# Technology Assessment



**Technology Assessment Program**

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## A Proposed Framework to Evaluate Home Tests for Use in the Management of Chronic Diseases

**FINAL REPORT**

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# A Proposed Framework to Evaluate Home Tests for Use in the Management of Chronic Diseases

Technology Assessment Report

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None of the investigators has any affiliations or financial involvement related to the material presented in this report.

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# Introduction

The Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS) requested a report from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ). The focus of this report was to propose a framework to evaluate home testing and to apply the framework to evaluate glycosylated hemoglobin (HbA1C) and cholesterol home tests in the management of chronic diseases. AHRQ assigned the report to the following Evidence-based Practice Center: Tufts Medical Center EPC (Contract No. HHSA 290 2007 100551).

The shift in the societal attitude that emphasizes an active participation of individuals in their health care,[1] advances in technology, and the need to provide health care outside the traditional setting have led to the development, marketing, and popularity of home monitoring devices.[2] At least 500 devices/tests have been approved or cleared by the FDA and marketed in the USA for home use[3] and this number will rise as the demand for patient monitoring systems is expected to increase 5.4 percent annually to $9.1 billion in 2010.[4]

The need for ongoing and repeated test in the management of certain diseases is a major impetus for the development of home tests. Some home tests have been approved or cleared by the FDA for the diagnosis of acute or chronic illnesses and for disease management. Tests for pregnancy, Human Immunodeficiency Virus (HIV) and fecal occult blood are examples of the available tests that can be done in the home setting. Glucose and cholesterol/lipid tests and tests that assess drug levels or response to drug therapy such as prothrombin time for anticoagulation therapy are examples of the home tests available for the management of chronic diseases.

Potential tradeoffs for the increased privacy, speed and convenience of home tests (test kits) are erroneous results and interpretations, and faulty subsequent actions which may result in

substandard care. However, home self testing could lead to closer monitoring of conditions and rapid implementation of changes that may translate into improved health outcomes, reduced number of patient encounters in the emergency department and hospital admissions.[5]

The purpose of this report is to adapt and apply the framework developed by Fryback and Thornbury[6] (see below) to the assessment of glycosylated hemoglobin (HbA1c) and cholesterol home tests; these particular home tests are being reviewed at the behest of CMS. The Fryback and Thornbury approach has been used successfully in the EPC program to evaluate diagnostic technologies.[7] This framework organizes published literature on diagnostic tests into six categories:

1. Technical feasibility: technical issues with the diagnostic test
2. Diagnostic accuracy: sensitivity and specificity
3. Diagnostic thinking: impact of test on physician subjective estimate of diagnostic probabilities pre- and post-test
4. Therapeutic efficacy: change in patient management due to test
5. Patient outcomes: proportion of patients improved with test compared to without test
6. Societal outcomes/cost effectiveness

This framework makes explicit the relationship between the diagnostic test and health outcomes. A test that is technically feasible and has high accuracy will provide the necessary information to help determine the best course of action and select the appropriate therapy and management; this will in turn affect patient outcomes and allow the assessment of societal benefits and weighing the corresponding cost effectiveness. CMS requested the evaluation of glycosylated hemoglobin (HbA1c) home testing in the management of diabetes and cholesterol home monitoring in the management of dyslipidemia using this framework. These two home

tests are of interest because diabetes and dyslipidemia are prevalent and impose a substantial health burden to society.[8] Their treatments are associated with substantial health benefits.[9] HbA1c is used to confirm blood glucose test results and to assess the effectiveness of a treatment plan for patients with diabetes. It can also help in showing patients "how healthy choices can make a difference in diabetes control" (diabests.org/type-1-diabetes/a1c-test.jsp, accessed 9-26-2008). As high blood cholesterol level is a major risk factor for coronary heart disease and stroke, patients with high blood cholesterol concentration should be given appropriate therapy (lifestyle modifications with or without pharmacological regimens) and the blood cholesterol level followed to assess the effectiveness of the treatment program. Recent technology assessments have not considered either glycosylated hemoglobin or cholesterol measurements. Although glucose home testing has been extensively studied, the glycosylated hemoglobin home test deserves further evaluation; this will complement the 2005 technology assessment of point of care testing of HbA1c produced by the Duke EPC.[10] In addition to the application of the framework to two home tests, CMS has also requested cataloguing the kinds of home tests currently available for the management of chronic diseases by examining the grey literature.

## Summary of tasks and key questions:

1. The EPC will propose a framework vis-à-vis the Fryback and Thornbury model to perform future technology assessments of home testing.
2. Application of framework to HbA1c and cholesterol home tests
    a. Implementation feasibility (issues related to using the tests in a home setting)
        - What is the variability in results (or total random and systematic error) with a single testing device (precision or coefficient of variation) used in a home setting?

- Do published studies of %HbA1c and cholesterol home tests assess variation of test results (e.g., due to collection by finger stick instead of venipuncture) in the home setting? Do any published studies follow accuracy or precision of home tests over an extended follow-up period of use in the home setting?
- What training do patients need to use %HbA1c and cholesterol home tests correctly (i.e., to properly collect a sample; to perform the testing procedure; to recognize and interpret the result; to maintain or calibrate the home test)?
- Are there patient characteristics associated with increased likelihood of correctly using home %HbA1c and cholesterol tests?
- How do published studies define "patient adherence" with home testing (e.g., timing; accuracy; persistence)? What are the rates of patient adherence to home %HbA1c and cholesterol testing? What factors (e.g., patient-perceived pain of sample collection) or interventions (e.g., feedback from healthcare provider) have been found to be associated with improved or worsened patient adherence?
- What if any requirements exist for maintenance or periodic re-calibration of home testing?

b. Diagnostic accuracy of the tests used in a home setting

- Have published studies assessed the test performance characteristics (e.g., accuracy, precision) of home %HbA1c and cholesterol tests?

What "gold standard" methods of HbA1c or cholesterol measurement are used in assessment of home tests' diagnostic accuracy?

c. Impact of the test on diagnostic thinking and medical decision making

- How are the results of the home testing for %HbA1c and cholesterol used in the studies? Are they part of a disease management plan?
- Do home %HbA1c and cholesterol tests improve patients' satisfaction with their care, compared to laboratory testing?
- Does the use of home %HbA1c and cholesterol tests affect medical decision making and practice? If so, how? Are actions taken by the patient after consulting the healthcare provider, or autonomously?
- Does the use of home %HbA1c and cholesterol tests obviate the use of laboratory tests for glycosylated hemoglobin and cholesterol?

d. Impact of the test on patient outcomes

- Does the use of home %HbA1c and cholesterol tests improve health outcomes? If so, which health outcomes have been improved, according to published studies?
- What are the potential harms of home %HbA1c and cholesterol tests (e.g., false positive and false negative results, more workups, self changes in drug schedules that led to adverse events, etc)?

3. Horizon Scan:

a. What home tests are currently available for management of chronic disease in patients at least 65 years old?

b. What types of specimens are used in home tests for chronic disease management?

c. Summarize publicly available information on tests that are currently under FDA pre-approval review.

# Methods

## Framework

To craft a framework to evaluate home testing, we consulted experts and gathered ideas from primary studies and narrative reviews identified from literature search on home test topics.[5, 11-17] The operational definition of a "framework" to evaluate home testing was developed based on reviews of other frameworks. In this report, a framework is a conceptual analytic approach to evaluate the effects (i.e., benefits, harms, costs, and other effects) of the introduction of a specific home test into a disease management program. It is a suggested approach for evaluating available information. In instances where scientific data are lacking, the framework posits a number of conjectures based on professional experience, expert opinions (e.g., see the introductory statements in Walford 1985[18]), and commonsensical reasoning (e.g., some one who is blind will not be able to read a color test strip). Home test in this framework refers to any test that is not conducted in a healthcare setting. Even though the test is not conducted in a healthcare setting, our framework specifically focuses on those tests that are either prescribed or recommended (in instances where the tests have been cleared for over-the-counter use) by a healthcare provider in the specific context of continual management of a chronic disease. A home test that was neither prescribed nor recommended by a healthcare provider for a specific patient is not the focus of this proposed framework. Because the purpose of the test is to help manage a chronic disease, home testing for the purpose of making a diagnosis is not considered in this framework. We also adapted the term "chronic disease" from the term "chronic condition" as defined by the National Center for Health Statistics (i.e., conditions that are not cured once acquired and must have been present 3 months or longer).
(cdc.gov/nchs/datawh/nchsdefs/healthcondition.htm#chronic, accessed 3/26/2008)

As have been mentioned in the introduction, we have developed our framework based on the model first proposed by Fryback and Thornbury.[6] This framework suggests that six aspects of a home test be described and evaluated: 1) feasibility of the implementation of the test for actual home use (N.B., please note that the actual technical aspects of the test like laboratory testing reliability and stability are not addressed in this framework, it is assumed those aspects have been evaluated and the specific test has been cleared by the FDA), 2) diagnostic accuracy of the test (How well does the test perform at identifying patients with disease and without disease when use in a home setting?), 3) impact of the test on decision making (either by the physician or by the patient or by both), 4) impact of the test on changes in actual management, 5) impact of the test on health outcomes, and 6) impact of the test on societal outcomes (e.g., disease burden, cost).

## Home tests for hemoglobin A1c and cholesterol

We searched Medline and the Cochrane CENTRAL Register of Controlled Trials for English-language studies on the home use of hemoglobin A1c (HbA1c) and cholesterol testing. Key words to identify home test, ambulatory test, or point-of-care testing were searched and crossed with key words to identify HbA1c, diabetes, cholesterol, or dyslipidemia. The complete search strategy is described in Appendix A. We also examined reviews for potentially relevant citations. The populations of interest were adults with type 1 and 2 diabetes or dyslipidemia. Tests considered were any tests marketed for home use with the express purpose of measuring either the glycosylated hemoglobin (HbA1c) or cholesterol. Because of the low yield from our abstract screening (see Results), we also contacted the manufacturers of the home tests for HbA1c and cholesterol via email, or telephone for additional published or unpublished information. In all cases, we either did not receive a reply, or the contact email provided was

invalid. When contacted by telephone, the company representatives were not able to provide assistance, nor were they able to direct us to a department that could provide us with helpful information.

## Horizon scan

We first consulted experts to identify potential tests amenable to home use, then we conducted a grey literature search to answer questions concerning the currently available home tests by examining various commercial and government websites. According to the Fourth International Conference on Grey Literature in Washington, DC, in October 1999, grey literature was defined as: "That which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers." Grey literature can include, but is not limited to; reports, memoranda, conference proceedings, standards, technical documentation, government documents, and in this case also includes information retrieved from commercial manufacturer and distributor websites.

For the first step in collecting data for the horizon scan grey literature, we utilized the “Google” search engine that listed home testing devices which are used for the management of chronic disease. The grey literature search is complicated due to the nature of the Google search engine. It is very sensitive but not very specific; there are hundreds of repeat hits, and even more results that have little or no relation to the keyword. Also, the same key word may be searched the following day, but the results will always differ, and therefore, duplicating a web-based grey literature search is not possible. We decided the most efficient way to proceed was to create a list of chronic diseases of interest, then search for devices used by patients with these specific diseases. The chronic diseases included: diabetes mellitus, hyper- and hypothyroid disorders,

asthma, anemia, hemostasis disorders, cardiovascular diseases including dyslipidemia, hypertension, and sleep apnea. After conducting the search using specific illnesses, general key words were used, such as home testing, consumer diagnostics, home test kits, home diagnostics, outpatient care, outpatient testing, home monitoring, ambulatory care, home care monitoring, and other variations of these terms. After inspection, the most relevant and pertinent information relating to the key word invariably appeared within (at most) the first five pages of the Google search. Thus, we relied on these relevant pages to gather home test information.

Other websites such as: healthhometest.com, homediagnostics.com, homehealthtesting.com and homeaccess.com provided a number of testing kits for many different diseases. Most of the sites provided a list of disorders, which the consumers could then search for a home test kit relating to their specific need. Other sites, such as healthtestingathome.com, not only provided a list of diseases to search, but also a list of manufacturers of each testing device to search through as well. All these sites were geared toward the consumer; they provided facts about the diseases and descriptive directions on how to use the home testing devices. We also searched internet consumer marketplaces such as Target.com, CVS.com, OscoDrug.com, Ebay.com, Amazon.com, americandiabeteswholesale.com, diabetesnet.com, and pricegrabber.com. Dozens of results for home testing devices that were sold at these stores appeared on each site.

All home testing devices found were recorded in a table. For each test we collected the following data: type of chronic diseases the device is used for, type of specimen, collection methodology, test results display method, methods of interpretation, and details of the manufacturer and/or distributor including name and website. (Table 1)

Following the original search conducted in December 2007, the collected list of home testing devices was crosschecked. This was performed by running a keyword (e.g., “blood glucose home

test") through the Google search engine, which then would return a large number of hits that included approximately a dozen to two dozen distributor websites. These distributor websites were then searched for additional home testing products. When a new home test was found that was not included in the original search, it was added to the list. After crosschecking the original searches, and adding the newly discovered home testing devices, each individual test was searched using the Google search engine to locate the manufacturer website and obtain pertinent information.

As the manufacturer and/or distributor websites varied in their description concerning the FDA regulatory status of the specific tests, we searched for the relevant information in the FDA website. Specifically, we searched the publicly accessible FDA 510(k) database for information regarding the FDA clearance status of the home test devices that were identified from our grey literature search using the following method: we searched the 510(k) database (accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm, accessed April 17th, 2008) by Product Code, Applicant Name (or the manufacturer), or Device Name. The Product Code identifies the generic category of a device. The following codes were searched:

- DXH: transmitters and receivers, electrocardiograph, telephone
- DPS: electrocardiograph
- CHH: enzymatic esterase--oxidase, cholesterol
- JKA: tubes, vials, systems, serum separators, blood collection
- DCK: c-reactive protein, antigen, antiserum, and control
- LCP: assay, glycosylated hemoglobin
- NBW: system, test, blood glucose, over the counter
- CGA: glucose oxidase, glucose

- JIR: indicator method, protein or albumin (urinary, non-quant.)
- KHG: whole blood hemoglobin determination
- GJS: test, time, prothrombin
- JLW: radioimmunoassay, thyroid-stimulating hormone
- DQA: oximeter
- BZH: meter, peak flow, spirometry

When the product name is not in the list of in vitro devices under each Product Code, the name of the product (or the brand name) was used as keyword for the search of the device name. If the device still could not be found, we searched for the name of the manufacturer and examined the relevant 510(k) documents. We also recorded the FDA regulatory status for the device into Table 1 when this information was available. When the information was not available, the status "no data" was entered.

# Results

## Framework for evaluating a home test in the management of a chronic disease

The following framework is constructed to present the rationale and the necessary processes in evaluating the implementation of a home test in the management of a chronic disease. (**Figures 1 & 2**) As have been mentioned in the Methods section, some of the themes in this framework evolved from ideas suggested by experts and also ideas mentioned in selected articles and reviews.[5, 11-17]

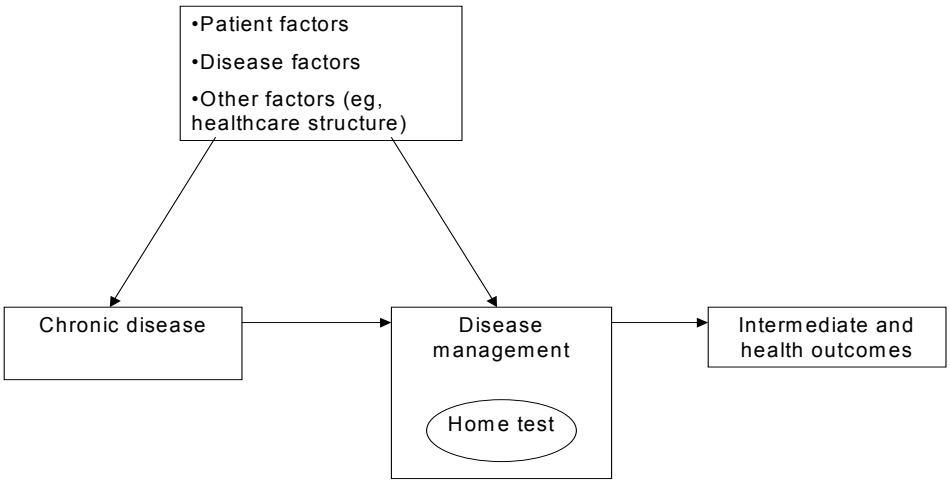



**Figure 1. Home test as one aspect of overall disease management**

**Rationale for implementing a specific home test**

Patients who are afflicted with chronic diseases have to cope with many direct and indirect sequelae of the diseases. Direct sequelae affect their immediate day-to-day function (e.g., immobility due to chronic arthritis, compromised visual ability due to diabetes) and quality of life; indirect sequelae affect their abilities to participate fully in societal functions (e.g., regular and gainful employment). Chronic disease also affects family members who care for the patient (e.g., taking time off to take the patient to doctor's appointment). Many chronic diseases require prevalent laboratory monitoring to optimize the required treatments (e.g., hemoglobin A1c monitoring in diabetes once every 3 months or more).

The overriding rationale for recommending a specific home test in the management of a specific chronic disease is the plausibility that such an implementation will improve health outcomes. An important question that should be asked is whether the adoption of a specific test will have a bearing on clinical decisions and therapeutic changes that would not be made if the test were not adopted. It should be underscored that "health outcome" is defined broadly in this context; it could be a direct and immediate health outcome (e.g., preventing rapid deterioration in visual acuity) or a direct and long-term health outcome (e.g., mortality) or an indirect health outcome (e.g., less disability leading to gainful employment and increased productivity). Changes in test results (e.g., reduced HbA1c concentration, prothrombin time International Normalized Ratio (INR) within the desired range) are intermediate outcomes, and are not considered health outcomes (both HbA1c and INR are considered surrogate outcomes). Plausible reasons for improved health outcomes from home testing include the supposition that frequent monitoring will result in timely adjustment of treatment which in turn may lead to fewer complications for certain diseases (e.g., glucose monitoring in patients with insulin dependent

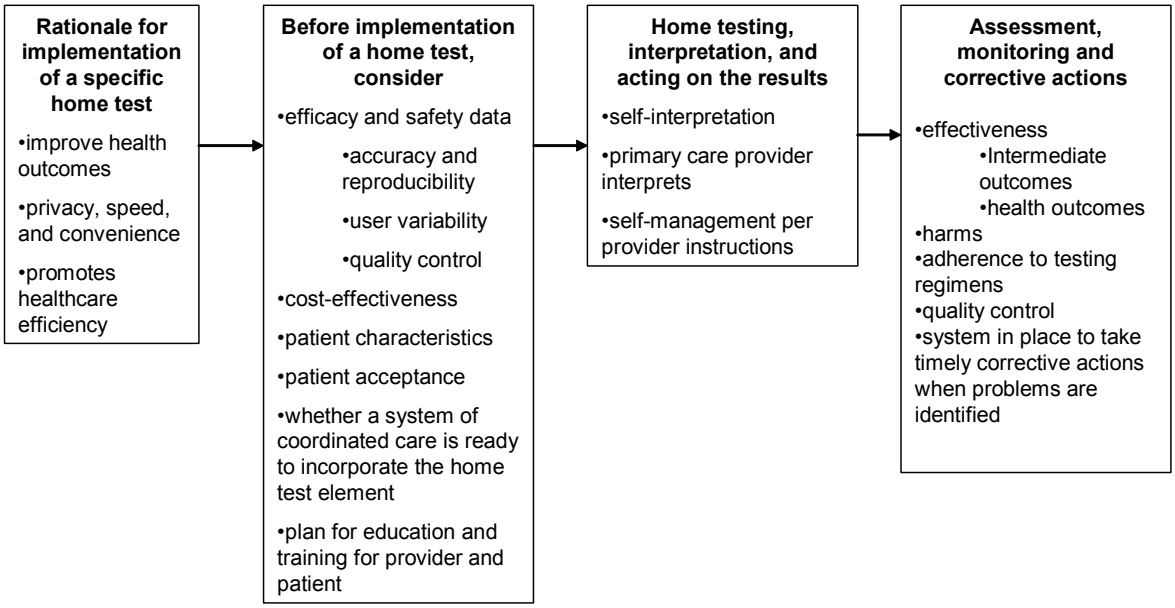
diabetes mellitus[19]); more frequent and more timely monitoring and rapid implementation of corrective actions may reduce visits to emergency facilities and hospital admissions (e.g., see the Cochrane review on self-management and self-monitoring in patients with asthma[20]); empowering the patient to manage her/his own disease is in of itself desirable and could lead to better health outcome (in a study on the self-management of prothrombin time INR, subjects in the self-management group scored higher in treatment satisfaction, self-efficacy and scored lower in daily anxieties and distress[21]); patient armed with the latest information (from the home test) at a doctor's visit promotes efficiency and could improve therapeutic outcomes (in a study on the availability of the result of HbA1c at the time of a primary care visit, those patients with readily available baseline HbA1c information received more frequent intensification of therapy, resulting in lower HbA1c concentration, compared to control;[22] in another study, patients with rapid availability of HbA1c determination had more favorable followup HbA1c profile compared to those patients without rapid availability, this effect occurred independent of the decision to intensify therapy, "suggesting the involvement of other factors such as enhanced provider and/or patient motivation."[23]). Having the test result at the time of the doctor's visit may also help improve communication (please note that the test could also be done as a waived test in the physician's office where the physician has more confidence in the validity of the result and could provide immediate clinical feedback). If a doctor has to order the test after the office visit, there is the potential for mishaps in communicating the result of the test.

Other potential benefits for implementing a home test include privacy, speed, and convenience to the patient and family members. Instead of waiting for an office visit with her/his caring doctor, with appropriate instructions, patient can act immediately upon the finding of the

home test. And family members do not have to take time off to take the patient to a healthcare facility.

There is potentially an indirect benefit to the health care system as well. Conducting a test at home implies one less visit to a healthcare facility in certain instances (in other instances, the home test finding can be used to discuss the optimal management at a doctor's visit, but it does not preclude the office visit itself), the time freed up could be allotted to another patient.

**Figure 2. Aspects to consider in implementing a home test regimen in a healthcare system**




Potential tradeoffs for the increased privacy, speed, and convenience of home testing are inaccurate results, erroneous interpretations, and faulty subsequent actions. The introduction of

home testing may potentially engender an over-reliance on self-diagnosis and self-care. What effects that might have will need to be assessed.

**Before implementation of a home test**

In evaluating the introduction of a home test to the health care system, one will need to examine the evidence for health benefits in adopting such a test. To put it another way, questions should be asked whether adoption of such a test will have a bearing on clinical decisions that affect health outcomes. If such evidence does not exist, one will have to examine critically the biological and clinical plausibility that the adoption of a specific home test for a specific chronic disease has a good likelihood of improving health outcomes. Efficacy data from experimental studies (like randomized controlled trials) will then be needed. Once the test is in general use, data from continual observational studies will help improve the assessment of its true effectiveness. In addition to possible benefits, one will also have to examine possible harms stemming from the introduction of a home test (e.g., see two case reports of hypoglycemia caused by excessive changes in insulin regimen when patients were not properly educated what to do with the home glucose testing results[24]). After the benefits and harms are carefully considered and weighed, the technical feasibility of introducing a home test is then explored (see following sections).

Last but not least, cost-effectiveness of adopting a home test should also be comprehensively estimated. Monetary cost of the test and monetary cost to the patient (dependent on the insurance reimbursement structure and the extant government regulations), increased productivity and quality of life of the patient and her/his family, cost of dealing with testing errors (inaccuracies and misinterpretations) and subsequent faulty and remedial actions, and improved efficiency of the health care system as a whole (e.g., shorter appointment wait time to see a primary care

physician, decreased use of emergency facilities and hospitalizations) should all be factored into this equation.

**Patients suitable for home testing**

Home self-testing is not appropriate for all patients. At a minimum, patients need to be willing and able (either self or through family members) to perform the test. The patient and her/his primary care provider will come to a joint decision regarding the initiation of a home self-testing program. Heterogeneous factors (e.g., socioeconomic status, education, co-morbidities, family structure, and healthcare reimbursement structure) will play a role in this decision. One will need to examine carefully the characteristics of those patients who would benefit from home testing. Patients affected with the same chronic disease could very well have different degrees of morbidity. Therapeutic changes initiated secondary to results from home testing could affect patients differently depending on the baseline degree of morbidity (i.e., there may be larger therapeutic effects on sicker patients). Other variables that should also be assessed are any co-morbidities that may interfere with the test (e.g., low hematocrit leading to a spuriously high level of glucose[25]) or impaired visual neuro-motor functions (secondary to the chronic disease) which may affect the ability to interpret a test (e.g., visual impairment leading to an erroneous interpretation of colors on a test strip). Last but not least, a successful implementation of a home testing regimen will likely also depend on a patient who is motivated to manage and take control of one's chronic ailment and therefore is willing to do the test. Reasons for patients not willing to do the home test should be explored (e.g., in a study on the home use of HbA1c test kit, 210/380 subjects did not do the home test; reasons cited were duplication of tests done by physicians, too busy, wanted to talk with their physician, or the kit was too difficult to use[26]). Knowledge from such studies will help identify unforeseen issues.

The acceptance of a home test by targeted patients should also be evaluated. Barriers (e.g., sociocultural, economic, prevailing health care milieu) towards a successful implementation of home testing should be explored. To optimize compliance, home test will likely require continual patient training and a coordinated and efficient support system. Ideally, a system of coordinated care that is proficient in dealing with home testing regimens should be in operation when a new home test is introduced. It must be recognized that home testing is only one component of the overall disease management. The patient (or whoever designated to do the test) should have received clear instructions on how to do the test, demonstrate the ability to do the test correctly, understand what to do after the test is conducted (either send to a laboratory or interpret the test result directly), and know whom (primary care coordinator, test manufacturer…etc.) to contact for assistance. Patients who are on a home testing regimen should be kept track of diligently. Potential issues with specific home testing regimens should be anticipated and methods of appropriate resolution should be crafted *a priori*. It must be underscored that a home test that is cleared by the FDA was likely to have been evaluated under a carefully controlled laboratory setting and data on evaluating the test when used by the intended user have been examined. This is quite different from the real world use of a home test, issues like forgetting to do the test, using an expired test strip, having an untrained family member to do the test…etc. are not commonly reproduced in an experimental situation. Therefore, test accuracy and precision of a home test in the real world setting should be monitored. Experiences from real world settings would be of value in improving home testing regimens.

**Test performed at home versus outside laboratory**

There are different ways to categorize home tests (e.g., by diseases, by testing methodologies like biochemical or electromechanical or others). One way to categorize the tests

is to differentiate the test that is performed at home from the test that is performed at an outside laboratory. The former expects the patient to procure her/his own specimen, run the test, interpret the test result and take any pre-directed (by the primary care provider) action; this type of test is generally prescribed by the primary care provider. The latter expects the patient to procure her/his own specimen, but the specimen is then sent directly to an outside laboratory, the laboratory in turn will send the result back to the patient (and/or primary care provider), the patient then acts on the result as either directed by the manufacturer's instruction or the primary care provider. This kind of testing is frequently known as direct-to-consumer marketed test or direct-access test (DAT). The DAT process eliminates the misinterpretation of results by the patients but it does not monitor whether patients would take the appropriate and recommended subsequent action.

**Non-patient and patient factors in evaluating the test performance**

Ideally, a home test should be easy to do and result obtained should be unambiguous. Above all, a home test should be accurate and reproducible. To assess the diagnostic accuracy of a home test, it is essential to have a reference standard of the test measurement. For example, in the FDA guidance[1] for premarket review on home cholesterol tests,[28] the manufacturers are advised to submit the diagnostic accuracy data of the cholesterol home test device using the reference standard of Abell-Kendall[29] performed in a CDC-certified Cholesterol Reference Method Network Laboratory. Studies on reproducibility should be performed to quantify the variability

[1] A home test device must acquire FDA's clearance to be legally marketed in the United State. The goal of the FDA's device premarket review is to evaluate the accuracy (or bias), precision, and analytical and diagnostic sensitivity and specificity of the test devices to determine if the new device is "substantially equivalent" to its predicate(s). The premarket review is entirely a paper evaluation based on data submitted by manufacturers, although the agency does have the legal authority to review raw data as part of its oversight process and can check the information submitted through the use of onsite bioresearch monitoring inspections as a quality-control measure, and can use ongoing Current Good Manufacturing practice inspections to audit for conformance to FDA manufacturing requirement.[27]

of the test results; standard deviation and coefficients of variation (within test and between tests) are commonly determined. Ideally, a home test performed by a lay person should produce results equivalent to those performed by a professional. In order to assess the real life test performance, it is therefore important to assess the test in a home setting (in reality, it is likely that a test is assessed by intended users in a simulated setting unsupervised by technicians or health care professionals rather than the actual home setting).

Home tests are performed by a wide variety of individuals. Even with clear and accurate instructions on how to perform the test at home, in reality, users of the test device contribute a great deal to the observed variability.[12] Some of this user variability is due to the fact that the test was performed by an unskilled user, which potentially can lead to operator-dependent errors (e.g., forgetting to do a test at a specific time and improperly entering a value for the time-specific test). For certain tests, it should be underscored that the disease process itself may also limit the necessary hand-eye coordination and visual acuity in obtaining the proper specimen, performing the test, and interpreting the results. For all these reasons, quality control of both the user and the test itself are needed to evaluate the reliability of the test data. To improve quality control, individuals who are charged with performing the test must undergo training until the goals of quality control is met (i.e., within a reasonable range of the results of the reference measurement). The test technique itself could be evaluated at regular intervals by comparing the patients' test results with a concurrently obtained measurement on the same specimen using a reference method. This may be readily accomplished at the time of follow-up visits with the health-care professional. For the test system itself, a built-in quality control scheme is best as it will simplify the quality control routine and likely increase user compliance. Such a scheme could include automated calibration checks, an error reporting system (if the testing is done

incorrectly) with a memory device to record results and "lapses" in doing the test. If such a scheme is not available, it behooves a designated individual to conduct periodic quality control on the test system. It should be underscored that these methods of quality-control do not measure errors generated during collection and application of specimens to the test device.

Lastly, if the design of a home test is for the user to collect the specimen, then perform and interpret the result directly (versus the user collecting the specimen (or the data as in the case of electrocardiogram), then sending the specimen to a professional laboratory for testing with interpretation of the result by the primary care provider), the result should be unequivocal and any necessary action (due to the result) should be clearly delineated and explained to the user before hand.

**Education and training for everyone**

A system should be in place to educate, assess, and train a patient who is expected to perform self-testing at home (e.g., Patients with newly diagnosed diabetes routinely receive instructions on the proper use of glucose monitors. Instructions on the use of HbA1c testing kit could also be incorporated into these training sessions.) The rationale for the implementation of the home test should be carefully explained and any issues raised by the patient addressed. It is difficult to assess a patient's motivation before the home test regimen is implemented. But if a patient does not comply with the testing program, reasons for the non-compliance should be explored and corrective actions taken, if possible. A home testing program could very well be novel in a particular health care milieu; the health care professionals themselves should be educated and properly trained to deal with this new element. A system of coordinated care including the home test element should be crafted before hand before the actual implementation of the home test regimen.

**Action after test**

Self-interpretation of test results by patients relies on patients' judgment and knowledge of test results, and the nature, intent, and accuracy of the test itself. Therefore, patients should be adequately trained in both the testing procedure and the correct reading of the test results which would then lead to the necessary and proper action (as a result of the test). Acting on the home test results may have immediate clinical impacts (as in immediate therapeutic action due to a particular blood glucose reading) or it may not (as in HbA1c or cholesterol testing). Furthermore, training program updates would seem reasonable in order for patients to adapt to the constantly evolving testing technology. Patients may also benefit from a continuing education program concerning self-testing to optimize outcomes (in a study on the effectiveness of a self-management training program in children with diabetes, those subjects who received supplemental training during the first year had lower HbA1c than control subjects[30]).

Although patients who self test may also self manage their disease conditions without additional consultations from their primary care providers, certain critical test results should be related to the primary care provider in a timely manner. Automated reporting pending certain critical test results using either the Internet or some form of telemetry could serve that purpose. The primary care providers can then intervene in a timely manner. A telephone call from the primary care provider to the patient explaining what therapeutic actions need to be taken may obviate the need for a face-to-face meeting. To enhance a primary care provider's ability to intervene in a timely manner about a critical test result, information connection can be established through a multimedia system (e.g., The ProTime® HomeTest™ Program, ProTime PT-INR Testing®). Also, if a patient forgets to perform a test on schedule, the multimedia system can send a reminder to the patient and a notice to the primary care provider. Rapid relay

of important information is made possible through these remote systems. This will promote efficient management of disease conditions and may help decrease or eliminate certain preventable complications.

**Assessment and monitoring**

Objective intermediate (e.g., changes in laboratory values or dosages of medications) and health outcomes (e.g., long-term survival) of a chronic disease as a result of the introduction of a particular home test should be assessed in a formal study. As has been stressed throughout this article, home test is only one component of the overall disease management plan. A patient sent home on a home test regimen should not be forgotten and will need to be diligently monitored. Whether that is done through the primary care provider or some other health care coordinator system will depend on one's local health care structure.

Although home test devices are designed to be easy to use and have minimal errors, problems like storing the test kit improperly, not checking for test kit shelf life, not following the proper instruction for specimen collection, having untrained person doing the test, misinterprets the test result, not taking the recommended subsequent action, and poor quality control of the testing materials can still occur. A system should be in place to monitor and be ready to take any necessary remedial actions for potential problems.

**Harms and responsibility**

A home test could be adequately performed, appropriately interpreted, and necessary subsequent response diligently carried out, but, in reality, we still have to deal with false-positive and false-negative results because no useful test is ever 100 percent sensitive and specific. It would be important for patients, health care providers, manufacturers, and testing laboratories to share responsibilities in dealing with these issues. Patients should be carefully instructed and

reminded by the health care providers what to expect from action subsequent to the test result and the health care providers promptly notified if that were not the case. Manufacturers and testing laboratories could collaborate to implement a continual and frequently tested quality control system which would include the monitoring of any relevant electro-biochemical testing materials (e.g., test strip) and testing procedures.[2]

**Cost**

Any time a new test or a testing regimen is introduced, one must ascertain the potential cost to our health care system. The cost to develop the test, the cost to pay for the test, the cost of management of the disease with or without the test, the cost of dealing with inaccurate results, and the potential cost savings from fewer clinician office and emergency facility visits and improved productivity from the patients are some of the factors that should be entered into this equation. A cost-effectiveness analysis for the implementation of such a test will be of value. Patients, health care providers, insurers, manufacturers, and policy makers will have to come to an agreement as to the best way to share the cost burden, provided that data exist to suggest that such a test will improve the overall health outcomes for the individuals and lessen the disease burden for the society.

## Literature review of HbA1c and cholesterol home tests

For questions on HbA1c and cholesterol, we screened a total of 2,183 abstracts, of which three[31-33] mentioned home test for cholesterol, and six[26, 34-38] mentioned home test for HbA1c.

[2] Currently, this is not required for CLIA waived tests (home tests that are FDA cleared are as a rule, waived tests). "Only tests of moderate and high complexity must meet requirements for proficiency testing, patient test management, quality control, quality assurance, and personnel." (fda.gov/CDRH/DEVADVICE/3122.html, accessed 4-16-2008) Future ongoing quality assurance guidelines for home tests may need to be established by a panel of laboratory experts and government agencies.

Examination of the full text articles of these abstracts showed that three studies[26, 34, 38] reported data of some relevance. We also contacted 18 manufacturers for information concerning home tests for either HbA1c or cholesterol, none responded.

**HbA1c**

1. What is the evidence on the feasibility for the implementation of home testing for HbA1c?

There was no study that addressed this question.

One study addressed the patient characteristics associated with the likelihood of performing the test at home.[26] Rector 2001,[26] an industry supported study, surveyed subjects with type 1 diabetes enrolled in two health plans and analyzed why they would or would not use the HbA1c self-test kit provided by their health plans. Out of 380 subjects, 170 used the kit. HbA1c measurements were >8 mg/dL in 43%. Most common reason for using the kit was to find out how well-controlled their blood glucose were. Of the 210 subjects who did not use the kit, the most common reason for not using the kit was concern that the kit would duplicate tests done by physicians, other reasons were too busy, wanted to talk with their physician, or the kit was too difficult to use. The authors concluded that "because the majority of health plan members did not use the kit and the majority who did use the kit had HbA1c levels <8 mg/dL, sending home test kits to members did not result in a high yield of members with elevated HbA1c levels. Physicians' support for use of the kits and efforts to make kits easier to use might increase use."

2. What is the diagnostic accuracy for home testing for HbA1c?

Klonoff 2006,[34] an industry supported study, analyzed the performance of a disposable HbA1c test (Bayer A1CNow+ (formerly Metrika A1CNow)) when used by an untrained subject compared to a trained medical professional. The study did not take place in a home setting, but the untrained subject was asked to "imagine they had purchased A1cNow at their local

pharmacies". In the study sites, 297 (282 with diabetes and 15 without diabetes) untrained subjects read the product labeling, performed the test on themselves, and recorded the results. The data were analyzed using a Deming regression. Comparing untrained to professional, the slope and y intercept were 0.972 and 0.269, respectively, with r=0.88 (P=0.58). The study also compared A1CNow to a reference laboratory test using the National Glycohemoglobin Standardization Program Secondary Reference laboratory (NGSP) method. Comparing untrained to reference laboratory, the slope and y intercept were 0.988 and 0.168, respectively, with r=0.93 (P=0.50). Comparing professional to reference laboratory, the slope and y intercept were 0.965 and 0.400, respectively, with r=0.94 (P=0.21).

3. What is the impact of the home test for HbA1c on decision making by the physician, the patient, or both?

There was no study that addressed this question.

4. What is the impact of the home test for HbA1c on changes in actual management?

There was no study that addressed this question.

5. What is the impact of the home test for HbA1c on health outcomes?

There was no study addressed this question. One study did address the effect of home testing on an intermediate outcome, the change in HbA1c value.[38] Holman 1987, in a prospective cohort study, enrolled 200 patients with diabetes.[38] The patients drew their own blood into bottles that would take precise volume (Unistep, Owen Mumford, Oxford, UK) and mailed them to the laboratory before visits with their physicians. In a 12-month period, 883 out of 1046 bottles were returned and 776 had adequate specimens for analysis. In 115 patients who had an initial HbA1c value and at least one subsequent measurement the following year, the mean HbA1c decreased from 10.9 ± 2.2 percent to 10.1± 2.2 percent (P<0.01).

6. What is the impact of the home test for HbA1c on societal outcomes (e.g., disease burden, cost)?

There was no study that addressed this question.

**Cholesterol**

1. What is the evidence on the feasibility for the implementation of home testing for cholesterol?

There was no study that addressed this question.

2. What is the diagnostic accuracy for home testing for cholesterol?

There was no study that addressed this question.

3. What is the impact of the home test for cholesterol on decision making by the physician, the patient, or both?

There was no study that addressed this question.

4. What is the impact of the home test for cholesterol on changes in actual management?

There was no study that addressed this question.

5. What is the impact of the home test for cholesterol on health outcomes?

There was no study that addressed this question.

6. What is the impact of the home test for cholesterol on societal outcomes (e.g., disease burden, cost)?

There was no study that addressed this question.

## Horizon scan

For each of the search terms using the Google search engine, as well as the search terms used for specific chronic diseases, hundreds of thousands to millions of hits were returned. For example, on December 12th, 2007, the search term “home test kits” was used and Google

produced 8,070,000 results. The term "home diagnostics" resulted in a significantly lower number of hits at 2,680,000, and the term "outpatient care" resulted in only 536,000. It should be noted that search results from Google are not stable; a different search date will return a different number. All information taken either from the distributor's or manufacturer's websites (which were found through Google) regarding home testing devices was recorded in Table 1.

The search for the FDA 510(k) database for information regarding the FDA clearance status of the home test devices that were identified from our grey literature search yielded over 2,500 records.

We have no access to information on home testing devices that have not yet been cleared by the FDA because this information is not readily available.

**Home tests identified through grey literature sources**

Our web-based search identified 168 home tests that are available to consumers in the US for the management of chronic disease. (**Table 1**) Table 1 is not an exhaustive list, as there are hundreds of tests (see above FDA 510 (k) result) available on the market for use in the home, recording every available test through a grey literature method would not be feasible. This table reports the results that were found within the first three pages of each keyword searched through Google.

We included home tests for management of the following diseases: cardiovascular diseases (including dyslipidemia) (23); diabetes mellitus (107); hematological disorders (3); thyroid (1); asthma (31); and sleep apnea (2). We excluded diagnostic tests for acute and chronic diseases, and diagnostic tests for pregnancy. We found that the majority of home tests required a finger prick for the test (e.g., cholesterol), while a minority utilized a non-invasive monitoring system (e.g., ECG). A high percentage of the tests displayed the results numerically, while a few

utilized either color read out or sample analysis at an outside laboratory (also known as direct access testing). Cross-checking with the FDA 510 (k) database showed that many of the tests have been cleared by the FDA for either prescription use specifically in a point-of-care setting (i.e., an in vitro diagnostic test (IVD) operated by a health care worker) or specifically in a home setting or over-the-counter use. It is evident that some of the tests from the same manufacturer have been cleared by the FDA, but the manufacturer also listed many more tests with similar names or slightly different model numbers which have no explicit information on FDA clearance status. Cross-matching the entire relevant FDA 510 (k) database with our grey literature search proved problematic as the brand name of the test device was not consistently reported in the 510(k) document and the name of the manufacturer was not always readily available from grey literature sources.

## Table 1. Description of home tests identified through grey literature sources

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| **CARDIOVASCULAR DISEASE Monitors** | | | | | | |
| HeartOne™ Pocketsize Transtelephonic ECG Event Recorder | N/A | no collection: thumbs on designated electrodes to record rhythm | By device within phone | Digital read out on screen: results transmitted to lab | Aerotel www.aerotel.com | Yes 11/6/2002 DXH |
| HeartView™ 12L Professional 12-Lead ECG Recorder/ Transmitter | N/A | no collection: patients position the 10-wire cable. | By device: transmits to receiving center | Interpretation by cardiac diagnostics center | Aerotel www.aerotel.com | Yes 6/16/1998 DXH |
| Home-CliniQ™ PC-Based Homecare Multi-Parameter Multi-User Medical Acquisition Center | N/A; software application | no collection | Evaluation on screen: transmits results to receiving center | Interpretation by Aerotel receiving center | Aerotel www.aerotel.com | no data |
| Read My Heart Hand Held V2O ECG Monitor | N/A | no collection: thumbs on designated electrodes to record rhythm | By device: suggested to consult with physician | Digital read out on screen | DailyCare Biomedical Inc. www.dcbiomed.com | Yes 01/06/2005 DPS |
| **CHOLESTEROL** | | | | | | |
| Accu-check Instant Plus Cholesterol/ Glucose Meter | Blood | Finger prick, collection with capillary | Device measures levels and calculates | Results presented on digital read out | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | Yes 8/23/2005 CHH |
| Accu-Stat Total Cholesterol Home Test | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | Accu-Stat Diagnostics www.accu-stat.com | no data |
| Alternecare Choless RX Cholesterol Home Test Kit | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | Alternecare Health Products www.alternecare.com | no data |
| BioSafe Home Cholesterol Panel | Blood | Finger prick | Blood is evaluated by lab technicians | Mail in test results to lab for interpretation | BioSafe Medical Technologies, Inc. www.ebiosafe.com | Yes 9/26/2001 CHH |
| CardioCheck PA (Cholesterol + Glucose panel) | Blood | Finger prick, collection with capillary | By device: digital read out | Results interpreted by patient at home | Polymer Technology Systems, Inc. www.cardiocheck.com | Yes 9/24/2002 7/23/2004 CHH; NBW |
| CardioCheck ST | Blood | Finger prick, collection with capillary | Digital read out | Results interpreted by patient at home. | Polymer Technology Systems, Inc. www.cardiocheck.com | Yes 9/24/2002 CHH |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| Chemcard Total Cholesterol Test | Blood | Finger prick | By device: color read out | Results interpreted by patient: compares test read-out and color chart | Chematics, Inc. www.chematics.com | no data |
| CholesTrak Total Cholesterol Home Test | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | Accu-tech, LLC. www.accutech-llc.com | Yes 12/27/2007 LBS |
| Cholestech LDX(R) (lipid, CRP … etc.) | Blood | Finger prick | Mailed to CLIA certified laboratory | Results mailed to patient from certified lab. | Cholestech Corporation www.cholestech.com | Yes |
| Cholestech GDX™ (HbA1c) | Blood | Finger prick | Test read out | Patient/physician interprets results | Cholestech Corporation www.cholestech.com | no data |
| FirstCheck Home Test Cholesterol | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | WorldWide Medical www.wwmed.com | no data |
| Home Access "Checkup America" Cholesterol Panel | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | Home Access Health Corporation www.homeaccess.com | Yes K063852 JKA |
| Home Access Instant Cholesterol Test | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | Home Access Health Corporation www.homeaccess.com | no data |
| Landmark Dx Cholesterol Panel Test – HDL, LDL Profile Test | Blood | Finger prick | Blood is evaluated and analyzed by lab technicians | Results sent to patient through mail after reviewed by physician | Landmark Diagnostics http://landmarkdx.com/ | no data |
| TestMedica Home Cholesterol Test | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | TestMedica www.iherb.com | no data |
| Venture Home Cholesterol Test Kit | Blood | Finger prick | Test read-out similar to thermometer | Patient interprets results by referring to enclosed chart | Vitro Diagnostic www.vitrodiagNostic.com | no data |
| **C-Reactive Protein** | | | | | | |
| Cholestech hs-CRP | Blood | Finger prick | Mailed to CLIA certified laboratory for analysis | Results mailed to patient from certified lab | Cholestech Corporation www.cholestech.com | Yes 06/18/2004 DCK |
| Landmark hs-CRP Test | Blood | Finger prick | Mailed to CLIA certified laboratory for analysis | Results mailed to patient from certified lab | Landmark Diagnostics http://landmarkdx.com/ | no data |
| **DIABETES MELLITUS** | | | | | | |
| **Glucose** | | | | | | |
| Accu-Chek Compact Plus Blood Glucose Meter | Blood | Finger, palm, forearm prick | By device: digital read out in five seconds, ability to download to computer software | Results presented on screen | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | no data |
| Accu-Chek Aviva Blood Glucose Meter | Blood | Finger, palm, forearm prick | By device: digital read out in five seconds, ability to download to computer software | Results presented on screen | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | no data |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| Accu-Chek Compact Blood Glucose Meter | Blood | Finger, palm, forearm prick | By device: digital read out in five seconds, ability to download to computer software | Results presented on screen | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | no data |
| Accu-Chek Advantage Blood Glucose Meter | Blood | Finger prick | By device: digital read out in five seconds, ability to download to computer software | Results presented on screen | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | no data |
| Accu-Chek Active Blood Glucose Meter | Blood | Finger prick | By device: digital read out in five seconds, ability to download to computer software | Results presented on screen | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | Yes 6/20/2001 NBW |
| Accu-Chek Complete Blood Glucose Meter | Blood | Finger prick | By device: digital read out in five seconds, ability to download to computer software | Results presented on screen | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | Yes 7/23/2002 NBW |
| Accu-Chek Voicemate Blood Glucose Meter | Blood | Finger prick | By device: digital read out in five seconds, ability to download to computer software | Results presented on screen | Roche Diagnostics www.accu-chek.com www.roche-diagnostics.us | no data |
| Advance Microdraw Blood Glucose Monitoring System | Blood | Finger prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | Yes 03/25/2005 GGA |
| Advance Intuition Blood Glucose Monitoring System | Blood | Finger prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | no data |
| Advocate Diabetes Meter Kit TD-4223B - Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: digital read out | Results presented on screen | Diabetic Supply of Suncoast, Inc www.dsosi.com. | no data |
| Advocate Duo TD-3223 Talking Blood Glucose + Blood Pressure | Blood | Finger, palm, forearm, thigh prick | By device: digital read out | Results presented on screen | Diabetic Supply of Suncoast, Inc www.dsosi.com Taidoc Technology www.taidoc.com | Yes 4/9/2007 NBW |
| Advocate Redi-Code Talking Glucose Meter Kit TD-4223E - Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: digital read out | Results presented on screen | Diabetic Supply of Suncoast, Inc www.dsosi.com. Taidoc Technology www.taidoc.com | Yes 10/3/2007 NBW |
| Ascensia® CONTOUR® Blood Glucose Monitoring System | Blood | Finger prick | By device: easy-to-read display | Results presented on screen | Bayer Healthcare www.bayerdiabetes.com | Yes 4/12/2006 NBW |
| Ascensia® Elite and Elite XL® Blood Glucose Monitoring System | Blood | Finger prick | By device: easy-to-read display | Results presented on screen | Bayer Healthcare www.bayerdiabetes.com | Yes 4/29/2002 NBW |
| Ascensia® Breeze® Blood | Blood | Finger prick | By device: easy-to-read display | Results presented on screen | Bayer Healthcare www.bayerdiabetes.com | Yes 11/22/2006 |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| Glucose Monitoring System | | | | | | NBW |
| Ascensia® Breeze 2® Blood Glucose Monitoring System | Blood | Finger prick | By device: easy-to-read display | Results presented on screen | Bayer Healthcare www.bayerdiabetes.com | 11/22/2006 NBW |
| Assure II Blood Glucose Monitoring System | Blood | Finger prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | Yes 10/4/2005 NBW |
| Assure 3 Blood Glucose Monitoring System | Blood | Finger prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | no data |
| Assure 4 Blood Glucose Monitoring System | Blood | Finger prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | no data |
| Assure Pro Blood Glucose Monitoring System | Blood | Finger prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | no data |
| BD Logic® | Blood | Finger prick | By device: easy-to-read display | Results presented on screen | Sanvita (BD Diabetes Glucose Monitoring Products) www.bddiabetes.com | Yes 10/28/2004 CGA |
| Bionime Rightest GM300 Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: digital read out | Results presented on screen | Bionime Corporation www.bionime.com | Yes 1/3/2005 NBW |
| The Chemcard® Glucose Test | Blood | Finger prick | By device: identifies abnormal blood glucose levels | Patient at home analysis: color match | Chematics, Inc. www.chematics.com | Yes 07/23/1996 CGA |
| Clever Chek Auto Code Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | by device: digital read out | Results presented on screen | Simple Diagnostics simplediagnostics.com Taidoc Technology www.taidoc.com | Yes |
| Clever Chek Auto Code Blood Glucose and Blood Pressure Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: digital read out | Results presented on screen | Simple Diagnostics simplediagnostics.com Taidoc Technology www.taidoc.com | Yes K062800 |
| CONTROL AST Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | by device: easy-to-read display which provides fast, accurate results | Results presented on screen | US Diagnostics, Inc www.usdiagnostics.net | no data |
| Diachex Diabetes Glucose Monitoring System | Blood | Finger prick | By device: read display | Results presented on screen | Tyson Bioreseach, Inc. www.tysonbio.com | Yes 10/10/2006 NBW |
| Duo-Care Combined Blood Glucose and Wrist Blood Pressure Monitor | Blood | Finger prick | by device: digital read out; also monitors blood pressure | Results presented on screen | Genexel-Sein, Inc. www.genexel.com Taidoc Technologies www.taidoc.com | no data |
| EasyGluco Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | US Diagnostics, Inc. www.usdiagnostics.net | Yes 1/12/2007 CGA |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| EasyGluco G1 Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | US Diagnostics, Inc. www.usdiagnostics.net | Yes 1/12/2007 CGA |
| FreeStyle Flash™ Blood Glucose Monitoring System | Blood | Finger prick | Device analysis | Digital read out | Abbott www.abbottdiabetescare.com | Yes 3/9/2006 NBW |
| FreeStyle Freedom® Lite Blood Glucose Monitoring System | Blood | Finger prick | Device analysis | Digital read out | Abbott www.abbottdiabetescare.com | no data |
| FreeStyle Lite™ Blood Glucose Monitoring System | Blood | Finger prick | Device analysis | Digital read out | Abbott www.abbottdiabetescare.com | Yes 4/10/2007 |
| FreeStyle Navigator Continuous Glucose Monitoring System | N/A; sensor placed under skin for 5 days | No collection | Transmitter snaps into sensor mount and sends glucose info wirelessly to receiver | Evaluation by device system every minute | Abbott www.abbottdiabetescare.com | no data |
| Glucocard X Meter Blood Glucose Monitoring System | Blood | Finger, palm, forearm prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | Yes 8/9/2007 NBW |
| Glucopack Phone | Blood | Finger prick | Results analyzed by device within phone | Results on screen, uploaded to website | HealthPia America http://healthpia.us | Yes 6/5/2006 NBW |
| Home Aide Diagnostics Easy Check Diabetes Meter - Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display | Results presented on screen | Home Aide Diagnostics, Inc. None available (purchase product through distributors) | no data |
| KidneyScreen At-Home Test | Urine | collection paddle collects the urine, which dries on a strip | Dried urine is analyzed by lab technicians | Mail-in laboratory test for measuring microalbumin levels in the urine | Flexsite Diagnostics, Inc. www.flexsite.com | Yes 08/14/2000 JIR |
| Loss of Protective Sensation Test for the Foot (In-Home Sensory Test) | N/A | Site testing on the top and bottom of each foot using a pricking tool | Results provided to physician for interpretation | Physician evaluation | Diabetes Technologies www.diabetestechnologies.com | no data |
| MAXIMA™ Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | US Diagnostics, Inc. www.usdiagnostics.net | no data |
| MediSense Optium Diabetes Meter Kit - Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | Abbott www.abbottdiabetescare.com | Yes 9/9/2002 NBW |
| NovaMax Blood Glucose Monitoring System | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display which provides fast, accurate results | Results presented on screen | Nova Biomedical www.Novacares.com | Yes 6/13/2007 NBW |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| OneTouch Ultra Mini Blood Glucose Meter | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | Yes 5/19/2006 NBW |
| OneTouch Ultra 2 Blood Glucose Meter | Blood | Finger, palm, forearm prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | no data |
| OneTouch UltraSmart Blood Glucose Meter | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | Yes 8/23/2002 |
| OneTouch Select Blood Glucose Meter | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | no data |
| OneTouch Ultra Blood Glucose Meter | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | no data |
| OneTouch Basic Blood Glucose Meter | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | no data |
| OneTouch SureStep Blood Glucose Meter | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | no data |
| OneTouchProfile Blood Glucose Meter (NO LONGER SOLD) | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | no data |
| OneTouch FastTake Blood Glucose Meter (NO LONGER SOLD) | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | no data |
| OneTouch InDuo Blood Glucose Meter (NO LONGER SOLD) | Blood | Finger prick | By device: read display | Results presented on screen | Life Scan, Inc. (a Johnson & Johnson Company) www.lifescan.com | Yes 2/7/2003 |
| Outcomes Management Tool (HEDIS/NCQA) Mail-In Test | N/A | site testing on the top and bottom of each foot using a pricking tool and mono filament | Results analyzed by lab | Lab evaluation: results mailed to patient | Diabetes Technologies www.diabetestechnologies.com | no data |
| Paradigm Link® | Blood | Finger prick | By device: easy-to-read display | Results presented on screen | Sanvita (BD Diabetes Glucose Monitoring Products) www.bddiabetes.com | Yes 5/19/2004 NBW |
| PocketChem EZ Blood Glucose Monitoring System | Blood | Finger or palm prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | no data |
| Precision Xtra® Blood Glucose and Ketone Monitoring System | Blood | Finger prick | By device: digital read out | Results presented on screen | Abbott www.abbottdiabetescare.com | Yes 6/18/2001 NBW |
| Prestige IQ Smart System Blood Glucose Monitor Starter Kit | Blood | Finger prick | By device: easy-to-read display which provides fast, accurate results | Results presented on screen | Home Diagnostics, Inc. www.prestigesmartsystem.com | no data |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| Prestige IQ® Blood Glucose Monitor | Blood | Finger prick | By device: easy-to-read display | Results presented on screen | Home Diagnostics, Inc. www.prestigesmartsystem.com | Yes 03/26/2001 NBW |
| Prodigy Advance Meter | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display which provides fast, accurate results | Results presented on screen | Diagnostic Devices, Inc. www.prodigymeter.com | no data |
| Prodigy Audio Meter | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display which provides fast, accurate results | Results presented on screen | Diagnostic Devices, Inc. www.prodigymeter.com | no data |
| Prodigy Autocode Meter | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display which provides fast results | Results presented on screen | Diagnostic Devices, Inc. www.prodigymeter.com | no data |
| Prodigy Duo Meter | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display which provides fast, accurate results | Results presented on screen | Diagnostic Devices, Inc. www.prodigymeter.com | no data |
| Prodigy Eject Meter | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | Diagnostic Devices, Inc. www.prodigymeter.com | no data |
| Prodigy Voice Meter | Blood | Finger, palm, forearm, thigh, calf prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | Diagnostic Devices, Inc. www.prodigymeter.com | Yes 3/5/2008 |
| Quicktek Blood Glucose Monitoring System | Blood | Finger prick | By device: Digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | no data |
| Sidekick® Blood Glucose Testing System | Blood | Finger prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | Home Diagnostics, Inc. www.prestigesmartsystem.com | Yes 7/12/2005 NBW |
| Smartchex Diabetes Glucose Monitoring System | Blood | Finger prick | By device: read display | Results presented on screen | Tyson Bioreseach, Inc. www.tysonbio.com | no data |
| Supreme Plus | Blood | Finger prick | By device: digital read out | Results presented on screen | Arkray USA (formerly Hypoguard) www.arkrayusa.com | no data |
| TRUEread™ Blood Glucose Monitor | Blood | Finger prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | Home Diagnostics, Inc. www.prestigesmartsystem.com | no data |
| TrueTrack Smart System® Blood Glucose Monitor | Blood | Finger prick | By device: easy-to-read display: provides fast, accurate results | Results presented on screen | Home Diagnostics, Inc. www.prestigesmartsystem.com | Yes 7/11/2003 NBW |
| Ultimate EZ Smart Plus Diabetes Glucose Monitoring System | Blood | Finger prick | By device: read display | Results presented on screen | Tyson Bioreseach, Inc. www.tysonbio.com | Yes 6/16/2006 NBW |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| WaveSense Jazz Codeless | Blood | Finger, palm, forearm prick | By device: easy-to-read display | Results presented on screen | AgaMatrix, Inc. http://www.wavesense.info | Yes 7/20/2007 NBW |
| WaveSense KeyNote | Blood | Finger, palm, forearm prick | By device: easy-to-read display | Results presented on screen | AgaMatrix, Inc. http://www.wavesense.info | Yes 1/30/2008 NBW |
| **HbA1C** | | | | | | |
| A1c-At-Home Test | Blood | Finger prick | Blood is analyzed in lab | Results interpreted by lab: mailed to patient in report | Flexsite Diagnostics, Inc. www.flexsite.com | Yes 9/5/1997 LCP |
| AccuBase A1c Test Kit | Blood | Finger prick | Blood is analyzed in CLIA certified lab | Results interpreted by lab: mailed to patient | Diabetes Technologies www.diabetestechnologies.com | Yes 11/30/1998 LCP |
| Biosafe Hemoglobin A1c Test | Blood | Finger prick | CLIA certified lab | Numerical results interpreted by lab, then mailed to patient | Biosafe Diagnostics www.ebiosafe.com | Yes 11/26/1999 LCP |
| Home Access Checkup America Diabetes Test | Blood | Finger prick | CAP certified lab | Mail-in laboratory test for results | Home Access Health Corporation www.homeaccess.com | no data |
| Landmark A1c Diabetes Test | Blood | Finger prick | CLIA lab evaluation | Test results mailed to patient | Landmark Diagnostics, Inc. http://landmarkdx.com/ | no data |
| Bayer A1CNow+ | Blood | Finger prick | By device: read display | Results presented on screen | Bayer HealthCare LLC www.A1CNow.com | Yes 9/26/2000 LCP |
| **HYPERTENSION: BLOOD PRESSURE MONITORING** | | | | | | |
| Clever Chek Digital Wrist Blood Pressure Monitor | N/A | No collection: wrap cuff around wrist | By device: digital read out | Results presented on screen | Simple Diagnostics http://simplediagnostics.com Taidoc Technology www.taidoc.com | no data |
| Digital Wrist Blood Pressure Monitor - Heart Sense YS-760 | N/A | No collection: wrap cuff around wrist | By device: digital read out | Results presented on screen | Home Aide Diagnostics, Inc. None available (purchase product through distributers) | no data |
| Home Aide DiagNostics Health Sense Fully Automatic Upper Arm Blood Pressure Monitor ZSBP-101 | N/A | No collection: wrap cuff around arm | detects blood movement through brachial artery and converts the movements | Results presented on screen with digital read out | Home Aide Diagnostics, Inc. None available (purchase product through distributers) | no data |
| HoMedics BPA-200 TheraP Automatic Blood Pressure Monitor with Irregular Heartbeat Detector | N/A | No collection: wrap cuff around arm and press start | detects irregular heartbeats by device | Digital panel gives read out of heartbeats | HoMedics www.HoMedics.com | no data |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| LifeSource Blood Pressure Monitor, Model UA-789AC | N/A | No collection: wrap cuff around wrist | By device: digital read out | Results presented on screen | LifeSource None available (purchase product through distributers)<br><br>A & D Engineering, Inc. www.andweighing.com | Yes 1/19/2007 |
| Lumiscope Blood Pressure Monitor, Flat Screen LCD | N/A | No collection: wrap cuff around wrist | By device: digital read out | Results presented on screen | The Lumiscope Co. Inc | no data |
| Mabis Advanced Automatic Digital Blood Pressure Monitor 04-346-000 | N/A | No collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net | no data |
| Mabis Automatic Digital Blood Pressure Monitor (Wide Range Cuff) 04-342-000 | N/A | No collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net | no data |
| Mabis Duro-Med Digital Blood Pressure Monitor | N/A | no collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net | no data |
| Mabis Self-Taking Home Blood Pressure Kit 04-174-021 | N/A | No collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net. | no data |
| Mabis Semi-Automatic Digital Blood Pressure Monitor 04-340-000 | N/A | No collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net | no data |
| Mabis SmartRead Automatic Blood Pressure Monitor (Large Adult Cuff) 04-310-006 | N/A | No collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net | no data |
| Mabis SmartRead Plus Wrist Blood Pressure Monitor 04-248 | N/A | No collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net | no data |
| Mabis SmartSpeed Automatic Digital Blood Pressure Monitor 04-330-006 | N/A | No collection: wrap cuff around arm | By device | Results presented on screen with digital read out | Mabis Healthcare, Inc. www.mabis.net | no data |
| North Safety 045039 Blood Pressure Cuff | N/A | No collection: wrap cuff around arm | Gauge reading | Results interpreted by patient or doctor | Northern Safety Co. www.northernsafety.com | no data |
| Omron HEM-780 (-711AC, -712C, -790IT, -650 Wrist) Automatic Blood Pressure Monitor with ComFit Cuff | N/A | No collection: wrap cuff around arm | Digital read out: detects irregular heartbeats while your blood pressure is being measured | Digital panel displays blood pressure and pulse readings | Omron Healthcare, Inc. www.omronhealthcare.com | Yes<br><br>Multiple records on FDA |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| Oregon Scientific Talking Wrist Blood Pressure Monitor | N/A | No collection: wrap cuff around wrist | By device | Digital panel displays read out | © Oregon Scientific Inc. www.oregonscientific.com | no data |
| Panasonic Portable Automatic Arm Blood Pressure Monitor, Model EW 3109 W (EW3152A, EW3122S, EW3039S, EW3006S, EW3106W) | N/A | No collection: wrap cuff around arm | By device | Digital panel displays read out | Panasonic www2.panasonic.com | no data |
| Samsung Healthy Living Blood Pressure Monitor, Automatic Inflation | N/A | No collection: wrap cuff around arm | By device | Digital panel displays blood pressure and pulse readings | Samsung www.samsungamerica.com | no data |
| **ANEMIA** | | | | | | |
| Biosafe Anemia Meter | Blood | Finger prick | By device: numerical read out within 20 minutes | Numerical reading of hemoglobin level | Biosafe Diagnostics www.ebiosafe.com | YES<br>KHG |
| **HEMOSTASIS DISORDERS** | | | | | | |
| Coaguchek XS PT/INR Monitor | Blood | Finger prick | By device | Measures the clotting activity of blood | Roche Diagnostics www.accu-chek.com www.roche-diagNostics.us | Yes<br>8/11/2006<br>GJS |
| INRatio PT/INR Monitor | Blood | Finger prick | By device | Measures the clotting activity of blood | Hemosense, Inc. www.hemosense.com | Yes<br>5/6/2002<br>GJS |
| ProTime(R) Microcoagulation System | Blood | Finger prick | By device | Measures the clotting activity of blood | ProTime: International Technidyne Corporation is a wholly owned subsidiary of Thermo Biomedical of Thermo Electron Corporation www.protimesystem.com | Yes<br>7/2/2001<br>GJS |
| **THYROID DISORDER (Hyperthyroidism and Hypothyroidism)** | | | | | | |
| Biosafe Thyroid Test | Blood | Finger prick | Certified lab analyzes numerical results | Mailed to patient in an easy to read report | Biosafe Diagnostics www.ebiosafe.com | Yes<br>07/16/2001<br>JLW |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| **RESPIRATORY DISORDER (Asthma)** | | | | | | |
| 2120 Spirotrac Lite | N/A | No collection | By device | Digital read out: ability to download to PC | Vitalograph, Inc. www.vitalograph.com | no data |
| 920M Plus and 2500A with Alarms Hand-Held Oximeters with Memory | N/A | No collection | By device | Digital read out on screen: interpreted by patient | Respironics http://global.respironics.com | no data |
| 950 Finger Pulse Oximeter | N/A | No collection | By device | Digital read out on screen: interpreted by patient | Respironics http://global.respironics.com | no data |
| Assess Full Range Peak Flow Meter | N/A | No collection: patient must breathe into meter | Analysis by patient: meter measures peak expiratory flow | Patient reads scale | Respironics http://global.respironics.com | no data |
| AsthmaMentor Peak Flow Meter with AutoZone | N/A | No collection: patient must breathe into meter | Analysis by patient: meter measures respiratory capacity | Color match system on side of meter | Respironics http://global.respironics.com | no data |
| Avant® 4000: Oximetry Unplugged® Wireless Wearable Oximetry | N/A | No collection: patient wears device on finger | By device | Digital read out on screen: interpreted by patient | Nonin www.nonin.com | Yes 12/23/2005 DQA |
| BCI DIGIT FINGER OXIMETER | Pulse monitor on finger | a spot check monitor for blood oxygen saturation, heart rate | Digital read out: at home | Pulse rate reading display | BCI www.portablenebs.com | Yes 6/22/1994 DQA |
| C-3 Fingertip Pulse Oximeter | Pulse monitor on finger | Measurements of oxygen saturation of arterial hemoglobin | Digital read out: at home | Automatic SpO2%, pulse rate reading display and tone modulation | Devon Medical www.devonsuperstore.com | no data |
| IgE Mediated Asthma Panel | N/A | No collection | test analysis by CLIA Certified Laboratory | Interpreted by lab, then results mailed to patient | Biosafe, Inc. www.ebiosafe.com | no data |
| Invacare TruZone Peak Flow Meter Model No. IRC1198 | N/A | No collection: patient must breathe into meter | Analysis by patient: meter measures respiratory capacity | Color match system on side of meter | Monaghan Medical Corporation www.monaghanmed.com | Yes 11/06/1996 BZH |
| Medair OxyCheck Digital Finger Pulse Oximeter | N/A | No collection: patient wears device on finger | By device | Digital read out on screen: interpreted by patient | Medair (a Nonin, Inc. company) http://www.medair.se/ | no data |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| Microlife Digital Peak Flow/FEV1 Meter for Spirometry | N/A | No collection: patient must breathe into meter | Analysis by patient: meter measures respiratory capacity | Digital read out on screen | Microlife www.microlife.com | Yes 11/14/2003 BZH |
| Microlife PF 100 | N/A | No collection: patient must breathe into meter | Analysis by patient: meter measures respiratory capacity | Digital read out on screen | Microlife www.microlife.com | no data |
| Nonin Onyx® 9500 and 9550 | N/A | No collection: patient wears device on finger | By device | Digital read out on screen: interpreted by patient | Nonin www.nonin.com | Yes 6/1/2005 DQA |
| Nonin PalmSAT® 2500 Series | N/A | No collection | By device | Digital read out on screen: interpreted by patient | Nonin www.nonin.com | Yes 10/11/2000 DQA |
| Nonin PalmSAT® 8500 Series | N/A | No collection | By device | Digital read out on screen: interpreted by patient | Nonin www.nonin.com | Yes 7/20/2000 DQA |
| Omron Peak Flow Meter, Adult or Pediatric, Model PF 9940 | N/A | no collection: patient must breathe into meter | Analysis by Patient: meter measures respiratory capacity | Patient reads scale | Omron Healthcare, Inc. www.omron.com | no data |
| Personal Best Peak Flow Meters - 50-390 liters/minute, Low Range | N/A | no collection: patient must breathe into meter | Analysis by patient: meter measures respiratory capacity | Patient reads scale | Respironics http://global.respironics.com | no data |
| Respironics Full Range Assess Peak Flow Meter | N/A | no collection: patient must breathe into meter | Analysis by patient: meter measures respiratory capacity | Patient reads scale | Respironics http://global.respironics.com | no data |
| Vitalograph Asma-1 Electronic Asthma Monitor | N/A | no collection: patient breaths into mouthpiece | By device | Digital read out | Vitalograph, Inc. www.vitalograph.com | no data |
| Vitalograph Asmaplan and Asmaplan+ Mechanical Peak Flow Meters | N/A | no collection: patient breaths into mouthpiece | By device | Digital read out: ability to download to PC | Vitalograph, Inc. www.vitalograph.com | Yes 12/14/1995 BZH |
| Vitalograph Micro | N/A | no collection: patient breaths into mouthpiece | By device | Digital read out: ability to download to PC | Vitalograph, Inc. www.vitalograph.com | Yes 2/4/2000 BZH |

| Name of Test | Type of Specimen | Collection | Analysis | Interpretation | Manufacturer and/or Distributor Websites | Status reported by FDA; Year of clearance; Product code |
|---|---|---|---|---|---|---|
| SPO Medical PulseOx 5500™ (6000, 6100, 7500) | N/A | no collection: patient wears device on finger | By device | Digital read out on screen: interpreted by patient | SPO Medical www.spomedical.com | Yes 9/10/2004 DQA |
| SPO Medical 90605500 Check Mate II Pulse Oximeter | N/A | no collection: patient attaches to hand and finger | By device | Digital read out on screen: interpreted by patient | SPO Medical www.spomedical.com | no data |
| WristOx™ Ambulatory Digital Pulse Oximeter | N/A | no collection: patient wears on wrist | By device | Digital read out on screen: interpreted by patient | Respironics http://global.respironics.com | no data |
| WristOx® 3100 | N/A | no collection: patient wears on wrist | By device | Digital read out on screen: interpreted by patient | Nonin www.nonin.com | Yes 10/17/2003 DQA |
| **SLEEP DISORDER (Sleep Apnea)** | | | | | | |
| Body Balance Sleep Check Test Kit | Saliva | Saliva in collection tube | Results analyzed by a certified laboratory | Results mailed to patient | Body Balance www.bodybalance.com | no data |
| Sleep Strip: Disposable Sleep Apnea Screener and Monitor | Patient applies equipment under nose while sleeping | Sensors monitor breathing | Digital read out: SAS severity score is calculated based on patient's AHI and permanently displayed on the built-in electrochemical display | Miniature flow sensors monitor the patient's respiration while integrated microprocessor analyzes patterns to detect and count each apnea and hypopnea event | S.L.P. Ltd. http://www.templerepair.com/sleepstrip.htm?gclid=CNKM1v_K6ZACFQwsOAodOUvxYw | Yes 10/06/2004 |

**N/A: not applicable**

# Discussion

We have suggested a theoretical framework to evaluate a home test. Adoption of such a framework in future evaluation is likely to provide helpful information. In our view, an ideal home test would have the following properties: 1) useful in chronic disease management and improving health outcomes, 2) simple and easy to use with minimal operator dependency, 3) provides unambiguous result, 4) has a built-in control testing system, and 5) cost-effective. Because of the paucity of data concerning the evaluation of testing for hemoglobin A1c or cholesterol in a home setting, we are not able to provide definitive answers posed by the key questions. The AHRQ technology assessment on point of care testing of hemoglobin A1c in 2005[10] similarly identified only one study that took place in a home setting.[38] There are many studies on point-of-care testing. But data gathered from evaluation of a test in a point of care setting could and should not be generalized to a home setting because of differences in operator expertise, training, and other factors. Evaluation of a potential home test using the Fryback and Thornbury model will allow one to properly comprehend the utility of such a test. Also, one needs to bear in mind the difference between an efficacy and an effectiveness trial. Efficacy studies tend to take place in controlled settings for relatively short periods. For instance, home blood pressure monitoring has only been tested in clinical efficacy trials, but not in the effectiveness settings. "These devices have not been regularly incorporated into clinical care to assist primary care providers in treating their patients".[39] Real world experiences will also be needed in assessing a test's true effectiveness.

Our horizon scan showed that many of the tests marketed for chronic disease management have been either approved or cleared by the FDA. Some tests' regulatory status was unclear; reasons are not immediately apparent. We speculate that some of the manufacturers' and

distributors' websites might have marketed the same test under slightly different names and made verification via cross-matching between different databases not possible.

## Future studies

A randomized controlled study in a real world setting would be ideal in evaluating the efficacy of a specific home test in improving health outcomes. The study could compare home test with no test or with other forms of testing (e.g., in vitro diagnostic testing in physician's office with immediate availability of result, conventional laboratory testing with result available only sometime after the health care visit). It must be cautioned that even with well-established randomization technique, it will not be easy to control for the many variables that affect the course of a chronic disease and its attendant health outcomes. It is also not easy to determine what health outcomes will be of interest. Post-marketing observational data will help assess the effectiveness of such a testing regimen. Such data should report any improved health outcomes as well as harms (e.g., consequences of false positive and false negative results like repeated needs of confirmatory testing, unnecessary anxiety, and excessive dosages of medications). A testing device with a built in memory chip could be programmed to record results as well as adherence to testing routine. Such device could also be designed to keep track of disease flare-ups. This will help promote further understanding of a particular relationship between test results and the chronic disease of interest. Large databases that collect health outcome and healthcare utilization pattern could also be examined to see if there is any relationship between the introduction of a specific home test and those data. As the Internet continues to expand, one will also need to assess the impact of telemedicine and related emerging technologies (e.g., home blood glucose result made available to the provider immediately over the Internet).

Reference List


(1) Neuberger J. Do we need a new word for patients? Lets do away with "patients". *BMJ* 1999 June 26;318(7200):1756-7.

(2) Lehmann C. Management of point-of-care testing in home health care. *Clin Leadersh Manag Rev* 2002 January;16(1):27-31.

(3) CDRH. FDA. Center for devices and radiological health. *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm* 2007;Available at: URL: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm. Accessed1907.

(4) Kyriakos T. Self-care, innovation boost today's home health offering - brief article - statistical data included. *http://findarticles.com/p/articles/mi_m3374/is_4_22/ai_61492765* 2000;Available at: URL: http://findarticles.com/p/articles/mi_m3374/is_4_22/ai_61492765.

(5) Lehmann CA. The future of home testing--implications for traditional laboratories. *Clin Chim Acta* 2002 September; 323(1-2):31-6.

(6) Fryback DG, Thornbury JR. The efficacy of diagnostic imaging. *Med Decis Making* 1991 April;11(2):88-94.

(7) Tatsioni A, Zarin DA, Aronson N et al. Challenges in systematic reviews of diagnostic technologies. *Ann Intern Med* 2005 June 21;142(12 Pt 2):1048-55.

(8) Khot UN, Khot MB, Bajzer CT et al. Prevalence of conventional risk factors in patients with coronary heart disease. *JAMA* 2003 August 20;290(7):898-904.

(9) Grover SA, Paquet S, Levinton C, Coupal L, Zowall H. Estimating the benefits of modifying risk factors of cardiovascular disease: a comparison of primary vs secondary prevention. *Arch Intern Med* 1998 March 23;158(6):655-62.

(10) Duke Evidence-based Practice Center. Point of Care Testing of Hemoglobin A1c. *http://www cms hhs gov/determinationprocess/downloads/id35TA pdf* 2005.

(11) Vincze G, Parthan A. The value of home monitoring kits in diabetes, hypertension, asthma, and oral anticoagulation therapy. *Journal of Pharmacy Practice* 2004;17(3):182-96.

(12) Consensus statement on self-monitoring of blood glucose. *Diabetes Care* 1987 January;10(1):95-9.

(13) Greenwald JL, Burstein GR, Pincus J, Branson B. A rapid review of rapid HIV antibody tests. *Current Infectious Disease Reports* 2006 March;8(2):125-31.

(14) Samsa GP, Matchar DB. Relationship between test frequency and outcomes of anticoagulation: a literature review and commentary with implications for the design of randomized trials of patient self-management. [Review] [37 refs]. *Journal of Thrombosis & Thrombolysis* 2000 April;9(3):283-92.

(15) Tran N, Kost, Gerald J. Guidelines for Home Testing in Primary Care: Education, Integration, Information, Limitations, and Indications. *Point of Care: The Journal of Near-Patient Testing and Technology* 5[4], 145-154. 2006.
Ref Type: Generic

(16) Scolaro KL, Stamm PL, Lloyd KB. Devices for ambulatory and home monitoring of blood pressure, lipids, coagulation, and weight management, part 2. *Am J Health Syst Pharm* 2005 September 15;62(18):1894-903.

(17) Datta AK, Selman TJ, Kwok T, Tang T, Khan KS. Quality of information accompanying on-line marketing of home diagnostic tests. *Journal of the Royal Society of Medicine* 2008 January;101(1):34-8.

(18) Walford S, Alberti KG. Biochemical self-monitoring: promise, practice and problems. *Contemp Issues Clin Biochem* 1985;2:200-13.

(19) Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy: the Epidemiology of Diabetes Interventions and Complications (EDIC) study. *JAMA* 2003 October 22;290(16):2159-67.

(20) Gibson PG, Coughlan J, Wilson AJ et al. Self-management education and regular practitioner review for adults with asthma. *Cochrane Database Syst Rev* 2000;(2):CD001117.

(21) Cromheecke ME, Levi M, Colly LP et al. Oral anticoagulation self-management and management by a specialist anticoagulation clinic: a randomised cross-over comparison. *Lancet* 2000 July 8;356(9224):97-102.

(22) Miller CD, Barnes CS, Phillips LS et al. Rapid A1c availability improves clinical decision-making in an urban primary care clinic. *Diabetes Care* 2003 April; 26 (4):1158-63.

(23) Thaler LM, Ziemer DC, Gallina DL et al. Diabetes in urban African-Americans. XVII. Availability of rapid HbA1c measurements enhances clinical decision-making. *Diabetes Care* 1999 September; 22(9):1415-21.

(24) Beer SF, Lawson C, Watkins PJ. Neurosis induced by home monitoring of blood glucose concentrations. *BMJ* 1989 February 11;298(6670):362.

(25) Tang Z, Lee JH, Louie RF, Kost GJ. Effects of different hematocrit levels on glucose measurements with handheld meters for point-of-care testing. *Arch Pathol Lab Med* 2000 August;124(8):1135-40.

(26) Rector TS, Venus PJ, Thayer SR. Use of home hemoglobin A1c test kits to monitor the effectiveness of diabetes care. *Joint Commission Journal on Quality Improvement 27(5):265 -77,* 2001 May.

(27) Gutman S, Richter K, Alpert S. Update on FDA regulation of in vitro diagnostic devices. *JAMA* 1998 July 8;280(2):190-2.

(28) Food and Drug Administration. Guidance for 510(k) on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use. Rockville, Maryland; 1995.

(29) ABEL LL, LEVY BB, BRODIE BB, KENDALL FE. A simplified method for the estimation of total cholesterol in serum and demonstration of its specificity. *J Biol Chem* 1952 March;195(1):357-66.

(30) Delamater AM, Bubb J, Davis SG et al. Randomized prospective study of self-management training with newly diagnosed diabetic children. *Diabetes Care* 1990 May;13(5):492-8.

(31) Home testing of cholesterol. *Medical Letter on Drugs & Therapeutics 36 (932):85-6,* 1994 September 30.

(32) Noble D. Home test for cholesterol. Look, ma, no instrument. *Analytical Chemistry 65(23):1037 -41,* 1993 December 1.

(33) Ross J. Home test measures total cholesterol. *Nurse Practitioner 28(7 Pt 1):52-3,* 2003 July.

(34) Klonoff DC, Bergenstal RM, Cole TG et al. Clinical Evaluation of a Rapid A1C Test (A1CNow) for Home Use. *Point of Care: The Journal of Near-Patient Testing and Technology* 2006 September;5(3):116-20.

(35) Kordella T. Home A1C test on the way. *Diabetes Forecast 55 (6):47-8,* 2002 June.

(36) Ruder K. At-home A1C device flawed. *Diabetes Forecast 60(6):40 ,* 2007 May.

(37) Parkes J, Ray R, Kerestan S, Davis H, Ginsberg B. Prospective evaluation of accuracy, precision, and reproducibility of an at-home hemoglobin A1c sampling kit.[see comment]. *Diabetes Technology & Therapeutics* 1999;1(4):411-9.

(38) Holman RR, Jelfs R, Causier PM, Moore JC, Turner RC. Glycosylated haemoglobin measurement on blood samples taken by patients: an additional aid to assessing diabetic control. *Diabet Med* 1987 January;4(1):71-3.

(39) Bosworth HB, Olsen MK, Dudley T et al. The Take Control of Your Blood pressure (TCYB) study: study design and methodology. *Contemp Clin Trials* 2007 January;28(1):33-47.