Home Tests

Home testing is a growing area of health care that places new responsibilities on the health care consumer.

If you need additional information or would like to learn about recently approved tests, visit the FDA web page Over-the-Counter In Vitro Diagnostic Devices. Another FDA page, Currently Waived Analytes, includes links to a broad range of tests kits and devices that are identified by brand. Not all are for home use -- those that are will be clearly marked. The following home testing kits are available.

KEY: This key applies to all of the tests listed below
SA=stand-alone test, results available to consumer in the home
OTC=over-the-counter, no prescription needed.
N/A= not applicable

Glucose
Condition: Diabetes
Purpose: To monitor blood sugar levels
Format: SA
Availability: OTC, physician recommendation
Comments: Home testing for diabetes has advanced from urine testing to whole blood testing. Less invasive or painful procedures, such as alternate site testing meters and those that use infrared technology to "read" blood sugar through the skin, are becoming more common. In 2001, the FDA approved a watch-like device for testing blood sugar.

Cholesterol
Condition: Heart disease
Purpose: Screening for total cholesterol in blood
Format: SA
Availability: OTC
Comments: Does not separate out cholesterol. Natural variations in cholesterol may make test results hard to interpret. If results indicate potential heart disease, see your doctor.

Luteinizing Hormone
Condition: Ovulation
Purpose: Predicting time when woman is most likely to be fertile
Format: SA
Availability: OTC
Comments: Certain monitoring devices can store information and accessed by the couple and their health provider for retrospective review.

Human Chorionic Gonadotropin (hCG)
Condition: Pregnancy
Purpose: Screening for possibility of pregnancy
Format: SA
Availability: OTC
Comments: Results should be confirmed by doctor or laboratory testing

Fecal Occult Blood
Condition: Colo-rectal cancer
Purpose: Screening for blood in the stool
Format: SA

Availability: OTC
Comments: Subject to false positives; substances in the body or in your system can affect results.

Prothrombin Time (Coagulation Testing)
Condition: Heart disease, stroke, atherosclerosis
Purpose: Measuring the concentration of blood thinner in the body
Format: SA; portable, battery-operated device.
Availability: By prescription
Comments: Relatively new; safety and efficacy are still being evaluated. Requires considerable patient training and compliance to be useful. Cost covered by some insurers.

Drugs of Abuse
Condition: Possible current or past illicit drug use that results in organ systems damage
Purpose: Screens for the possibility that the consumer takes illegal or restricted drugs of abuse
Format: SA; In commercial employer situations, positive results are then referred to laboratories for confirmation.
Availability: OTC
Comments: Results could be affected by medications or foods, such as poppy seeds.

HIV Antibody
Condition: Forerunner of AIDS; susceptibility to other sexually transmitted diseases (STD)
Purpose: Screens for infection by HIV, the virus that causes AIDS
Format: Kit; sample sent to lab for analysis.
Availability: OTC
Comments: Results available by phone, which protects anonymity. Counseling is required if test is positive and recommended if test is negative.

Hepatitis C
Condition: Liver dysfunction
Purpose: Screens for past or current infection by Hepatitis C.
Format: Kit; sample sent to lab for analysis. Lab runs same tests used by doctors and hospitals to determine whether antibodies to Hepatitis C are present.
Availability: OTC
Comments: Like HIV, combines telephone registration/pretest counseling, collection of blood sample, shipping, laboratory testing, telephone results retrieval, and post-test counseling.

Other Home Tests
Condition: Various, such as osteoporosis, hormone levels, STD's
Purpose: Screening
Format: N/A. Varies.
Availability: N/A. Some tests may be available internationally but are not yet approved in the U.S.

Comments: The FDA continuously updates its list of tests approved and cleared for marketing. For example, recent approvals include a monitoring test for patients who have been diagnosed for bladder cancer, a screening test for blood in urine, etc.

FOR MORE INFORMATION, VISIT: http://www.labtestsonline.org/

Document Released: 01/20/2006 Document Re-Released: 10/14/2010
ExitCare® Patient Information ©2011 ExitCare, LLC.