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At home testing: optimizing management for the infertility physician

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Objective: To review and describe various over-the-counter testing products available to the infertility patient, a billion-dollar a year industry that continues to grow.
Design: Methodology involved a detailed Medline search of literature, use of online search engines, and focused communications with various manufacturers to determine the usefulness and validity of existing products.
Conclusion(s): Although some home tests have been subjected to scientific scrutiny, others have not. At-home testing represents an opportunity for physicians to involve patients actively in their care. When properly used, these tests also may result in cost savings. However, physicians and consumers must understand the limitations of these tests. Many of the technologies used are innovative and, with proper evaluation and implementation, could serve as valuable adjuncts to medical practice. (Fertil Steril® 2011;95:1867–78. ©2011 by American Society for Reproductive Medicine.)

Key Words: Over the counter, at home, testing

The medical paradigm in which physicians practice is constantly changing. The field of infertility is no exception. Increasingly, patients look for ways to simplify their care and minimize perceived, unnecessary visits to health care providers or undergo invasive testing. One such example of this trend is in the area of at-home testing.

Not long ago many of the tests available for over-the-counter use were only possible through a hospital or physician's office. At present, there are myriads of tests commercially available to consumers that claim to be accurate without the need for invasive blood testing. This billion-dollar-a-year industry continues to grow as a result of improved technology, an increased patient demand for autonomy and privacy, and the increasing cost of office-based services (1).

The purpose of this review is to provide physicians with an up-to-date survey of over-the-counter devices available to their patients. This review focuses specifically on tests designed to aid couples in matters related to human reproduction and infertility. The goals of the review will be to identify available tests and evaluate their advantages and disadvantages as defined by reliability, effectiveness, accessibility, cost, usefulness, and other available indicators. Although the review concentrates primarily on testing for infertile couples, it does not necessarily encompass all the modalities that have been promoted at this time.

Some of the products available over the counter have been thoroughly tested and offer value to patients and their physicians. Other products, however, at the present time, seem to lack enough practical application, relevance, or sound science to be broadly recommended to patients as a valuable adjunct to medical management. Based on the interpretation of the data reviewed by the investigators, suggestions of testing modalities that may be of maximal and minimal benefit are outlined in Tables 1–3.

The methodology used to compose this article involved several approaches. A detailed Medline search was first performed to identify available literature in the English language discussing over-the-counter testing. We then searched the online inventory of several major retailers to obtain pricing data and also alert us as to new devices commercially available. Online search engines, including www.google.com, were also used to identify testing modalities and their prices that were not found through mainstream retailers. In several cases, the manufacturers were contacted directly to provide further information regarding their products.

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OVULATION

The ovum only survives 12–24 hours after ovulation without fertilization, whereas sperm may survive in cervical mucus for up to 5 days (2). Therefore, defining the time at which ovulation occurs is vital to determine the fertile period. The ability of women to predict the day of ovulation without formalized measures of specific physical changes has been documented to be imprecise (3). One study found that the ability of women to predict ovulation without formally monitoring cervical mucus or basal body temperature (BBT) was only 28% in highly motivated, regularly cycling women (3).

Basal Body Temperature

Ovulation is accompanied by physiologic changes that can be monitored by the patient. A biphasic pattern in the BBT is an increase,

TABLE 1

Testing useful in most patients.

Type of testing	Examples
Ovulation prediction	LH testing kits Clear Blue Easy Fertility Monitor
Pregnancy detection	B-hCG testing kits

Note: Valuable adjuncts to clinical practice.

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ranging from 0.5°–1.0°F (0.278°–0.555°C) as measured with a thermometer, which corresponds with the production of P after ovulation (4). It is useful to establish a pattern of ovulation rather than to predict ovulation (4, 5).

Advantages of BBT are its low cost and ease of application at home (5). The test's accuracy, however, is questionable. Studies place the ability of BBT to precisely predict the LH surge to the day at 18.3%–30% and to within 1 day at 56.7%–70% (6). However, not all women display a clear shift in BBT after ovulation and conditions including illness, changes in sleep patterns, alcohol consumption, and certain medications may alter the BBT (4, 7).

The method also requires women to check and record their BBT daily. This is significantly burdensome for many women (8). Commercially available thermometers are able to track BBT electronically and then predict, based on past patterns, the most fertile points in a cycle. Natural Methods (Natural Methods, Inc., Orangeville, Ontario, Canada) is a company that provides such electronic devices that range in price from USD $279–$685 (9). The Natural Methods website provides the text for a study abstract presented at the International Meeting on Infertility and Assisted Reproductive Technology in 1997 which showed the device to confirm ovulation in 80% of women (10). However, the study (10) did not comment on the ability of the product to predict the ovulatory day and included only 10 women in the study. A Medline search by the authors could not find this work in the published literature.

Summary of BBT Records

Advantages (4, 5, 9):

- Cost
  - Low cost of traditional thermometer
- Accessibility
  - Highly accessible to consumers
  - Traditional thermometer available over the counter in a variety of retail stores

Disadvantages (4, 6–9):

- Accuracy
  - Able to predict the LH surge to the day at 18.3%–30% and to within 1 day at 56.7%–70%
  - Requires patient interpretation of results
- Cost
  - Significant up-front cost for electronic monitors
- Accessibility
  - Electronic monitors not easily accessible to consumers
  - Electronic monitors available at few retailers
    - Products are available online
- Ease of use
  - Requires high level of patient compliance
  - Often requires instruction by physician's office to train patient

Brand Evidence and Cost (9–11):

- Over-the-counter oral thermometers
  - Brand data
    - Specific brand data not found by literature review conducted by investigators
  - Cost
    - At USD $5.99–$19.99
- Natural Methods electronic monitors:
  - Brand data
    - One study of 10 women indicated that the device could accurately confirm 80% of ovulatory cycles retrospectively
  - Cost
    - Natural Methods produces
      - Baby-Comp at USD $685
      - Bioself at USD $279

Cervical Mucus

Another physiologic change that may be monitored by the patient is the characteristic of the cervical mucus that accompanies ovulation. The volume and viscoelasticity of the cervicovaginal fluid (CVF) increase in the late follicular phase and immediately after ovulation (12, 13). There have been attempts to quantify the volume of CVF. A plastic volumetric aspirator called the Rovumeter was developed in the mid-1990s that allowed women to aspirate CVF from the cervical os (13). The results of this device, however, were disappointing, causing the Rovumeter to fall out of favor and it is currently no longer in production (13).

Other investigators have evaluated the ability of women to detect qualitative changes in CVF at the level of the vulva to predict ovulation (14). Studies evaluating the accuracy of this method in

TABLE 2

Testing useful in selected patients.

Type of testing	Examples	Advantages	Limitations
Ovulation prediction	BBT (thermometers)	Low cost	Poor predictive value
	Cervical mucus	Low cost	Conflicting data
	Salivary ferning	Low cost	Conflicting data
Ovarian reserve	FSH testing kits	Low cost	Difficult to interpret an isolated result

Note: Adjuncts to clinical practice that may be helpful in some patients due to financial barriers. BBT = basal body temperature.

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