



# THE FAMILY PHARMACIST

A QUICK READ FOR YOUR OTC NEED!

VOLUME 1, ISSUE 7

JULY 15, 2020

By Bob Jaeger, BS Pharm

## OVER-THE-COUNTER HOME USE TESTS

The US Food and Drug Administration (FDA) refers to home health testing kits as *home use tests*. The availability and popularity of home use tests began in the early 1970s with the introduction of a home pregnancy test. It was slow to take off in the United States due to fear about possible erroneous results and doctor's concerns that patients could not accurately interpret the test readings. Physicians at that time were skeptical that any patient had the education to make decisions about their own health care.

Today, patients are better educated and more health conscious than previous generations, and numerous home use tests are common on pharmacy shelves and are readily available through on-line testing services. Home blood pressure monitors, blood sugar testing devices, DNA ancestry kits, pregnancy tests, and even paternity testing are available for home use. But there are some over-the-counter kits for home testing that you may not know about. These tests can be very useful in our busy lives, may eliminate anxiety, can save you an unnecessary trip to the doctor's office, and help you partner with your physician to get efficient and timely health care.

Many home use tests are packaged as kits. Kits are simply all of the materials you need assembled in one package. It can be a digital device for sampling blood (like a glucose meter) or a cuff for measuring blood pressure, etc. Or, it can simply be a number of test strips, swabs, or a collection tube, and an envelope for mailing them off to a lab to get the results. Many of the kits are intended entirely for home use (no mailing to the lab) and are simply test strips applied to urine or blood from a finger stick. You determine the results yourself from a color chart or graph that is usually provided with the test. Most tests can be performed at the kitchen table. The kits range in price from just a few dollars to hundreds of dollars.

Test kits currently available fall into the following general categories:

- ◇ Breath Analyzer Kits (alcohol, intestinal gas)
- ◇ Allergy/Food Sensitivity Tests
- ◇ Tests/Devices for diseases and conditions
- ◇ DNA Tests (health, paternity, etc.)
- ◇ Drug Panels (commonly abused drugs)
- ◇ HIV/Sexually Transmitted Diseases

The kits discussed below are examples of the more popular home tests.

**COVID-19 Test Home Collection Kit.** On May 16, 2020, the US Food and Drug Administration (FDA) authorized an at-home sample collection kit that can be sent to specified laboratories for Covid-19 diagnostic testing. The FDA issued what it calls a EUA, that is, an *emergency use authorization* to Everlywell, Inc. to produce and distribute the test. An individual can self-collect a nasal sample in the privacy of their home using the kit. The kit contains nasal swabs (to collect a sample) and a tube filled with saline to transport the sample back to a specified lab where the test is done. Everlywell's kit is authorized to be used by individuals at home who have been screened through an online questionnaire that is reviewed by an online health care provider. So you need a prescription even though the test is done at home, but the kit includes the prescription online. In a personal communication with Everlywell I got the following response, "Interested individuals will be asked to complete a pre-purchase symptom questionnaire based on CDC guidelines and provided by our third-party telehealth provider. If they are qualified based on the questionnaire, that's when they will be permitted to purchase and take the COVID-19 Test Home Collection Kit." The test is \$109. So, if you're interested, see this link:

<https://www.everlywell.com/products/covid-19-test>

**Women's Health Tests and Devices.** Home tests and devices to evaluate women's health concerns are available for fertility, pregnancy, menopause, colon cancer,

breast cancer, and urinary tract and vaginal yeast infections. Because there is an abundance of information about the reliability and effectiveness of these tests in the medical literature, let's look at just one example, urinary tract infection (UTI) kits. Many women (less frequently men) are troubled with urinary tract infections. Over-the-counter test strips, like *AZO Urinary Tract Infection Test strips*, are FDA approved to help those who have infections that are recurrent (keep coming back) and are uncomplicated. Recurrent is usually defined as two or more episodes in the last 6 months or three or more episodes in the last 12 months. The symptoms of a UTI can be similar to those of other disorders and infections. And since uncomplicated UTIs can easily be treated with an appropriate antibiotic, it makes sense to have a simple at-home test that can be used early, especially when symptoms occur in those who are experienced with these infections. In fact, self-testing at home is discouraged for someone who has a first time UTI. If this is the case you should contact your healthcare provider first.

**Multi-panel Drug Tests.** These are easy to use, quick, sanitary kits that provide a number of test strips that test human urine for the presence of narcotics, depressants, stimulants, tranquilizers, hallucinogens, and antidepressants, to name a few general classes of drugs. Individual kits will specify drugs they test for, like cocaine, marijuana, oxycodone, amphetamine, and so on. These can be prescription or illegal drugs present in the urine. The kits can allow as many as 25 individual tests for multiple drugs. While these tests are sensitive they usually give only a preliminary (or presumptive) positive test result. If you get a preliminary positive result, the test kit makers and the FDA recommend sending the urine sample to a certified laboratory for confirmation before any action is taken.

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**Point-of-Care (POC) Testing.** While this is something hospitals, doctor’s offices, and urgent care clinics have been doing for a long time, it is now gaining popularity as another type of testing and a growing service that is offered in pharmacies. It’s not exactly “home testing” but it *doesn’t require a doctor’s prescription for you to get the test*. POC tests are available for acute and chronic illnesses. For example, tests exist for flu, strep, A1C (a diabetes test), hepatitis C, HIV, and COVID-19. Administration of these tests by pharmacists usually requires special training or certification by state boards. While not available in all pharmacies right now it is a growing trend and we can expect to see more of this in the very near future.

**A Word of Caution.** Studies have shown that most people are able to successfully perform home tests, but even so, the accuracy of home use kits varies with the type of test and all tests can produce false negative or false positive results. Some tests and devices are “home use” but they still require a prescription, like a home test that measures your blood clotting ability. This is so you can work closely with your health care provider to interpret the results, which may change the way you take your medicine, for example. So home testing is useful but the tests are designed to be used in partnership with your health care provider. If you purchase any one of the kits available in a pharmacy, always ask the pharmacist for advice and tips on how to use the kit to get the best results.

The tests in the table below are just a sampling of the many home use tests on the market.

At Home™ Drug Test 12	Immediate results test for 12 common drugs of abuse or drugs taken for non-medical purposes
At Home™ Nicotine Test	Detects nicotine and cotinine (a biomarker that indicates exposure to tobacco smoke) in urine
AZO™ Urinary Tract Infection Test	Tests urine for nitrite and white blood cells indicating a bacterial infection
BACtrack™ Keychain (breathalyzer)	Gives blood alcohol concentration by breathing into a device small enough to fit on a keychain
Cbox™ Complete Test STD	Tests for 10 common sexually transmitted diseases (STDs) using a blood drop sample and a urine sample
Check Up America™ Cholesterol Panel	Total cholesterol, HDL, LDL, and triglycerides with mailing and lab services included
Clearblue™ Digital & Rapid Pregnancy Test	Test has a color change tip and provides fast results with a clear plus (+) or minus (-) result in under 3 minutes
Everlywell™ Food Sensitivity Test	Finger prick blood test to measure your immune response to 96 foods to help you manage an elimination diet
Everlywell™ Hepatitis C Test	Finger prick blood test for blood borne hepatitis C
EZ Detect™ Colon Disease Test	Test for blood in the stool indicative of colorectal disease
Home DNA™ Food & Pet Sensitivity	Measures gluten, lactose, cow milk protein, egg, peanut, histamine, and pet dander; send to lab, get results online
Home DNA™ Paternity analysis + Report	Cheek swab collection of DNA; send to lab, get results online
23andMe™ Ancestry	Uses your DNA from a saliva collection kit to figure out where you and your family came from
23andMe™ Health + Ancestry	The health part covers more than 10 different disease risks by using DNA from a saliva collection

References on file

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