

OTC Advisor

Selection and Use of Home Testing Products

Monograph 3



A continuing
pharmacy
education activity
for pharmacists



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ACTIVITY PREVIEW

Increased public interest in health and preventive medicine has prompted patients to take a more active role in their personal health care. Patients have easy access to home testing products that allow them to screen for health conditions or to monitor a disease state or response to medication therapy. A few decades ago, pregnancy tests were the only home tests available, however the market for home testing products has grown tremendously and continues to grow. Home testing products are convenient and provide patients with quick, confidential results in the privacy of their own home.

This monograph provides an overview of the most commonly used home testing products to allow pharmacists to assist patients with the appropriate selection and use. Concise product reviews include a discussion of how the home testing product works, when self-testing is appropriate, factors to consider in product selection, benefits and limitations of the product, patient counseling information, how to interpret the test results, and when evaluation by a primary care provider is needed.

LEARNING OBJECTIVES

At the completion of this activity, the pharmacist will be able to:

1. Describe the appropriate selection and use of common home testing products.
2. Explain how selected home testing products work and how to interpret the test results.
3. Summarize the benefits and limitations of common home testing products.
4. List possible causes of false-positive and false-negative results of home testing products.
5. Identify factors that should be considered before recommending a home testing product.
6. Describe reasons for patients to consult a primary care provider for evaluation based on the results of a home testing product.

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ACCREDITATION INFORMATION



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DEVELOPMENT

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DISCLOSURES

Jean-Venable "Kelly" R. Goode, PharmD, BCPS, FAPhA, FCCP, has served as an advisory board member for Zicam and a speaker for GlaxoSmithKline.

Macary Weck Marciniak, PharmD, BCPS, discloses that her spouse is employed by the American Pharmacists Association.

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INTRODUCTION

The first home pregnancy test was introduced to the market by Warner-Lambert in 1977. Since that time, the market for home testing products has grown tremendously. Several factors have affected the growth in home testing products. Increased public interest in health and fitness, with an emphasis on preventive medicine, has prompted patients to take a more active role in their own health care. Patients can use home testing products to screen for health conditions or to monitor a disease state or response to medication therapy.

A few decades ago, pregnancy tests were the only home test available. Now, various products are available to provide information about major health conditions such as fertility, menopause, bacterial and viral infections, high cholesterol, diabetes, and hypertension. This monograph provides an overview of the most commonly used home testing products.

REGULATORY CONSIDERATIONS

The U.S. Food and Drug Administration (FDA) regulates home testing products to ensure safety of the products and reliability of the results. The FDA requires that a home testing device must perform the same way in the hands of a lay user as it would in the hands of a professional. To reduce the possibility of a false result, user-friendly labeling must be included to ensure that the lay user can follow the product instructions and interpret the test results correctly. The FDA recommends that manufacturers include diagrams and photographs to help explain the testing procedure and suggests that patient information be provided in a simple question-and-answer format.

THE VALUE OF HOME TESTING PRODUCTS

Home testing products can be a valuable addition to patient care. These products are easily accessible and provide patients with quick, confidential results in the privacy

of their own home. Home testing products can help patients detect a health condition early in the disease process and seek medical care early. However, human error plays an important role in the ultimate value of home testing products. Validity of the results depends solely on the patient performing the test correctly and appropriately interpreting the results. Improper use of the test can affect the test results, and misinterpretation of the results could delay treatment of a medical condition. Patients who use home testing products should be informed that they are self-testing, not self-diagnosing. These products should never serve as a replacement for medical care.

Positive test results should always be reported to the patient's primary care provider. The primary care provider can evaluate the test results within the context of the patient's whole health picture and provide information, support, and follow-up advice regarding these results.

ROLE OF THE PHARMACIST

Pharmacists are in an ideal position to assist patients with the appropriate selection and use of home

testing products. Pharmacists have the knowledge and skills to assess patient-specific information to determine whether home testing is appropriate for an individual patient. For example, a patient with visual impairment may not be able to accurately interpret test results of a device that requires observation of a color change, or a patient who has a medical disorder that causes excessive bleeding may not be an appropriate candidate for home testing that involves collecting a blood sample.

If home testing is a valid option, the pharmacist can assist the patient in selecting an appropriate product. In some product categories, deciding which home testing product to recommend to a patient can be challenging because several brands and product types may be marketed. Once a product is selected, the pharmacist should provide patient education about the product. The pharmacist should ask whether the patient has past experience using the product. If the patient previously had difficulty using the product, the pharmacist should troubleshoot the testing procedure with the patient to help clarify any misunderstanding of directions. In addition to providing

Table 1. General Counseling Tips for Home Testing Products

- Choose a simple test (i.e., the one with the fewest number of steps) to help limit the potential for human error.
- Store the test as recommended by the manufacturer until use.
- Always check the expiration date before use.
- Read all instructions carefully and completely before performing the test.
 - Determine the time of day the test should be performed.
 - Determine the length of time required to complete the test.
 - Identify any necessary equipment needed to complete the test.
- Remove the testing device from the package immediately before use.
- Follow the instructions exactly as described and in sequence.
- Collect the sample as directed by the product instructions.
- Use an accurate timing device and wait the specified length of time between steps.
- Wait the maximum time recommended in the product instructions before reading the results.
- Use the instructions to interpret the test results.
- Report the test results to the primary care provider.
- Schedule a follow-up appointment with a primary care provider if a test result is positive or if the patient has a negative test result but continues to experience symptoms.
- Never reuse or share a lancet, and always discard used lancets in a puncture-proof container.

product-specific patient counseling, pharmacists can provide general counseling tips to a patient using a home testing product (TABLE 1). Finally, pharmacists can assist the patient with result interpretation and help the patient understand when it is appropriate to seek further evaluation and follow-up medical care.

HOME FERTILITY TESTS

On average, the menstrual cycle is 28 days long. The follicular phase of the menstrual cycle begins on the first day of menses and ends when ovulation occurs. During the follicular phase, hormones are released that promote the development of an ovarian follicle. At midcycle (approximately the 14th or 15th day of a 28-day cycle), a surge of luteinizing hormone (LH) results in the final maturation of one follicle. The follicle ruptures and the ovum is released, resulting in ovulation. This occurs approximately 20 to 48 hours after the LH surge. The ovum remains receptive to fertilization for only a short period of time (approximately 12 to 24 hours) after ovulation. Sperm may remain viable for up to 72 hours if the conditions are appropriate. For conception to occur, viable sperm must be present while the egg is still receptive to fertilization.

Therefore, the window for conception is small, and a couple must identify this fertile window and time intercourse appropriately to maximize the possibility of conception.

The inability to conceive a child can be caused by a number of factors and the struggle to become pregnant can cause emotional distress for patients. Women who want to become pregnant may choose to use a home fertility test before seeking medical intervention to address fertility issues.

Several home fertility tests are available to help a woman identify the time during her menstrual cycle when conception is most likely to occur. There is also a product that can determine the man's sperm count. Decreased sperm count can be a factor in some cases of infertility and this product can help determine if a low sperm count could be contributing to a couple's infertility issues.

Female Fertility Tests

Initially, the methods for identifying the fertile window and predicting ovulation were limited to measuring basal body temperature, evaluating cervical mucus, and using the calendar method. However, the number of ovulation prediction tests available on the market has multiplied in

recent years to include urine testing kits, saliva-testing microscopes, and chloride ion–based fertility monitors. TABLE 2 lists selected ovulation prediction tests and devices; additional information about some of these ovulation prediction methods is provided below. Saliva microscopes are not discussed in detail in this monograph because of conflicting data on accuracy with these devices.

Pharmacists should consider the benefits and limitations of each method and the patient's preferences before recommending an ovulation prediction method. Some couples may enjoy the increased feeling of control that ovulation prediction methods offer, whereas other couples may dislike the necessity of watching the calendar. Examples of questions to ask when helping patients select an ovulation prediction method are provided in TABLE 3.

Some couples who choose to use natural family planning as a means of birth control employ ovulation prediction methods to avoid pregnancy. However, ovulation prediction methods should never be recommended as a reliable means of birth control.

Basal Body Temperature

Resting basal body temperature is usually slightly below normal during

Table 2. Selected Ovulation Prediction Tests and Devices

Trade Name	Reaction Time	Product Features
BD Basal Thermometer	1 minute	Digital thermometer; auto memory for last reading; continuous beep to indicate it is working; signals when done; large lighted display
Clearblue Easy Ovulation Test Pack	3 minutes	7-day kit; uses urine test sticks; predicts ovulation within 24–36 hours; most sensitive product in <i>Consumer Reports</i> test; easy to read
Answer One-Step Ovulation Test Kit	5 minutes	7-day kit; uses urine test sticks; predicts ovulation within 24–36 hours
First Response Easy-Read Ovulation Test	5 minutes	7-day kit; uses urine test sticks; predicts ovulation within 24–36 hours
Clearblue Easy Fertility Monitor	5 minutes	Reusable monitor; uses urine test sticks; predicts 1- to 5-day window of peak fertility; easy to read; permits only one reading per day; tests for luteinizing hormone and estrone-3-glucuronide; requires patient to purchase new test strips for each cycle
OV-Watch Fertility Predictor	Measures chloride ions every 30 minutes up to 12 readings	Lightweight watch worn while the patient is sleeping; detects up to 4 days prior to ovulation; easy to use and read

the first part of the menstrual cycle and then rises to a level closer to normal (98.6°F [37°C]) approximately 24 to 48 hours after ovulation occurs. With this method, women measure basal body temperature daily using a basal thermometer and record the results on a graph to identify the slight rise in temperature.

Digital basal thermometers are preferred over older mercury basal thermometers because the digital versions provide precise results, eliminating the need to interpret the temperature reading. (Basal thermometers that contain mercury are no longer marketed because of environmental concerns about toxicity.)

Patient education pearls for measuring basal body temperature are highlighted in TABLE 4.

Interpretation of Results. Identification of a slight rise in temperature indicates that ovulation has already occurred and the fertility window for this cycle has ended. However, this method can help patients determine whether they are consistently ovulating and provide information about the pattern of ovulation. Patients should chart their temperature for a minimum of 2 to 3 months. The information the chart reveals may help patients estimate their probable window of fertility during subsequent months.

Benefits. Using the basal body temperature method is inexpensive because the only equipment needed is the basal thermometer. An additional benefit is that this method does not require patients to collect a urine sample.

Limitations. Daily monitoring of basal body temperature may be impractical for some patients. Patients need to be able to record their temperature on a graph and then appropriately interpret the graph to identify the slight rise in temperature. They may have trouble identifying the temperature increase because incremental increases are slight. In addition, basal body temperature can be influenced by multiple factors (TABLE 4).

Basal body temperature is not a reliable method to prospectively identify the window of fertility. As noted previously, when the slight rise

Table 3. Questions to Ask When Helping Patients Select an Ovulation Prediction Method

Have you recently been pregnant, discontinued breastfeeding, or discontinued use of oral contraceptives?

Any patient who has recently been pregnant, discontinued breastfeeding, or discontinued the use of hormonal contraceptives should wait to begin using ovulation prediction methods until two natural menstrual cycles have occurred.

Do you have any chronic medical conditions or are you taking any medications?

Certain medical conditions and some medications can interfere with the test results. Pharmacists should screen patients to determine whether any of these health conditions are present or if the patient is taking any medications that can interfere with the ovulation prediction method (see TABLE 6).

How regular are your periods?

Women with very regular periods may achieve pregnancy more quickly with products that predict the timing of ovulation based on the surge in luteinizing hormone, such as traditional urine-based ovulation prediction tests. Patients with irregular periods may have more success with fertility monitors that can monitor the entire menstrual cycle.

Table 4. Patient Education Pearls for Measuring Basal Body Temperature

- Use a digital basal thermometer that clearly displays the read out of the temperature measured. (Mercury thermometers should no longer be used.)
- Record resting basal body temperature daily throughout the menstrual cycle.
- Measure basal body temperature at the same time each morning before rising and after at least 5 hours of sleep.
- Plot the temperatures on a graph and monitor for a slight rise in temperature.
- Monitor for a consistent rise in temperature of 0.4°F to 1.0°F (0.2°C to 0.6°C), which indicates that ovulation has occurred.
- Use a consistent anatomical site (i.e., oral, rectal, or vaginal) for measuring the temperature each time.
- Limit factors that can influence basal body temperature. Factors that might interfere with monitoring include:
 - Eating
 - Emotions
 - Drinking
 - Infection or illness
 - Movement during the measurement
 - Smoking
 - Talking

in temperature is identified, ovulation has already occurred and the window of fertility has closed for the current cycle.

Traditional Urine-Based Ovulation Prediction Test Kits

Traditional urine-based ovulation prediction test kits use monoclonal antibodies to detect LH in the urine. An enzyme-linked immunosorbent assay (ELISA) elicits a color change on the testing device, indicating the

amount of LH present in the urine.

A variety of urine-based ovulation prediction test kits are available, varying in the length of time needed to complete the test, the method for urine sample collection, the method for displaying the result, and the number of tests available in the kit. These factors may influence patients' selection of a urine-based ovulation prediction test kit, depending on individual patient preferences.

Patient education pearls for us-

ing traditional urine-based ovulation prediction test kits are highlighted in TABLE 5.

Interpretation of Results. The traditional urine-based ovulation prediction tests require patients to visualize color and interpret a change in color intensity because the intensity of the color on the testing device reflects the amount of LH detected in the urine. When the patient identifies a change in the color intensity on the test stick compared with that on the previous day, this indicates that the LH surge has occurred.

Benefits. LH in the urine is considered a reliable predictor of ovulation. If urine-based ovulation prediction tests are used appropriately and interpreted correctly, patients can expect ovulation to occur within 12 to 24 hours following detection of the LH surge.

Limitations. To use the traditional urine-based prediction test kits, women must have information about the length of their past menstrual cycles to determine when to begin testing. However, some women have unpredictable menstrual cycles or cycles that vary from month to month. Women who have irregular cycles or long cycles should read the product-specific instructions to determine when to begin testing.

Patients may fail to detect an LH surge during their cycle when using a urine-based testing kit. If this occurs, they should be counseled to evaluate their testing technique to determine whether the test was performed appropriately. For example, if the patient tested too early or too late in the cycle, the amount of LH in the urine may have been too low to detect. In addition, some women may have a very short LH surge (less than 10 hours) that can go undetected with a once-daily test. If patients do not detect the LH surge with the first test kit, they can continue with a second test kit to try to identify the LH surge. If no LH surge is detected on more than one cycle, patients should consult with a primary care provider.

Certain medications and medical conditions can result in false-positive results with traditional urine-based ovulation prediction test kits (TABLE 6).

Fertility medications used to induce ovulation can artificially elevate LH levels and result in a false-positive test. However, patients taking clomiphene can use these kits to correctly identify the true LH surge if they are counseled to begin testing the second day after drug therapy ends. Medical

conditions associated with high levels of LH (e.g., menopause, polycystic ovary syndrome) can produce false-positive results. Women with these conditions should be advised not to self-test with urine-based ovulation prediction test kits. Pregnancy also can result in a false-positive result.

Table 5. Patient Education Pearls for Using Traditional Urine-Based Ovulation Prediction Test Kits

- Read the product-specific instructions to determine when to begin testing based on previous menstrual cycles.
 - In general, testing should begin 2 to 4 days before ovulation is expected unless otherwise indicated by the testing kit.
 - Continue testing on subsequent days until the LH surge is detected.
- Identify whether the kit requires a specific time of day to conduct the test.
 - Use a consistent time of day on each subsequent day of testing.
- Restrict fluid intake for 4 hours prior to testing to avoid dilution of urine.
- Compare the color intensity of the test line with that of the control line.
- Watch for the first significant increase in color intensity compared with the previous day of testing, which indicates that the LH surge has occurred.
- Intercourse should take place within 12 to 24 hours of the positive test to optimize the chance of conception.

LH = luteinizing hormone.

Table 6. Potential Sources of False-Positive Results for Ovulation Prediction Methods

Test Method	Potential Sources of False-Positive Results
Traditional urine-based ovulation prediction tests ^a	<ul style="list-style-type: none"> • Fertility medications • Menopause • Polycystic ovary syndrome • Pregnancy
Clearblue Easy Fertility Monitor ^b	<ul style="list-style-type: none"> • Breastfeeding • Fertility medications • Hormone replacement therapy • Impaired liver or kidney function • Menopause • Oral contraceptives • Perimenopause • Polycystic ovary syndrome • Pregnancy • Tetracycline
OV-Watch Fertility Predictor ^c	<ul style="list-style-type: none"> • Breastfeeding • Hormone replacement therapy • Impaired liver or kidney function • Menopause • Oral contraceptives • Polycystic ovary syndrome

^a Measures luteinizing hormone in the urine.

^b Measures luteinizing hormone and estrone-3-glucuronide in the urine.

^c Measures chloride ion levels in perspiration.

Clearblue Easy Fertility Monitor

The Clearblue Easy Fertility Monitor also uses urine samples to predict ovulation, however it has an advantage over the traditional urine-based ovulation test kits because it can detect both a rise in estrone-3-glucuronide (E3G) and the LH surge. E3G is a component of estrogen associated with the appearance of “fertile mucus.” Fertile mucus is thin and slippery, which creates a conducive environment for sperm to thrive while waiting for the mature ovum to be released for fertilization. When the LH surge is detected by the monitor, ovulation will likely occur in the next 20 to 48 hours.

Patient education pearls for using the Clearblue Easy Fertility Monitor are highlighted in TABLE 7.

Interpretation of Results. Patients will receive a reading on the monitor of low, high, or peak fertility. “Low fertility” is indicated by one bar in the bottom left corner of the screen; this result suggests there is a small chance of conception. When the monitor detects an increase in estrogen levels, it displays a “high fertility” result, which is represented on the monitor by two bars on the left side of the screen. The chance of conception will increase when the

patient has intercourse during a high fertility reading because the monitor has detected favorable conditions for sperm to thrive while awaiting the release of the egg. When the monitor detects the LH surge, it displays a “peak fertility” reading, indicated by three bars on the left side of the screen in addition to a symbol of an egg. A peak fertility reading will be displayed on the monitor on the day of the LH surge and the day following the LH surge.

According to the manufacturer’s instructions, patients should have intercourse two or more times during the fertile period to maximize the chance of conception. Therefore, patients should have intercourse when the monitor displays both the high and the peak fertility results. Timing intercourse during the peak fertility time maximizes the chances of conceiving.

Benefits. The Clearblue Easy Fertility Monitor prospectively identifies a window surrounding the time of ovulation. The monitor detects both a rise in E3G and the LH surge, which increases test specificity when compared with urine-based ovulation tests that measure LH only. The monitor collects and interprets the patient’s information and displays the

fertility reading on the screen thereby eliminating the need for the patient to interpret the results to determine when the LH surge has occurred. The fertility monitor is often a good option for patients with short cycles, long cycles, or unpredictable cycles because it allows these patients to collect daily fertility information to be interpreted by the monitor.

Limitations. Some patients may have an LH surge that is too low to be detected or a short (less than 10 hours) LH surge. Patients who consistently test negative using the Clearblue Easy Fertility Monitor may want to test twice a day during the period of expected ovulation to increase the chance of detecting their LH surge.

Pharmacists should carefully evaluate a patient’s medication history and medical history before recommending the Clearblue Easy Fertility Monitor to become aware of potential sources of false-positive results (TABLE 6). Fertility medications, hormone replacement therapy, tetracycline, and oral contraceptives can cause false-positive results. High estrogen levels associated with taking clomiphene may result in more high fertility readings. In addition, the monitor may not be able to identify the peak fertility reading because it may not be able to detect the LH surge owing to the high estrogen levels. Pregnancy, perimenopause, menopause, and polycystic ovary syndrome can produce false-positive results. Impaired liver or kidney function also can interfere with the results of the monitor.

The Clearblue Easy Fertility Monitor is more expensive than other ovulation prediction testing methods, and this may be an important consideration for some patients. The monitor is reusable. However, the patient must purchase additional test sticks for the monitor to test on subsequent months.

Chloride Ion Level Fertility Predictor

Chloride ion levels found in perspiration fluctuate in relation to a woman’s menstrual cycle. Chloride ion levels are low at the beginning of the menstrual cycle, then a surge in chloride ions occurs approximately 5 to 6 days before ovulation. The OV-

Table 7. Patient Education Pearls for Using the Clearblue Easy Fertility Monitor

- Follow the product instructions to determine a “testing window.”
 - The testing window is a 6-hour time span during which the sample should be collected every day.
 - Because first morning urine should be used for the testing, the testing window should be set in the morning.
- Turn on the monitor every morning during the testing window before going to the bathroom and the monitor will indicate whether a test should be performed.
- If a test should be performed, the test stick should be placed into the urine stream for 3 seconds only.
- Follow the instructions carefully for collecting the urine sample and inserting the test stick into the monitor.
- The test stick must be inserted into the monitor within 15 minutes of placing the urine on the stick.
- For the first month, testing should begin 6 days after menstruation begins.
 - The monitor will then request a test every day for a total of 10 to 20 days to establish baseline data for the patient.
- In subsequent months, test 10 to 20 days a month as indicated by the monitor.
- Perform all of the tests requested by the monitor; do not skip a day of testing.
- Use only Clearblue Easy Fertility Monitor test sticks in the monitor.
- Always start a cycle of testing with at least 10 test sticks from the same box.
- Test sticks are not reusable.

Watch Fertility Predictor is a device worn on the patient's wrist that utilizes biosensor technology to detect the surge in the chloride ion levels in perspiration on the skin.

Patient education pearls for using the OV-Watch Fertility Predictor are highlighted in TABLE 8.

Interpretation of Results. The device will provide a reading indicating Fertile Day 1, Fertile Day 2, Fertile Day 3, Fertile Day 4, and the Day of Ovulation. Intercourse should be timed during this window of fertility to maximize the possibility of conception.

Benefits. The OV-Watch is worn like a wristwatch while patients are sleeping. It provides a noninvasive method of detecting a window of fertility. This device does not require the patient to collect urine samples or monitor body temperature.

Limitations. Incorrect set up of the OV-Watch can lead to unreliable results. If a patient misses more than 2 days of testing, the device will not be able to accurately identify the window of fertility. The OV-Watch can be used only by patients with regular monthly cycles lasting from 24 to 35 days. Contact with water or other liquids may damage the monitor, and excessive perspiration can interfere with test results.

Potential sources of false-positive results are listed in TABLE 6. Oral contraceptives, hormone replacement therapy, or breastfeeding can interfere with the results of the OV-Watch. Conditions such as impaired liver or kidney function, menopause, and polycystic ovary syndrome can produce unreliable results with this device.

The initial cost of the OV-Watch Fertility Predictor is comparable to that of the Clearblue Easy Fertility Monitor. An additional cost associated with the OV-Watch is replacement of the sensors, which must be done at the beginning of each menstrual cycle.

Male Fertility Tests

Male fertility issues can contribute to a couple's inability to conceive a child. A number of factors (e.g., sperm concentration, sperm motility,

Table 8. Patient Education Pearls for Using the OV-Watch Fertility Predictor

- Follow the manufacturer's instructions carefully to set up the device.
- Wear the device on the wrist while sleeping for at least 6 hours.
 - The device must fit the wrist correctly to function properly.
- Begin wearing the device on the first, second, or third day of the menstrual cycle and wear the device until the day of ovulation.
- Do not miss more than 2 days wearing the watch during the prefertility phase of the cycle.
- Replace the sensor at the beginning of each new cycle.
- Clean the sensor daily according to the manufacturer's instructions to minimize salt buildup on the sensor.
- Do not get the device wet and remove the device before exercise.

CASE 1. OVULATION PREDICTION TEST

LL, a 32-year-old woman, asks for your help in choosing a method for ovulation prediction. LL has been a loyal patient at the pharmacy for many years and recently stopped taking her oral contraceptives because she wants to get pregnant.

Which of the following would be the most appropriate *initial* question to ask the patient?

- How long have you been off birth control pills?
- How long have you been trying to become pregnant?
- Are you willing to collect urine samples for testing purposes?
- Have you ever used ovulation prediction methods in the past?

After assessing the patient, you determine that she stopped using oral contraceptives 6 months ago, although she has been trying to get pregnant for only the last 2 months. She wants to use an inexpensive ovulation prediction method to figure out her menstrual cycles so she can maximize the chances of becoming pregnant. She tried checking her temperature every day but could not figure out when she was ovulating. Now she wants to try a different method.

Which of the following ovulation prediction methods would be the most appropriate option for this patient?

- Basal body temperature.
- Fertility microscope.
- Traditional urine-based ovulation prediction test.
- Clearblue Easy Fertility Monitor.

Case study responses appear on pages 21–23.

sperm morphology) are known to impact male fertility. Sperm production can be influenced by physical, emotional, and psychological factors. One test is available for home use to measure sperm count, however this test does not provide information about the viability of the sperm.

BabyStart Male Infertility Test Kit

The BabyStart Male Infertility Test (also called FertilMARQ) measures

a man's sperm count. The test works by staining the cells in the collected sperm sample to produce a color change.

Patient education pearls for using the BabyStart Male Infertility Test are highlighted in TABLE 9.

Interpretation of Results. The BabyStart Male Infertility Test kit requires the man to visualize color and discern a change in color intensity to interpret the test results. The color

in the test well is compared with the color in the reference well on the test stick. If the shade of blue in the test well is as dark as or darker than the shade of blue in the reference well, the result is positive (defined by the World Health Organization as a concentration higher than 20 million sperm per milliliter). A color lighter than the color in the reference well indicates a negative result (defined by the World Health Organization as a concentration less than 20 million sperm per milliliter). Two tests on a single semen sample are necessary for comparison purposes.

The results of the two tests should be the same, either both positive or both negative. Two positive tests indicate the man has a normal sperm concentration. Two negative tests indicate the man has a decreased sperm concentration. If the results of the two tests are not the same, the man should retest in 10 weeks with a new kit and consult his primary care provider.

Benefits. This is a confidential test that can be performed in the privacy of the user's home.

Limitations. The overall accuracy of the test is only 78%. User error can contribute to unreliable results. For example, if the semen sample is not liquefied before adding it to the test stick, the results may be inaccurate. It is important for patients to understand that this test assesses only sperm concentration. Other sperm characteristics that may contribute to infertility (e.g., motility, morphology) are not assessed by this test.

When Should Patients Undergo Further Evaluation?

Women who have not become pregnant after using ovulation prediction methods for 3 months should review their technique to ensure they are properly using the product. If difficulty persists, patients should consult their primary care provider or a fertility specialist for further evaluation.

Men who use a home fertility test should share the results with their primary care provider. A man's sperm concentration may be influenced by emotional, physical, or psychological factors that should be addressed by the patient's primary care provider.

Table 9. Patient Education Pearls for Using the BabyStart Male Infertility Test (FertilMARQ)

- Wait 3 days after the last ejaculation before collecting a semen sample.
- Collect a semen sample using one of the methods described in the product instructions.
 - Use only the condoms provided in the test kit for sample collection.
- Add the semen to the liquefaction cups provided with the test kit and allow the semen to liquefy for at least 15 minutes.
 - The semen can be stored in the liquefaction cup for up to 12 hours.
- Add 1 drop of the liquefied semen to the appropriate testing well.
 - The test stick contains four wells labeled A, B, C, and D.
 - Wells A and C are blue and serve as the reference wells.
 - Wells B and D are white and serve as the test wells.
- Follow the product instructions to add the appropriate reagents to the test wells.
- Read the results within 5 minutes.
- Repeat the entire test with a new sample of semen at least 3 days, but not more than 7 days, after the first sample was collected.

Table 10. Questions to Ask When Helping Patients Select a Home Pregnancy Test

How late is your period?

Ensure that women are using the test at an appropriate time in their menstrual cycle. Pharmacists should encourage patients to wait at least 1 week after their expected menses before testing. Women who wish to test earlier than 1 to 2 weeks after their expected menses should be cautioned about the possibility of false-negative results. Women testing close to the date of their missed period may prefer to purchase a product that contains two tests in order to have a second test available to confirm the results.

What prescription and nonprescription medications are you taking?

Pharmacists should carefully review the use of any prescription or nonprescription medications for all female patients of childbearing age or those with a confirmed pregnancy. Certain medications (e.g., methotrexate, isotretinoin, nonsteroidal anti-inflammatory drugs) are contraindicated in pregnancy, and patients should be advised to discuss the use of these medications with their primary care provider and/or obstetrician-gynecologist immediately.

Are you taking prenatal vitamins?

All pregnant women should be advised to take a prenatal vitamin because prenatal vitamins contain many essential nutrients for the appropriate development of the fetus. In particular, folic acid taken early in pregnancy has been shown to reduce the incidence of certain birth defects, including spina bifida. Therefore, women who are attempting to conceive and those who detect pregnancy should begin use of prenatal vitamins.

Couples who use a home male fertility test must be educated that the results of this test provide only one piece of information that may be contributing to infertility.

HOME PREGNANCY TESTS

Approximately one third of women report using a home pregnancy test to determine whether they are pregnant before seeking professional

health care. Home pregnancy tests use monoclonal or polyclonal antibodies in an enzyme immunoassay to detect human chorionic gonadotropin (hCG) present in the urine; hCG is a hormone released after a fertilized egg successfully implants in the uterine wall. Typically, at least 1 to 2 weeks must elapse after conception before hCG concentrations reach levels that can be detected in the urine.

Available Products

A range of home pregnancy tests are available with slight variations (e.g., reaction times, display of results) among the different products. Examples of questions to ask when helping patients select a home pregnancy test are provided in TABLE 10.

Patient education pearls for using home pregnancy tests are highlighted in TABLE 11.

Interpretation of Results. Tests differ in their methods of displaying results. A positive pregnancy test result may be indicated by a positive sign (+), two lines (II), or a digital readout of “pregnant.” A negative pregnancy test result may be indicated by a negative sign (-), one line (I), or a digital readout of “not pregnant.” Patients should read the product instructions to determine how to interpret the results.

Benefits. Early detection of pregnancy is important. Identifying the pregnancy early allows the patient to seek appropriate prenatal care and change any lifestyle behaviors that could be detrimental to the developing fetus.

Devices that report the test result as a digital reading offer an advantage over other devices because the patient does not need to interpret the test result. However, the digital devices require additional steps in the testing procedure, which may increase the possibility for human error.

Limitations. Most home pregnancy tests are advertised as 99% accurate, however this reported accuracy rate assumes use under ideal conditions. In actual use, many home pregnancy tests are not performed under ideal conditions. Results from several studies question the accuracy rate of home pregnancy tests, and some studies have found the true accuracy rate of home pregnancy tests when performed by patients to range from 50% to 75%. One reason for this discrepancy is human error. For example, the patient may not follow the directions, may have difficulty interpreting the test results, or may read the test result too early—all of which can lead to false-negative results.

Many of the home pregnancy tests state that a patient can test as

Table 11. Patient Education Pearls for Using Home Pregnancy Tests

- Wait at least 1 week after the date of expected menstruation to perform the test.
- Use first morning urine because levels of human chorionic gonadotropin will be more concentrated at this time.
- Restrict fluid intake for 4 to 6 hours prior to testing if first morning urine is not used.
- Collect the urine sample as directed by the product instructions, and test the sample immediately after collection.
- Do not refrigerate urine prior to the test.
- Do not collect the urine sample in a waxed cup or a household container.
- After the urine is applied to the test stick, lay the device on a flat surface.
- Wait the maximum time recommended in the product instructions before reading the results.
- If the test is positive, the patient should assume she is pregnant and consult a primary care provider or obstetrician-gynecologist.
- If the result is negative, check the test steps to identify any errors. Wait the number of days recommended in the instructions and repeat the test. If the result is negative and menses is more than 1 week overdue, consult a primary care provider or obstetrician-gynecologist.

early as the first day of a missed menstrual period. However, a false-negative may result if the test is conducted before the concentration of hCG in the urine exceeds the threshold of detection for the test. A study published in the *Journal of the American Medical Association* found that 10% of pregnancies were undetectable on the first day of the patient’s missed period. The most accurate results with home pregnancy tests were obtained by waiting at least 1 week after the date of the expected menses.

Patients using home pregnancy tests may detect hCG levels from a fertilized ovum that fails to implant or an ovum that implants in the uterine wall but fails to progress to clinical pregnancy. Home pregnancy tests provide no information about the viability of the pregnancy. Earlier testing with home pregnancy tests increases the probability of recognizing very early pregnancy loss.

Although home test kits may allow earlier detection of pregnancy, and thus an opportunity to initiate prenatal care, the opposite outcome also may occur. Women using these tests incorrectly have a significant risk of obtaining false-negative results, which may result in delaying a prenatal health care visit and allowing patients to believe they can safely continue behaviors that can endanger the developing fetus (e.g., alcohol use, smoking).

Home pregnancy tests can produce false-positive results if a patient had a miscarriage or gave birth in the previous 8 weeks. Ectopic pregnancies also may produce positive test results. Medications containing hCG, such as Humegon, Pregnyl, Pergonal, Profasi, and APL, may cause false-positive results. Patients who have a history of ovarian cysts may get unreliable results from a home pregnancy test.

When Should Patients Undergo Further Evaluation?

Any positive test result from a home pregnancy test should be immediately reported to the patient’s primary care provider. If the test result is negative and the patient questions the accuracy of the result, she should carefully evaluate the testing technique to determine whether there was any potential for error or whether the test was performed too early. Pharmacists should recommend follow-up testing in 1 to 2 weeks if initial results are negative and menstruation does not begin. Any patient who questions the accuracy of the results of a home pregnancy test should consult a primary care provider for further evaluation.

CASE 2. PREGNANCY TEST

KB, a 21-year-old college student, asks you which pregnancy test she can use to find out right away if she is pregnant. She had unprotected sex with her boyfriend 5 days ago and is worried that she might be pregnant.

Which of the following would be the most appropriate *initial* question to ask the patient to determine whether self-testing with a pregnancy test is appropriate?

- Have you used a pregnancy test before?
- When was your last period and when do you expect your next period?
- Have you contacted your primary care provider yet?
- Have you ever been pregnant before?

KB wants to know when she can test to find out if she is pregnant.

Which of the following would be the most appropriate response to this patient?

- You can test as soon as you think you are pregnant.
- You can test as early as 3 days before your expected period.
- The best time to test is on the day of your expected period.
- You should wait at least 1 week after your missed period.

In your assessment, you find out the following information about KB. She is healthy, occasionally eats fast food, exercises regularly, and takes isotretinoin for her acne.

Which of the following statements would be most appropriate to tell this patient?

- Discuss discontinuing the isotretinoin with your primary care provider and/or obstetrician-gynecologist immediately if you think you are pregnant.
- Stop exercising immediately.
- Do not consume any fast food if you are pregnant.
- Prenatal vitamins are not necessary in early pregnancy.

Case study responses appear on pages 21–23.

HOME TESTING PRODUCTS FOR SPECIFIC CONDITIONS

A number of home testing products enable patients to check for the presence of specific conditions including menopause, urinary tract infections (UTIs), fecal occult blood, human immunodeficiency virus type 1 (HIV-1) infection, hepatitis C virus (HCV) infection, and high cholesterol.

Home Tests for Menopause

Menopause is clinically defined as the cessation of menstruation for a 12-month period resulting from a loss of ovarian follicular function. Ovarian failure is a gradual process; as ovarian function declines, estrogen levels decrease and follicle-stimulating hormone (FSH) levels increase. The decreasing estrogen levels can produce symptoms such as hot flashes, mood swings, irregular menstrual cycles,

and vaginal dryness.

Available Products

Urine-based menopause tests detect FSH levels using monoclonal antibodies specific to FSH. An ELISA will elicit a color change on the testing device in response to the amount of FSH in the urine sample. There are a number of urine-based menopause tests approved by the FDA: Early Detect Menopause Home Test, Meno-check Menopause Indicator Test, and the RU25 Plus FSH Menopause Test Kit.

Patient education pearls for using home menopause tests are highlighted in TABLE 12.

Interpretation of Results. The patient must be able to visualize color to interpret the test results. A positive test result from the home menopause tests indicates that the FSH level is

Table 12. Patient Education Pearls for Using Home Menopause Tests

- Use first morning urine.
- Do not drink large amounts of fluids the night before the test, and do not consume fluids after midnight the night before the test.
- Avoid touching reaction areas on the testing product.
- The two tests in the test kit should be performed approximately 1 to 2 weeks apart.
- Remind patients that the results of this test do not determine fertility or lack of fertility.

greater than 25 IU/L. Because FSH levels can fluctuate in relation to the patient's menstrual cycle, this test must be repeated 1 to 2 weeks later to confirm the results.

Benefits. The results of the test could provide the patient with some insight about the symptoms she has been experiencing. The results of a home menopause test should be shared with the patient's primary care provider.

Limitations. Several factors can interfere with the results of home menopause tests. For example, if first morning urine is not used, the urine may be too diluted thereby leading to inaccurate results. Patients taking oral contraceptives, hormone replacement therapy, or estrogen supplements can receive unreliable results with the home menopause tests. Health conditions that may affect FSH levels (e.g., ovarian or pituitary tumors) also can cause unreliable results.

Patients should be educated that a positive test result with the home menopause test does not guarantee infertility. Patients should not discontinue use of contraceptives based on the results of this test. Patients should always talk with a primary care provider before discontinuing contraceptive use or any other medication.

There is no one independent biologic marker to indicate that a woman is menopausal. Although FSH measurement may be used in a clinical

evaluation, many experts agree that FSH alone is not a reliable method for diagnosing menopause. Patients need to understand that home tests for menopause have limited clinical relevance because the tests do not provide enough information for primary care providers to make a clinical decision or diagnosis. The diagnosis of menopause should involve a thorough evaluation by the patient's primary care provider.

When Should Patients Undergo Further Evaluation?

If the patient chooses to use a home menopause test, any positive result should be communicated to her health care provider for further evaluation. A patient with a negative result who is experiencing menopausal symptoms should be evaluated by a primary care provider.

Home Tests for Urinary Tract Infection

UTIs are a common cause of visits to primary care providers each year. Risk factors for a UTI include previous UTIs, diabetes, urinary tract abnormalities, pregnancy, enlarged prostate, and the presence of a catheter. Behavioral factors such as sexual activity, delayed urination, inability to urinate, wiping from posterior to anterior, and the use of spermicides and diaphragms also may increase the risk of developing a UTI.

The majority of uncomplicated UTIs are caused by *Escherichia coli*, a gram-negative bacterium. The symptoms commonly reported by patients with a UTI include frequent urination, painful urination, a burning sensation while urinating, a sensation of an urgent need to urinate, and lower abdominal pain or discomfort. Without proper identification and treatment, a UTI can develop into a serious, complicated infection.

Pharmacists should educate patients that self-testing for a UTI is not appropriate for all patients with symptoms of a UTI. Self-testing may be appropriate for early detection of UTIs in patients with a history of recurrent UTIs. Early identification of a recurrent infection allows the patient to seek appropriate treatment. Self-testing also may be appropriate

for patients recovering from a UTI to determine whether antibiotic therapy has been successful. Self-testing should not be recommended when the patient reporting the symptoms does not have a history of UTI. These patients should be evaluated by a primary care provider.

Available Products

There are two types of home UTI tests available: the UTI Home Screening Test and the AZO Test Strips. The UTI Home Screening Test detects nitrites in the urine that are produced when gram-negative bacteria reduce nitrate to nitrite. The AZO Test Strips detect nitrites as well as leukocyte esterase. Leukocyte esterase is an enzyme associated with leukocytes, which are white blood cells that may be present in the urine when a patient has an infection. AZO Test Strips thus offer increased sensitivity and specificity compared with the UTI Home Screening Test.

Patient education pearls for using home UTI tests are highlighted in TABLE 13.

Interpretation of Results. A positive test result is indicated by pink coloration on the test pad for the UTI Home Screening Test. A positive test result is indicated by dark tan to purple coloration on the test pad for the AZO Test Strips.

Benefits. Patients with a history of recurrent UTIs may benefit from home tests. These tests may help detect a UTI early in the course of the infection, which would allow the pa-

tient to seek treatment before it progresses to a complicated infection.

Limitations. Several factors can interfere with the results of home UTI tests. The patient must avoid directly touching the testing area on the test pad because oil from the skin can interfere with the test results. Reading the test result after the maximal 3-minute limit can lead to inaccurate results. Patients who follow a strict vegetarian diet may produce insufficient amounts of urinary nitrates for accurate test results.

Phenazopyridine, which often is taken by patients to relieve the discomfort of a UTI, has been associated with false-positive results. Tetracycline and vitamin C may cause false-negative results.

When Should Patients Undergo Further Evaluation?

Patients who obtain a positive test result should contact their primary care provider immediately for evaluation and treatment. If the test is negative but symptoms of a UTI persist, patients should contact their primary care provider for evaluation.

Home Tests for Fecal Occult Blood

The presence of blood in the stool could indicate a potential colon problem such as bleeding ulcers, colitis, diverticulitis, hemorrhoids, or colorectal cancer. However, it can be difficult to detect the very small amounts of blood that may be present early in the course of the condition. Early detec-

Table 13. Patient Education Pearls for Using Home Urinary Tract Infection Tests

- Clean the genital area thoroughly prior to collecting the urine sample.
- Collect a midstream sample of urine as directed by the product instructions.
- Cover the entire test pad with urine.
- Test first morning urine if possible.
 - If urine is tested later in the day, urine should be held in the bladder for at least 4 hours prior to the test.
- Wait no longer than 3 minutes to read the result; any color change after 3 minutes should be disregarded.
- If the result is negative, test the urine on 3 consecutive days to confirm the test result.
- Avoid consuming vitamin C prior to testing.
 - For the UTI Home Screening Test: avoid doses of vitamin C in excess of 250 mg within 10 hours of testing.
 - For the AZO Test Strips: avoid doses of vitamin C in excess of 500 mg within 24 hours of testing.

tion greatly improves the chances of successful treatment. Fecal occult blood tests (FOBTs) are used to detect hidden (occult) blood in the stool.

Available Products

The available home FOBTs are categorized as: toilet tests (e.g., EZ Detect Stool Blood Test, First Check ColoCheck), stool wipes (e.g., Life Guard), and manual stool application devices (e.g., ColonTest-Sensitive). FOBTs for home use contain a colorimetric assay for hemoglobin. If blood is present in the stool, the heme portion of hemoglobin will oxidize the test reagent, producing a blue-green result in the test area. Because lesions may bleed intermittently, the test is performed on three consecutive bowel movements to increase the probability of detecting a possible lesion.

Patient education pearls for using FOBTs are highlighted in TABLE 14.

Interpretation of Results. The patient must be able to visualize color to interpret the test results. Patients should refer to product-specific instructions to determine how to read the results of the test.

Benefits. Home FOBTs are easily accessible, convenient, and affordable. These noninvasive tests can be used as an adjunct to more invasive testing.

Limitations. Medications that can cause gastrointestinal bleeding or rectally administered medications can interfere with the results of FOBTs. Medications such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, anticoagulants, and

iron can cause false-positive results. Patients should consult with their health care provider to determine whether these medications can be safely discontinued for 2 to 3 days prior to testing and throughout the testing period.

In addition to the medications listed above, patients using the LifeGuard or ColonTest-Sensitive products should not take high doses of vitamin C (250 mg/day or more) or consume red meat for 2 or 3 days before testing to avoid false-positive results. Patients who do not want to restrict their diet should choose either EZ Detect or First Check ColoCheck.

The ColonTest-Sensitive requires the patient to manually apply a stool sample. Patients who prefer a product that does not require manual handling of the stool may opt to avoid this product.

Patients should be informed that toilet bowl cleaners can interfere with the accuracy of these tests. Patients should be counseled to follow product-specific instructions to avoid this potential problem.

Factors to Consider Before Recommending Home Testing

The risk factors for colorectal cancer include ulcerative colitis, Crohn's disease, inflammatory bowel disease, or a family history of colorectal cancer (younger than age 60 years at diagnosis), colorectal adenomas, familial adenomatous polyposis, or hereditary nonpolyposis colon cancer. Patients with these risk factors should consult with their primary care provider to determine the appropriate

course of testing.

When Should Patients Undergo Further Evaluation?

Patients with a positive test result should consult their primary care provider for evaluation. Pharmacists should advise patients that a positive result does not necessarily indicate the presence of colorectal cancer, however further investigation is necessary to determine whether there is cause for concern.

Home Tests for Human Immunodeficiency Virus Type 1

The Centers for Disease Control and Prevention (CDC) has estimated that over 1 million people in the United States are living with HIV/acquired immunodeficiency syndrome (AIDS). Risk factors for HIV infection include having unprotected sex, having sex with a partner who has engaged in high-risk activities, having sex with an anonymous partner, having sex with multiple partners, sharing needles while using injectable drugs, or receiving blood or blood products before 1985.

Nearly one quarter of patients with HIV infection are unaware that they are infected. Lack of awareness delays appropriate treatment and allows further spread of HIV. Home testing offers a way for users to determine their HIV infection status in the privacy of their home. According to a study reported in the *Journal of the American Medical Association*, nearly 60% of all of the patients who used a home test had never been tested previously and 49% of the patients who tested positive for HIV with the home test had never before been tested. These results indicate that HIV home testing could have a substantial effect on public health by helping to identify individuals infected with HIV.

Available Products

Two products are available for home testing for HIV infection: the Home Access HIV-1 Test System and the Home Access Express HIV-1 Test System. The patient collects a blood sample at home and then sends the sample to a Home Access laboratory for processing. The laboratory is approved by the FDA, certified under

Table 14. Patient Education Pearls for Using Home Fecal Occult Blood Tests

- Follow product-specific instructions for completing each test.
- Do not perform the test during times of known bleeding (e.g. hemorrhoidal bleeding, menstruation).
- Perform the test on three consecutive bowel movements.
- Complete all three tests even if the first two tests are negative.
- Increase roughage in the diet for 2 to 3 days prior to testing because this will stimulate bleeding from any gastrointestinal lesions.
- Do not take nonprescription medications such as aspirin or nonsteroidal anti-inflammatory drugs for 2 to 3 days prior to testing.
- For the LifeGuard test or the ColonTest-Sensitive products: do not take high doses of vitamin C (250 mg/day or more) or consume red meat for 2 or 3 days before testing.

CASE 3. FECAL OCCULT BLOOD TEST

SJ, a 52-year-old African American man, is interested in purchasing an FOBT. He has heard that testing is recommended for those over 50 years of age. He has hypertension, which is controlled using lisinopril. He also regularly takes a multivitamin. He asks which test you would recommend.

Which of the following would be the most appropriate *initial* question to ask this patient to determine whether self-testing with an FOBT is appropriate?

- Do you eat red meat or take high doses of vitamin C?
- Do you have any risk factors for colorectal cancer, such as ulcerative colitis, inflammatory bowel disease, or a family history of colorectal cancer?
- Have you previously used any other home FOBT products?
- Do you take aspirin, NSAIDs, corticosteroids, or anticoagulants?

Your assessment of this patient reveals that he is not considered high risk for developing colorectal cancer. The patient has decided to use a home FOBT. He does not want to handle a stool sample and prefers not to discontinue eating red meat during the testing. Based on your assessment, you recommend the EZ Detect Stool Blood Test.

Which of the following points would you include when counseling the patient about using the home FOBT?

- Discontinue all medications prior to using the test.
- Decrease roughage in the diet for at least 2 to 3 days prior to testing.
- Complete all three tests even if the first two tests are negative.
- Hemorrhoidal bleeding will not interfere with the test results.

After using the home testing kit, the patient has a positive result. He is worried that he has colorectal cancer.

Which of the following would be the most appropriate response to this patient?

- A positive test result with the FOBT indicates the presence of blood in the stool. The patient needs to be evaluated by a primary care provider to determine the cause of the bleeding.
- A positive test result with the FOBT indicates the presence of colorectal cancer. The patient needs to be evaluated by a primary care provider to develop a treatment plan for colorectal cancer.
- A positive test result with the FOBT does not need to be evaluated by a primary care provider.
- A positive test result with the FOBT indicates that the patient performed the test incorrectly.

Case study responses appear on pages 21–23.

the Clinical Laboratory Improvement Amendments (CLIA), and accredited by the College of American Pathologists. An ELISA is performed on the sample to detect antibodies to HIV. The test measures antibodies to HIV-1, not the level of virus present in the blood. If a sample tests positive with the ELISA, the sample is rescreened twice. If both rescreenings of the tests are positive, an immunofluorescent assay is performed to confirm the positive result.

Patient education pearls for using

the home HIV-1 test are highlighted in TABLE 15.

Interpretation of Results. This test system does not require the patient to interpret the results. Rather, the patient must call the toll-free phone number provided with the kit. The patient will need to use the confidential home access code number that was registered with the kit as a patient-specific identifier to access the test results.

Benefits. Home testing products for HIV-1 are easily accessible and

convenient. Home testing offers a method for patients to receive confidential test results about their HIV infection status. Home testing may help identify individuals infected with HIV early in the disease process so they can receive appropriate treatment and modify behaviors to prevent further transmission of the virus.

Limitations. Failing to provide an adequate blood sample or waiting longer than 10 days after sample collection to send in the blood sample can lead to inaccurate results.

An individual infected with HIV may receive a false-negative result if insufficient levels of antibodies are present for detection in the blood sample. Waiting 6 months after the potential exposure will allow enough time for the detectable levels of antibodies to form in the blood.

Receiving a positive test result for HIV-1 can be devastating to a patient and this is an important concern about home testing for HIV-1. Another concern is the potential for patients to delay receiving treatment if they are in denial about their HIV-positive test results. The manufacturer provides patients with posttest counseling over the phone and patients have access to a referral service when they receive the home test result. However, receiving the test results from their primary care provider may be more appropriate and would provide an opportunity to develop an immediate treatment plan for the patient.

Factors to Consider Before Recommending Home Testing

Pharmacists should sensitively ask patients who want to purchase these tests whether they have any of the risk factors for HIV infection and whether 6 months have passed since the potential exposure to the virus. The 6-month waiting period is designed to ensure that an adequate amount of antibody is present. Pharmacists should consider the patient's level of concern about a possible positive result. Patients who appear highly distressed may benefit from a testing method that allows for personal pretest and posttest counseling. Some patients may choose to test for HIV-1 for their own peace of mind even in the absence of identifiable risk factors.

The only differences between the two available products are the price and the amount of time it takes to receive the test results, but the test system is the same. The Home Access HIV-1 Test System is sent to the laboratory by regular mail and allows patients to obtain their test results in 7 days. The Home Access Express HIV-1 Test System includes an envelope for expedited shipping of the test sample to the laboratory, and the increased cost of shipping is factored into the price. The express system allows patients to obtain their test results in 3 days. Patients who want faster results may prefer the express version, and patients for whom cost is a greater concern may prefer the standard version.

When Should Patients Undergo Further Evaluation?

Patients who test positive for HIV infection should be seen by a primary care provider immediately for confirmation testing and treatment. Early diagnosis of HIV is important to initiate effective treatment and take precautions against opportunistic infections associated with HIV infection and AIDS. Patients who test positive should avoid activities that may result in the transfer of blood or other bodily fluids to other people.

If a test has been performed prior to 6 months postexposure, the test should be repeated. If patients have had multiple possible exposures, they might choose to test multiple times. Patient education for individuals with negative test results should include a discussion of risk factors for exposure to HIV and education about strategies that minimize their risk of exposure.

Home Tests for Hepatitis C Virus

According to estimates by the CDC, approximately 4.1 million people in the United States have been infected with hepatitis C virus (HCV). HCV is transmitted exclusively by blood-to-blood contact. Risk factors for HCV infection include having sexual intercourse with multiple partners, a previous history of a sexually transmitted disease, or a history of injection drug use or cocaine use. Patients who received treatment with a clotting factor concentrate produced prior to

Table 15. Patient Education Pearls for Using Home HIV-1 Tests

- Patients should wait at least 6 months after possible exposure before performing the home test.
- Register the kit by calling the toll-free phone number provided with the kit.
 - The specific home access code number must be registered to access the test results.
- Write the specific home access code number and the date the sample was collected on the specimen collection card.
- Follow the product instructions to collect the blood sample.
 - Apply blood inside the circle on the specimen collection card until the circle is completely saturated.
 - Check the back of the circle to ensure the blood has soaked through.
 - If blood has not soaked through enough to cover the circle, apply more blood.
 - Allow the blood to dry for 30 minutes prior to sealing the sample in the envelope.
- Seal the sample in the envelope as directed in the instructions.
- Send the sample to the laboratory so it is received within 10 days of sample collection.
- Call the toll-free phone number in 3 to 7 business days, depending on which product was used, to obtain the test results.
- Individuals should be counseled to avoid activities that result in the transfer of blood or bodily fluids to other people.

HIV-1 = human immunodeficiency virus type 1.

1987, a blood transfusion or organ transplant prior to 1992, or long-term hemodialysis also are at risk for HCV infection. Health care workers and military personnel have an occupational risk of exposure to HCV. Infants born to mothers infected with HCV also are at risk of being infected.

The most common symptom of HCV infection is fatigue. However, according to the CDC, the majority of patients infected with HCV have no signs or symptoms. Therefore, people with HCV infection often are unaware they are infected until the chronic effects of the virus manifest, which may not occur until decades after contracting the virus. These patients are at risk for serious liver damage as well as for transmitting HCV to other people. Chronic HCV infection is one of the leading causes of chronic liver disease, and it is the most common condition leading to liver transplantation. HCV infection can lead to the development of cirrhosis or hepatocellular carcinoma, and may result in death in some patients.

Available Products

The Hepatitis C Check is the only home test for HCV approved

by the FDA. The patient collects a blood sample at home and sends the sample to a Home Access laboratory for processing. The laboratory is FDA approved, CLIA certified, and accredited by the College of American Pathologists. The Hepatitis C Check initially uses an ELISA to test for the presence of antibodies to HCV, called anti-HCV. Positive results are confirmed with a recombinant immunoblot assay.

Patient education pearls for using the home HCV test are highlighted in TABLE 16.

Interpretation of Results. This test does not require patients to interpret the results. Rather, patients must call the toll-free phone number provided with the kit to receive their results. Patients will need to use the home access code number that was registered with the kit as a confidential, patient-specific identifier to access the results.

Benefits. The Hepatitis C Check is easily accessible, convenient, and affordable. Home testing offers a method for patients to receive confidential test results about their HCV infection status in the privacy of their home. Home testing may help identify

Table 16. Patient Education Pearls for Using the Home Hepatitis C Virus Test

- The antibodies to hepatitis C virus generally can be detected within 6 weeks to 3 months after exposure, but it may take longer. It is recommended that the test be performed 6 months or more after exposure.
- Register the kit by calling the toll-free phone number provided with the kit.
 - The specific home access code number must be registered to access the test results.
- Write the specific home access code number and the date the sample was collected on the specimen collection card.
- Follow the product instructions to collect the blood sample.
 - Apply blood inside the circle on the specimen collection card until the circle is completely saturated.
 - Check the back of the circle to ensure the blood has soaked through.
 - If blood has not soaked through enough to cover the circle, apply more blood.
 - Allow the blood to dry for 30 minutes prior to sealing the sample in the envelope.
- Seal the sample in the envelope as directed by the instructions.
- Send the sample to the laboratory so it is received within 10 days of sample collection.
- Call the toll-free phone number in 10 business days to obtain the test results.
- Individuals should be counseled to avoid activities that result in the transfer of blood or bodily fluids to other people.

individuals infected with HCV early in the disease process so they can receive appropriate treatment and take precautions to prevent spreading the virus.

Limitations. Patients infected with HCV may receive a false-negative result if insufficient levels of antibodies are present. If the test is completed prior to 6 months postexposure, it may be too early to detect antibodies and this could result in a false-negative test result. Immunocompromised patients who are infected with HCV may test negative for anti-HCV because of their inability to produce sufficient numbers of antibodies. Failing to provide an adequate blood sample also can lead to inaccurate results.

A positive test result indicates the presence of anti-HCV antibodies. The presence of anti-HCV indicates that the patient has been infected with HCV, but does not specify whether the infection is acute, chronic, or no longer present.

Receiving a positive test result for HCV can be very upsetting to a patient. One concern about home testing for HCV is that patients may delay receiving treatment if they are in denial about their test results. Although the manufacturer provides patients with some posttest counsel-

ing over the phone along with the test result, receiving the test results from a primary care provider may be more appropriate for some patients.

Factors to Consider Before Recommending Home Testing

Pharmacists who counsel patients about using a home test for HCV should discreetly inquire about patient-specific risk factors for HCV transmission. As with HIV home testing, it is important to determine if the potential exposure to the virus took place at least 6 months prior to testing.

When Should Patients Undergo Further Evaluation?

Patients receiving a positive test result should immediately consult their primary care provider for a thorough evaluation and follow-up care. Patients with HCV should be counseled to avoid high-risk practices that may spread the infection to other people, such as unprotected sex and needle sharing. Patients with HCV should be advised to avoid alcohol and any medications that may damage their liver.

If a test has been performed prior to 6 months postexposure, it may be too early to detect antibodies and the test should be repeated. Patients

receiving a negative result who question the accuracy of the test results should be evaluated by a primary care provider and receive a follow-up test. Education for patients with negative test results should include a discussion of risk factors for exposure to HCV and strategies to minimize their risk of exposure.

Clinical Minute

Coinfection with HIV and HCV is common. If a patient is testing for either HIV or HCV, the pharmacist should talk discreetly with the patient to determine whether the patient also should test for the other virus. Information regarding coinfection with HIV and HCV may affect the treatment strategy for the patient.

Home Cholesterol Tests

Heart disease is the single largest killer of both men and women in the United States. Low-density lipoprotein (LDL) cholesterol is considered to be the primary risk factor for coronary heart disease. LDL cholesterol can accumulate along arterial walls, allowing plaque formation that leads to atherosclerosis. Plaque can detach from the arterial wall and form a thrombus that occludes arteries, resulting in a myocardial infarction or stroke. Lowering elevated LDL cholesterol concentrations has been shown to reduce cardiovascular morbidity and mortality.

The *Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)* recommends that all Americans aged 20 years or older have a fasting lipoprotein profile performed at least once every 5 years. The complete fasting lipoprotein profile includes all major blood lipid fractions: total cholesterol, LDL cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides. A complete lipid panel also is used to evaluate the effectiveness of treatment with cholesterol-lowering medications and lifestyle modifications.

Although products for the home

measurement of cholesterol are available, they are not recommended as substitutes for professional testing. The First Check Cholesterol Test and CholesTrak Total Cholesterol Test are single-use tests that provide rapid results. However, these tests measure the total cholesterol level only. While the information may be useful as a general screening, it is inadequate to fully evaluate a patient's cardiovascular risk. Patients should be encouraged to obtain the recommended fasting lipoprotein profile.

The CardioChek Home Cholesterol Test System is a reusable monitor that measures total cholesterol, HDL, and triglyceride levels. However, individual test strips must be used and each test strip provides only one test result. For example, there is a test strip for total cholesterol, a test strip for HDL, and a test strip for triglyceride levels; each result is reported individually, which increases patient costs. The LDL cholesterol level must be calculated from the results for total cholesterol, HDL cholesterol, and triglycerides, which introduces the potential for mathematical error.

HOME MONITORING FOR CHRONIC CONDITIONS

A number of home testing products on the market allow patients to take an active role in their own health care. Patients with chronic health conditions can become involved in monitoring the status of their condition and their response to therapy (e.g., medications). The most common home testing products used for monitoring chronic conditions are blood glucose monitors and blood pressure monitors.

Regular monitoring of glycemic control is an essential component of diabetes care. With knowledge of their glycemic status, patients are able to play a more integral role in managing and controlling their diabetes. Glycemic testing methods encompass both day-to-day measures (e.g., blood glucose levels) and chronic control measures (e.g., glycosylated hemoglobin [A1C]). Home testing devices are available for both types of monitoring.

Similarly, regular monitoring of blood pressure is central to the treatment of hypertension. Home blood pressure monitoring gives patients a sense of control over their health, allows them to track their progress toward a goal blood pressure level, and provides useful data about blood pressure values that occur away from the primary care provider's office.

Self-Monitoring of Blood Glucose

Patients with diabetes should strive to achieve and maintain near-normal glucose levels, which will help limit acute and chronic consequences of hypoglycemia or hyperglycemia.

Pharmacists play an important role in helping patients develop a treatment plan for managing their diabetes. This treatment plan should include specific monitoring parameters such as routine laboratory follow-up to assess blood glucose and A1C levels. The plan also may include self-monitoring of blood glucose (SMBG), which allows patients to evaluate their response to therapy and assess whether glycemic goals are being met. The frequency and timing for SMBG will be patient-specific, based on individual patient needs.

Factors to Consider Before Recommending a Blood Glucose Monitor

Blood glucose monitors are available in a broad range of sizes and styles, and they have different features. Because choosing a monitor can be overwhelming for patients, pharmacists should assist them in selecting the most appropriate one. First, the pharmacist should assess patient-specific factors that may influence the selection of a monitor, such as vision or dexterity problems. Next, the pharmacist should determine which features are most important to the patient (additional features generally increase the cost). The ongoing costs associated with the monitor may influence a patient's choice. For example, the cost of the test strips used with the monitor can quickly overshadow the cost of the monitor itself and should be considered when selecting a product.

The required sample blood volume may be an issue for patients who have difficulty obtaining an adequate blood sample. Shorter test times make testing simpler and may enhance adherence, especially for patients with an active lifestyle. Other patients may want a monitor that enables them to download results to their hand-held or home computer. Some monitors have backlit displays and lighted test strip ports, which can assist patients who have poor vision or who wish to be able to test in a dark environment.

After determining the patient's needs and preferences, the pharmacist can evaluate the available monitors and compare features such as cost, ease of use, sample size required, time to complete the test, memory capability, downloading capability, and the option for alternate site testing.

Once a monitor has been selected, the pharmacist should teach the patient how to use it correctly. The pharmacist should evaluate the patient's monitoring technique initially and at regular intervals thereafter to ensure the patient is using the monitor properly.

Blood Glucose Monitor Resources

A resource guide containing information about blood glucose monitoring and data management systems is updated annually and published in *Diabetes Forecast*. This guide provides helpful information for pharmacists who are assisting patients in selecting blood glucose monitors. The resource guide provides a side-by-side comparison of the blood glucose monitors and includes product-specific information such as size, weight, test strip used, range of blood glucose levels, test time, battery requirements, calibration requirements, control solution, and features of the monitor.

Self-Monitoring of A1C

Measurements of A1C provide information about the average glycemic control over the past 2 to 3 months for patients with diabetes. Correlations between A1C and mean plasma glucose levels are listed in TABLE 17. The American Diabetes As-

Table 17. Correlation of A1C to Mean Plasma Glucose Concentration

A1C (%)	Mean Plasma Glucose (mg/dL)
6	135
7	170
8	205
9	240
10	275
11	310
12	345

A1C = glycated hemoglobin.

sociation has routinely recommended A1C testing as a means to monitor glycemic control in patients with diabetes. In general, testing has been recommended at least twice a year in patients who are meeting treatment goals (and who have stable glycemic control) and more frequently (every 3 months) in patients whose therapy has changed or who are not meeting glycemic goals. In the *Standards of Medical Care in Diabetes—2010*, the American Diabetes Association has expanded the use of the A1C test. An international expert committee first recommended use of the A1C test to diagnose diabetes and the American Diabetes Association has now added the A1C test to their criteria for diagnosing diabetes. These standards specify that the A1C test should be performed in a laboratory using a method that is certified by the National Glycohemoglobin Standardization Program.

Product Selection

Currently, only one product is available for home testing of A1C: the A1cNow Selfcheck. This device requires the patient to collect a small blood sample and add it to the meter. The results are processed by the meter and provided to the patient in approximately 5 minutes.

Appropriateness of Home Testing for A1C

At this time, the home testing product available for A1C testing should not be used to diagnose diabetes. Home testing for A1C should be reserved for patients who are using this test for monitoring their glycemic control. Whether to use home testing for monitoring A1C is a decision that should be made collaboratively by the patient and the patient's primary care provider. Home testing of A1C levels should never replace routine medical care or follow-up, however it can provide additional valuable information for maximizing patient care.

Self-Monitoring of Blood Pressure

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) defines hypertension as systolic blood pressure greater than or equal to 140 mm Hg and/or diastolic blood pressure greater than or equal to 90 mm Hg in a person who is not taking antihypertensive medications. Patients with a systolic blood pressure between 120 and 139 mm Hg or a diastolic blood pressure between 80 and 89 mm Hg are considered to have prehypertension. In addition, the JNC 7 report recommends a blood pressure goal of less than 130/80 mm Hg for patients with diabetes or chronic kidney disease. The World Health Organization reports that inadequately controlled blood pressure increases the risk of developing coronary heart disease and stroke. Monitoring blood pressure is a key step in the management of hypertension.

Benefits. Some benefits of home blood pressure monitoring include the ability to (1) distinguish sustained hypertension from “white-coat hypertension”—the propensity for some patients to have elevated blood pressure when tested by a health care provider; (2) assess response to antihypertensive medication; and (3) improve adherence to treatment by showing the effect of interventions designed to lower blood pressure.

Limitations. Falsely low read-

ings may be generated if patients eat or take hot baths prior to testing. Elevated readings may be caused by smoking, stress, and drinking beverages containing caffeine. Using a cuff that is too small or too large can lead to unreliable test results. For example, if the cuff is too small, the blood pressure reading can be overestimated by as much as 20 to 30 mm Hg. The JNC 7 report notes that home blood pressure monitors should be checked regularly because they can provide incorrect readings if the calibration is imprecise.

Patients should be counseled to test their blood pressure in both arms, because readings may differ between arms. If patients note that their blood pressure is consistently higher in one arm, then they should regularly use that arm to test.

Available Blood Pressure Monitors

A variety of blood pressure monitors are available for home use. Blood pressure monitors can be classified into one of three categories: mercury column sphygmomanometers, aneroid manometers, and digital devices.

The mercury column sphygmomanometer is considered the gold standard in blood pressure measurement because it produces the most accurate and reliable results. However, these devices are impractical for home use because they are bulky and have the potential for mercury spills. In addition, the patient must have good dexterity, adequate eyesight, and the ability to hear well to use these devices appropriately.

Aneroid monitors often are a good choice for home use. These monitors are light, inexpensive, and portable. The device is typically inflated manually using a bulb. The patient must read the results by examining a pointer on a dial gauge while listening for the Korotkoff sounds. To successfully use an aneroid monitor, the patient must have good dexterity, good eyesight, and the ability to hear well. The cuff for many of these devices contains a stethoscope; therefore, a separate stethoscope does not need to be purchased. One drawback to aneroid monitors is the need for frequent calibration. If the needle of the gauge falls outside the small box at

the bottom of the device, the device needs to be recalibrated.

Digital devices are another good option for home use and they have some features that make them highly beneficial for home use. These devices are contained in a single unit and are easier to use than aneroid monitors. Some digital devices are semi-automatic, whereby the patient must manually inflate the cuff. However, many digital devices offer automatic inflation and deflation (the cuff inflates with one touch of a button) making them easier to use with one hand. The digital devices take the blood pressure measurement and provide a digital reading of the result. Digital devices eliminate the need for the patient to manipulate the device or listen for Korotkoff sounds. Therefore, digital devices provide an advantage for patients with vision, hearing, or dexterity problems. However, one drawback to digital devices is that patient movement can affect the results. Another nuisance is that the patient cannot determine whether the device needs to be recalibrated, therefore the device must be checked frequently in comparison with readings from a mercury column monitor. In addition, digital monitors may be more expensive than aneroid monitors.

Wrist manometers may be an alternative for a patient with a very large arm circumference, when a regular or large adult blood pressure cuff is not adequate. Wrist manometers can be less accurate because they are affected by the positioning of the wrist during the measurement. Patients who select a wrist manometer must be educated to hold the wrist at the level of the heart during the measurement. Finger manometers have not been proven to produce accurate results.

Factors to Consider Before Recommending a Home Blood Pressure Monitor

Many patients prefer the digital monitors because they are easy to use. Automatic operation may make patient training simpler and may enhance adherence to testing. Aneroid monitors are generally preferred if cost concerns are paramount, but they tend to be more difficult to use and require frequent calibration.

Another factor to consider is whether patients will have assistance while using the monitor or will need to apply the cuff themselves. Selecting a device that has a D-ring on the cuff allows patients to place the cuff on their own arm easily. Other factors that may impact monitor selection include vision problems, hearing difficulties, or physical limitations. Automatic digital monitors may be appropriate in these cases because they do not require the patient to manipulate the device or hear the Korotkoff sounds. Digital devices may provide inaccurate readings if patients have an irregular heartbeat, although some newer models are designed to accommodate these patients.

Pharmacists can assist patients by helping them choose a monitor that is accurate. However, accuracy of the monitor should not be judged solely on the basis of claims by the manufacturer. Instead, some widely accepted protocols from the Association for the Advancement of Medical Instrumentation, the British Hypertension Society, and the European Society of Hypertension are available to validate the accuracy of home blood pressure monitors. In addition, pharmacists may utilize an educational web site (www.dableducational.org) that provides a list of products and indicates whether the devices have passed the validation protocols.

Accuracy of home blood pressure monitoring is highly reliant on how well the blood pressure cuff fits the patient's arm. Improper cuff size can result in either overestimation or underestimation of the blood pressure reading. The bladder of the cuff (the portion of the cuff that is inflated) should encircle at least 80% of the arm. The patient's arm circumference should be measured around the midpoint of the upper arm. If the arm circumference is less than 34 cm (approximately 13.5 inches), the patient should use a regular adult cuff. If the measurement is 35 to 44 cm (13.75 to 17.5 inches), the patient should use a large adult cuff. Patients whose arm circumference measurement is 45 cm (approximately 17.75 inches) or larger should consider using a thigh cuff.

Examples of questions to ask

when helping patients select a blood pressure monitor are provided in TABLE 18.

Patient Education for Home Blood Pressure Monitoring

After helping with selection of an appropriate blood pressure monitor, the pharmacist should teach patients how to measure their blood pressure correctly. Patients should take the measurement while seated in a chair with their back supported and their arm supported at heart level. Any restrictive clothing should be removed from the arm prior to the measurement. The blood pressure cuff should be placed around the arm with the indicated detection device placed over the brachial artery. The bottom edge of the cuff should be placed 2.5 cm (1 inch) above the crease of the elbow. Once the patient is seated and the cuff is in place, the patient should rest for 5 minutes before taking the measurement. Patients should not smoke, drink caffeinated beverages, eat, or take a hot bath for at least 30 minutes before testing.

The cuff should be inflated to block the blood flow of the artery. Patients using aneroid devices should be taught how to listen for the heartbeat with the stethoscope while slowly releasing the cuff pressure. The pressure at which the heartbeat can first be heard is recorded as the systolic pressure. The pressure at which the heartbeat can no longer be heard is recorded as the diastolic pressure. For patients using a digital device, the cuff should be placed on the arm or wrist. The cuff is inflated and deflated, and the monitor provides a digital readout indicating the systolic and diastolic blood pressures.

Patients should record the blood pressure values, time of the measurement, and any possible interfering factors (e.g., stress) in a log to share with their primary care provider.

When Should Patients Undergo Further Evaluation?

Abnormally elevated blood pressure or any symptoms of elevated blood pressure (e.g., headaches, blurred vision, shortness of breath, chest pain, nose bleeds) could represent a life-threatening condition.

Table 18. Questions to Ask When Helping Patients Select a Blood Pressure Monitor

Why do you want to purchase a blood pressure monitor?

If patients think their blood pressure might be elevated, the pharmacist should take the patient's blood pressure and/or refer the patient to a primary care provider.

Have you received previous instructions about the use of a blood pressure monitor?

Pharmacists should tailor counseling and education to the patient's level of health literacy and knowledge about the monitors.

Do you have difficulty with your hearing or vision?

If patients have deficits in hearing or vision, recommend a monitor that compensates for these problems (e.g., a jumbo display), or advise them to obtain assistance using the monitor. Patients with hearing difficulties should not use monitors that require listening for their heartbeat with a stethoscope.

Do you think you will have a problem fastening the blood pressure cuff around your arm?

Patients with dexterity limitations should select a monitor with features that compensate for the limitation, such as automatic inflation and deflation, or a D-cuff or wrist cuff. In addition, patients who have large arms should select a monitor designed to accommodate their size to ensure accurate blood pressure measurement.

Pharmacists should educate their patients about the risks of elevated blood pressure and help them determine when they should seek medical attention based on their blood pressure readings or other symptoms. Patients should contact their primary

care provider immediately or seek emergency treatment if such signs or symptoms are present. Patients also should be instructed never to adjust their medication dosage without consulting their primary care provider.

ADDITIONAL HOME TESTING PRODUCTS

More products are becoming available that allow patients to screen for medical conditions in the privacy of their own home. Tests are available to monitor eye pressure, prostate-specific antigen, and thyroid-stimulating hormone. Other tests are available to detect drugs of abuse, alcohol consumption, and tobacco use. As the market for home testing products continues to grow, more patients may show an interest in using these products. Pharmacists should learn about new products that come on the market to assist patients in using these tests appropriately.

Pharmacists are in an ideal position to assist patients with the selection and use of home testing products. Pharmacists' knowledge and skills can assist patients in learning the proper use of these products to minimize the potential for human error, and pharmacists play an integral role in educating patients about the appropriate action to take following positive or negative results of a home test.

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CASE STUDY RESPONSES

Case 1. Ovulation Prediction Test

Which of the following would be the most appropriate *initial* question to ask the patient?

- a. **How long have you been off birth control pills?**
Correct. Discontinuation of oral contraceptives can delay ovulation for one to two menstrual cycles. If the patient is not having regular cycles, it may be difficult for home ovulation prediction methods to accurately predict ovulation. It is recommended that a patient wait for two natural cycles to occur prior to using ovulation prediction methods.
- b. How long have you been trying to become pregnant?
Incorrect. While this information is important to know, it would not be the initial question to ask this patient.
- c. Are you willing to collect urine samples for testing purposes?
Incorrect. This information will be important to know when you are determining which method to recommend. However, it is not the first piece of information to gather from the patient.
- d. Have you ever used ovulation prediction methods in the past?
Incorrect. While this information may be valuable to determine an appropriate method for ovulation prediction, it is not the first piece of information to gather from this patient.

Which of the following ovulation prediction methods would be the most appropriate option for this patient?

- a. Basal body temperature.
Incorrect. The patient has tried this method with little success and wants to try something different.
- b. Fertility microscope.
Incorrect. At this time, the data regarding accuracy of this method are conflicting so it may be better to try another method.
- c. **Traditional urine-based ovulation prediction test.**
Correct. She has not tried this method in the past. It will allow her to predict her window of fertility by identifying her LH surge, and these products are not expensive.
- d. Clearblue Easy Fertility Monitor.
Incorrect. While this may be an option, the patient is requesting an inexpensive option for ovulation prediction and cost of this monitor is much greater than the cost of the traditional urine-based ovulation prediction test.

Case 2. Pregnancy Test

Which of the following would be the most appropriate *initial* question to ask the patient to determine whether self-testing with a pregnancy test is appropriate?

- a. Have you used a pregnancy test before?
Incorrect. This may be helpful information to determine the patient's past experience with a home pregnancy test. However, it is not the first question that should be asked.
- b. **When was your last period and when do you expect your next period?**
Correct. This is the first question to ask a patient who is inquiring about a home pregnancy test. The pharmacist should ensure that the patient is using the test at an appropriate time in her menstrual cycle.
- c. Have you contacted your primary care provider yet?
Incorrect. Contacting the primary care provider is very important, especially if the patient is pregnant. However, this would not be the initial question to ask this patient.

- d. Have you ever been pregnant before?
Incorrect. This is not the initial question that should be asked.

Which of the following would be the most appropriate response to this patient?

- a. You can test as soon as you think you are pregnant.
Incorrect. Testing too early can increase the risk of a false-negative result or the possibility of identifying very early pregnancy loss.
- b. You can test as early as 3 days before your expected period.
Incorrect. Testing too early can increase the risk of a false-negative result.
- c. The best time to test is on the day of your expected period.
Incorrect. Testing too early can increase the risk of a false-negative result or the possibility of identifying very early pregnancy loss.
- d. **You should wait at least 1 week after your missed period.**
Correct. Patients should be encouraged to wait at least 1 week after their missed period before testing. Patients who wish to test earlier than 1 to 2 weeks after they expect their periods should be cautioned about the possibility of false-negative results and the possibility of early pregnancy loss.

Which of the following statements would be most appropriate to tell this patient?

- a. **Discuss discontinuing the isotretinoin with your primary care provider and/or obstetrician-gynecologist immediately if you think you are pregnant.**
Correct. Isotretinoin should not be taken during pregnancy because it can be harmful to the developing fetus.
- b. Stop exercising immediately.
Incorrect. The patient should be encouraged to consult with her primary care provider to discuss a healthy exercise plan that can be continued during pregnancy.
- c. Do not consume any fast food if you are pregnant.
Incorrect. The patient should be encouraged to consult with her primary care provider to discuss a healthy diet plan that can be continued during pregnancy.
- d. Prenatal vitamins are not necessary in early pregnancy.
Incorrect. Prenatal vitamins contain many nutrients that are important for pregnant women. In particular, folic acid taken early in pregnancy has been shown to reduce the incidence of certain birth defects.

Case 3. Fecal Occult Blood Test

Which of the following would be the most appropriate *initial* question to ask this patient to determine whether self-testing with an FOBT is appropriate?

- a. Do you eat red meat or take high doses of vitamin C?
Incorrect. This question would help determine which test would be most suitable for the patient, but would not help determine whether self-testing with an FOBT is appropriate.
- b. **Do you have any risk factors for colorectal cancer, such as ulcerative colitis, inflammatory bowel disease, or a family history of colorectal cancer?**
Correct. Before determining which home testing product is appropriate, the pharmacist should find out whether the patient has any risk factors. Patients at high risk should consult with their primary care provider to determine the appropriate course of testing.

- c. Have you previously used any other home use FOBT products?
Incorrect. This question would help determine which test would be most suitable for the patient, but would not determine whether self-testing with an FOBT is appropriate.
- d. Do you take aspirin, NSAIDs, corticosteroids, or anticoagulants?
Incorrect. This question is important to ask because these medications may need to be discontinued prior to and during testing with an FOBT. However, this information is not critical to determine whether self-testing with an FOBT is appropriate.

Which of the following points would you include when counseling the patient about using the home FOBT?

- a. Discontinue all medications prior to using the test.
Incorrect. While some medications, such as aspirin, NSAIDs, corticosteroids, and anticoagulants can affect the outcome of FOBT, it is not appropriate to advise patients to discontinue medications without consulting with the patient's primary care provider to determine if the medications can be safely discontinued before and during the testing.
- b. Decrease roughage in the diet for at least 2 to 3 days prior to testing.
Incorrect. The patient should increase roughage for 2 to 3 days prior to testing.
- c. **Complete all three tests even if the first two tests are negative.**
Correct. Because lesions may bleed intermittently, it is important to perform the test on three consecutive bowel movements to increase the probability of detecting a possible lesion.
- d. Hemorrhoidal bleeding will not interfere with the test results.
Incorrect. Patients should avoid testing during times of known bleeding (i.e., hemorrhoidal or menstrual bleeding) because this can result in a false-positive test result.

Which of the following would be the most appropriate response to this patient?

- a. **A positive test result with the FOBT indicates the presence of blood in the stool. The patient needs to be evaluated by a primary care provider to determine the cause of the bleeding.**
Correct. A positive test result from an FOBT indicates the presence of blood in the stool. The pharmacist should educate the patient that a positive test result does not necessarily mean that the patient has cancer. However, the presence of blood in the stool could indicate a potential colon problem such as bleeding ulcers, colitis, diverticulitis, hemorrhoids, or colorectal cancer. This result should not be ignored and the patient should be evaluated by a primary care provider to determine the cause of the bleeding. The earlier a potential problem is detected, the sooner treatment can be started.
- b. A positive test result with the FOBT indicates the presence of colorectal cancer. The patient needs to be evaluated by a primary care provider to develop a treatment plan for colorectal cancer.
Incorrect. The pharmacist should educate the patient that a positive test result does not necessarily mean that the patient has colorectal cancer.
- c. A positive test result with the FOBT does not need to be evaluated by a primary care provider.
Incorrect. The presence of blood in the stool could indicate a potential colon problem such as bleeding ulcers, colitis, diverticulitis, hemorrhoids, or colorectal cancer. This result should not be ignored and the patient should be evaluated by a primary care provider to determine the cause of the bleeding.
- d. A positive test result with the FOBT indicates that the patient performed the test incorrectly.
Incorrect. A positive test result indicates that blood has been detected in the stool and the patient should be evaluated by a primary care provider.



CPE EXAM

Instructions: The assessment questions printed below allow you to preview the online CPE exam. Please review all of your answers to be sure you have marked the proper letter on the online CPE exam. There is only one correct answer to each question.

- 1. A slight rise in a woman's resting basal body temperature indicates that ovulation:**
 - a. Has already occurred in this menstrual cycle.
 - b. Will occur in the next 1 to 2 days.
 - c. Will occur in the next 3 to 4 days.
 - d. Will occur in the next 5 to 6 days.
- 2. Patients taking clomiphene can use urine-based ovulation prediction test kits to identify the LH surge if they begin testing on:**
 - a. The day before drug therapy begins.
 - b. The day that drug therapy begins.
 - c. The day that drug therapy ends.
 - d. The second day after drug therapy ends.
- 3. After discontinuing oral contraceptives, patients should:**
 - a. Begin using ovulation prediction methods immediately.
 - b. Wait to begin using ovulation prediction methods until one natural menstrual cycle has occurred.
 - c. Wait to begin using ovulation prediction methods until two natural menstrual cycles have occurred.
 - d. Not use ovulation prediction methods to identify their window of fertility.
- 4. When using the BabyStart Male Infertility Test, collection of the second semen sample should occur:**
 - a. Within 3 days after the first sample was collected.
 - b. At least 7 days after the first sample was collected.
 - c. At least 3 days, but not more than 7 days, after the first sample was collected.
 - d. At least 7 days, but not more than 10 days, after the first sample was collected.
- 5. The most accurate results with home pregnancy tests are obtained when testing is performed:**
 - a. 1 week before the date of the expected period.
 - b. 3 to 5 days before the date of the expected period.
 - c. On the day before the expected period.
 - d. At least 1 week after the date of the missed period.
- 6. Home pregnancy tests are designed to provide patients with information about:**
 - a. The viability of a pregnancy.
 - b. The presence of detectable levels of hCG in the urine.
 - c. The gestational age of the fetus.
 - d. Whether there is more than one fetus.
- 7. Patients should be advised that home menopause tests:**
 - a. Have limited clinical relevance because they do not provide enough information for primary care providers to make clinical decisions.
 - b. Provide a definitive diagnosis of menopause.
 - c. Provide valuable information that can be used by primary care providers to make a clinical diagnosis of menopause.
 - d. Should be used by all women experiencing menopausal symptoms.
- 8. Home menopause tests use monoclonal antibodies to detect which of the following hormones?**
 - a. Estrogen.
 - b. FSH.
 - c. LH.
 - d. Testosterone.
- 9. The most appropriate candidate for use of a UTI home test is a patient who:**
 - a. Has recurrent UTIs.
 - b. Has no history of UTIs.
 - c. Eats a vegetarian diet.
 - d. Takes phenazopyridine.
- 10. A positive test result from using a home FOBT:**
 - a. Indicates the presence of colorectal cancer.
 - b. Indicates the need for evaluation by a primary care provider.
 - c. Is not clinically significant.
 - d. Indicates the presence of a serious, life-threatening disorder.

11. How many consecutive bowel movements should be tested when using a home FOBT?
- Two.
 - Three.
 - Four.
 - Five.
12. To decrease the potential for false-negative results with the HIV-1 home testing products, the patient should wait a minimum of:
- 6 weeks after the potential exposure.
 - 1 month after the potential exposure.
 - 3 months after the potential exposure.
 - 6 months after the potential exposure.
13. A positive result from the home test for HCV infection indicates that:
- The HCV infection is acute.
 - The HCV infection is chronic.
 - The HCV infection is no longer present.
 - Anti-HCV antibodies are present.
14. The *Adult Treatment Plan III* recommends that all Americans aged 20 years or older have a fasting lipoprotein profile performed at least once every:
- Year.
 - 3 years.
 - 5 years.
 - 10 years.
15. Which of the following is true regarding home testing for blood glucose?
- Patients using an A1C home test do not need to perform SMBG.
 - SMBG should be performed every 2 to 3 months by all patients with diabetes.
 - SMBG is ineffective for detecting hypoglycemia.
 - SMBG is a valuable method for evaluating a patient's response to therapy for diabetes.
16. An A1C result of 8% correlates to a mean plasma glucose level of:
- 135 mg/dL.
 - 170 mg/dL.
 - 205 mg/dL.
 - 240 mg/dL.
17. For a patient whose arm circumference measures 31 cm, which blood pressure cuff would you recommend?
- Finger manometer.
 - Regular adult blood pressure cuff.
 - Large adult blood pressure cuff.
 - Thigh blood pressure cuff.
18. An elderly patient, who has diminished hearing and difficulty gripping objects because of arthritis in his hands, needs assistance selecting a blood pressure monitor for home use. Based on this limited information, what type of blood pressure monitor would be most appropriate?
- Mercury column sphygmomanometer.
 - Aneroid manometer.
 - Digital monitor.
 - Finger manometer.
19. Which of the following can generate falsely low blood pressure readings if it occurs prior to performing a blood pressure measurement?
- Taking a hot bath.
 - Stress.
 - Drinking a caffeinated beverage.
 - Smoking.
20. When placing an aneroid blood pressure cuff on the upper arm for a blood pressure measurement, the bottom edge of the cuff should be placed:
- 1 inch above the crease of the elbow.
 - 2.5 inches above the crease of the elbow.
 - Over the elbow.
 - 1 inch below the crease of the elbow.

CPE INSTRUCTIONS

Completing a posttest at www.pharmacist.com/education is as easy as 1-2-3...

1. Go to **Online CPE Quick List** and click on the title of this activity.
2. **Log in.** APhA members enter your user name and password. Not an APhA member? Just click "Create one now" to open an account. No fee is required to register.
3. Successfully complete the CPE exam and evaluation form to gain immediate access to your Statement of Credit.

Live step-by-step assistance is available Monday through Friday, 8:30 AM to 5:00 PM ET from APhA Member Services at 800-237-APhA (2742) or e-mail InfoCenter@pharmacist.com.



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