pregnancy tests were performed by experienced clinical laboratory technologists, with strict attention to the manufacturer's directions.

Serum hCG measurement. Blood was sampled from each patient at the same time a urine specimen was collected. Serum beta-hCG concentrations were measured with a procedure and reagents supplied by Serono Laboratories. All sera were assayed in duplicate, with a 1-h incubation, and the results averaged. Quantification of serum beta-hCG was repeated for duplicates that did not agree within 5%. This procedure has an analytical sensitivity of 3 int. units of hCG per liter of serum. Concentrations of hCG of less than 3 int. units/L of serum are reported as "undetectable." Beta-hCG is undetectable in serum from normal, nonpregnant subjects.

Patients and control subjects. Samples of urine were obtained from 59 normal control subjects. Serum beta-hCG was undetectable in any of these women. The 29 patients in this study were being treated at a pregnancy termination clinic. To obtain urine specimens with a wide range of beta-hCG concentrations, urines were collected just before pregnancy terminations and at weekly intervals thereafter for up to four weeks. A total of 77 samples of urine were obtained from these patients.

Results and Discussion

Table 2 shows the percentage of pregnancy test results that were negative for nonpregnant subjects, i.e., the test's specificity. For four of the pregnancy tests—Betacept, Sensi-Tex, Sensi-Slide, and e.p.t.—97 to 100% of the results for this control group were correct. This specificity is consistent with results previously reported for other pregnancy tests (1–3). For Preg/Stat, however, only 90% of the results were negative for these nonpregnant subjects. This 10% false-positive rate is higher than has generally been reported for other procedures and would usually be considered unacceptable for a routine laboratory test of pregnancy.

Numerical statements of sensitivity and accuracy or efficiency are not easily applied to pregnancy tests. In spite of their name, urinary pregnancy tests do not detect pregnancy per se; rather, they are designed to give a positive result if the urinary hCG concentration exceeds a certain threshold, the analytical sensitivity of the test. For example, if a patient were pregnant but had a urinary hCG concentration less than the analytical sensitivity of the test, a positive result might be called either a true-positive or a false-positive result. To avoid such semantic problems, we simply show the percentage of positive results that were obtained for each of the five urinary pregnancy tests examined here for different ranges of serum beta-hCG concentrations (Table 3).

The Preg/Stat Urinary Pregnancy Test is very sensitive. A positive result was obtained with this test for all urine specimens that were from patients whose beta-hCG concentration exceeded 1000 int. units/L of serum. Unfortunately, the sensitivity of this test is offset by its lack of specificity (Table 2). Results obtained with the Betacept procedure were generally good, its sensitivity being equivalent to that of the more-sensitive tube-type urinary pregnancy tests (9). Unfortunately, unlike the tube tests for pregnancy, Betacept is a radioimmunoassay procedure. Because the Betacept results are only equivalent to those reported for tube-type pregnancy tests, but include the major technical problems associated with isotopic laboratory tests, we cannot endorse its routine use for pregnancy testing. The results we obtained with the

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Table 1. Features of Urinary Pregnancy Tests in This Study

<table>
<thead>
<tr>
<th>Principle</th>
<th>Claimed anal. sens., int. units/L</th>
<th>Performance time, min</th>
<th>Claimed reagent stability</th>
<th>Current cost of reagents for a single test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preg/Stat</td>
<td>150</td>
<td>55</td>
<td>5 wks</td>
<td>$1.26</td>
</tr>
<tr>
<td>Radioimmunoassay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Betacept</td>
<td>200</td>
<td>30</td>
<td>6 wks</td>
<td>0.90</td>
</tr>
<tr>
<td>Radioimmunoassay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensi-Tex</td>
<td>250</td>
<td>100</td>
<td>6 mo</td>
<td>1.75</td>
</tr>
<tr>
<td>Tube immunoassay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensi-Slide</td>
<td>800</td>
<td>3</td>
<td>6 mo</td>
<td>1.50</td>
</tr>
<tr>
<td>Slide immunoassay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e.p.t.</td>
<td>1250</td>
<td>125</td>
<td>1 yr</td>
<td>10.00*</td>
</tr>
</tbody>
</table>

*No additional laboratory expenses associated with this test. Lot nos. of kits no longer available.
other three pregnancy tests—Sensitex, Sensi-Strip, and e.p.t.—are generally as good as have been previously reported for slide-type pregnancy tests. The percentage of correct values for these tests is poorer than would be expected for most of the currently available tube-type pregnancy tests. These tests offer no advantage over other urinary pregnancy tests, and the results are distinctly inferior to those recently reported for some serum tests for pregnancy (16).

The manufacturers of the five urinary pregnancy tests evaluated in this report graciously donated the kits used in this study.

References