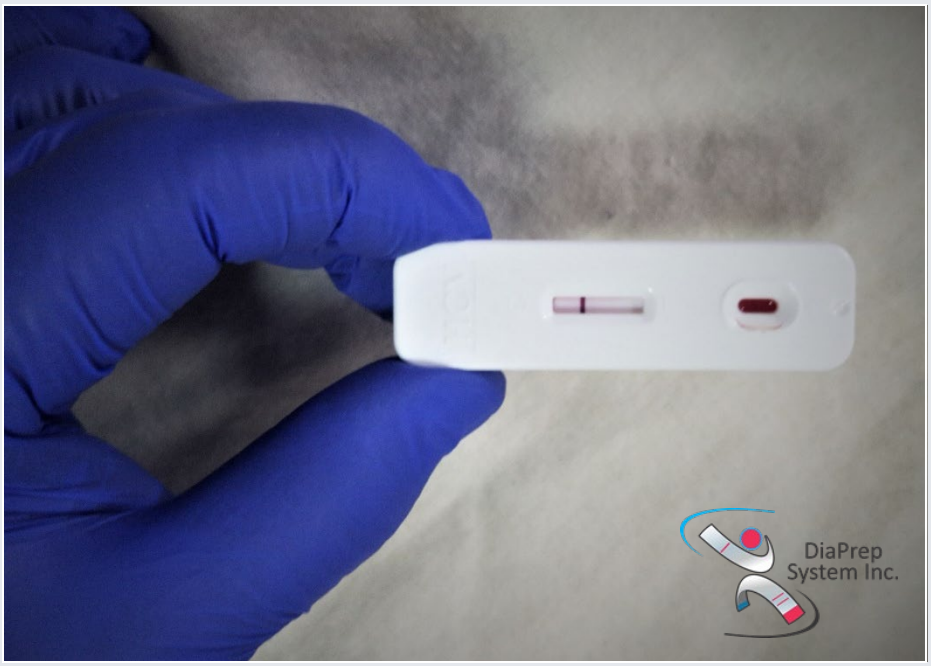

STATE-OF-THE-ART DIAGNOSTICS

POINT-OF-CARE RAPID TESTS

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POINT-OF-CARE RAPID TESTS: A CRUCIAL PUBLIC HEALTH TOOL

by DiaPrep System, Inc., Atlanta, USA

Point-of-care tests are diagnostic tools that can be used in a clinic, upon admission to a hospital, or at a patient's bedside. They can even be performed in workplace settings, such as during employee medical exams or by organizations serving high-risk groups, among many other uses.

Point-of-care tests are used throughout the world and are an **essential component of standard health care**. They are particularly important when care is provided under field conditions and during natural disasters or other emergencies, but are useful for public health in general.[i]

These tests allow results to be obtained **quickly**, which is why the adjectives "**rapid**" or "express" are used to describe them. As a rule, **rapid tests (RT) are inexpensive, fast, and reliable diagnostic tools**. They do not require drawing blood from vein, sophisticated laboratory equipment, or specialized components that tend to be expensive and therefore reduce the accessibility of laboratory testing. If you compare the cost of laboratory assays versus the cost of point-of-care testing using a kit, laboratory testing will be two or three times more expensive. This is evident, for example, if you compare the price of a laboratory test for hepatitis C virus versus a point-of-care test using a kit. However, not all test-systems are created equal, and you need to be confident that proper procedures and materials were used in analyzing the sample.

Rapid tests are ideally suited for clinical practice and preliminary, screening, and confirmational testing, as well as in emergency medicine. They are used both in top hospitals and by medical services with limited resources, but if the test kits are of high quality, the reliability of the results is the same no matter where the testing is conducted.[ii]

Today, rapid tests are common throughout the world and are often viewed as "simple." In fact, there is nothing simple about them, since they are intricately designed to ensure that they are as reliable as laboratory analysis. RT are based on the same principles that were once developed for the western blot or immunoblot assays and are highly sensitive due to the blending of specially selected individual antigens or monoclonal antibodies to identify the necessary markers. The high quality of such tests has been validated through evaluation studies. The results of such studies involving, for example, RT for HIV, have been published by the World Health Organization (WHO).[iii]

A rapid test showing the presence of IgG and IgM antibodies to SARS-CoV-2.

In recent decades, there has been a **trend toward obtaining test results at the point of care, right where patients are being evaluated and treated**. This has enabled medical professionals, including primary care providers, to improve the quality of care. Studies recently carried out in a number of countries, including Australia, Belgium, the Netherlands, Great Britain, and the United States, have shown that general-practice doctors, family doctors, and other providers feel a need for RT and wish they could be used more extensively in their work.[iv]

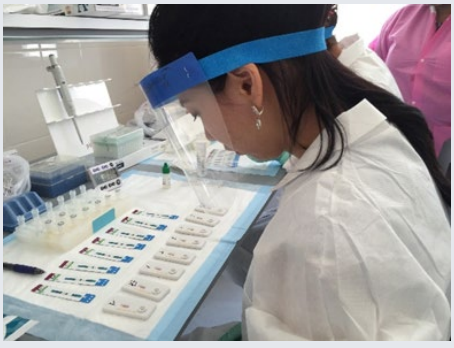
The primary advantages of RT are convenience, speed, and avoiding having to send patients to another building, facility, or even city for lab work. RT enable well-informed and **timely decision-making** concerning case management and treatment. There are RT to measure the level of glucose, gas, and electrolytes in the blood, as well as to evaluate coagulation parameters, cardiac and rheumatological function, and to screen for narcotics. They can be used to screen urine, test for pregnancy, check stool samples for blood (fecal occult blood tests), to screen for food-borne pathogens, to measure cholesterol and hemoglobin levels, and to detect specific infectious pathogens. The list goes on.[v]

RT require just a single drop of blood (whole, serum, or plasma), urine, or saliva, and can be performed and interpreted by any trained medical professional in just minutes (usually 15–20). Most diagnostic systems used at the point of care involve a membrane dipstick, often enclosed in a plastic test cassette. In some cases, an RT requires a portable reader (such as a glucometer or nerve-conduction measuring device).

RT have expanded the capabilities of health care overall and are a **cost-efficient way of diagnosing many diseases**, such as diabetes, acute coronary syndrome, and infectious diseases. In some cases, they can simultaneously measure different markers in a single sample of blood, plasma, or serum, which enables a fast, relatively inexpensive, and reliable evaluation of a patient's health. The efficiency comes from the ability to make quick, well-informed decisions on care, reducing dependence on laboratory services, reducing the time it takes to gather information relating to post-operative care and urgent care, reducing the number of patient visits to various medical facilities, reducing the number of needed hospital beds, and achieving optimal time efficiency for medical personnel.

The European Union defines an RT as an easy-to-use device that makes it possible to perform "qualitative or semi-quantitative in vitro-diagnostic medical devices, used singly or in a small series, which involve non-automated procedures and are designed to give a fast result."[vi]

In recent times, the spotlight has been on **rapid testing for infectious diseases** and the ability of RT to make testing widely available for **people in high-risk groups** who need it most.



However, not all tests are produced in adherence with the necessary standards, and not all appealingly packaged tests do a good enough job at detecting markers of infection. The prevalence of low-quality RT is largely a product of bidding systems in which purchasing decision-makers put price before quality. Purchasing agents often don't seem to know the old adage, "you get what you pay for." A **system of licensing and certification** for diagnostic products has been developed to guard against the use of low-quality tests, which are often produced by fly-by-night manufacturers.

A functioning quality assurance system

One of the most challenging and thorough regimes for evaluating test kits is the one imposed by the U.S. Food and Drug Administration (FDA). The process for earning the European Union's CE-Mark is almost as stringent. In recent years, the WHO, whose equivalent seal of approval is referred to as "prequalification," has tightened its quality control for diagnostic test systems. The reliability of diagnostic systems that have not been approved by any of these bodies should not be taken for granted. In other words, when selecting an RT, a primary consideration should the oversight and evaluation it has gone through. **The importance of test reliability cannot be overemphasized**, since inaccurate test results can have serious consequences for both individual patients and prevention programs.[vii]

For accurate and reliable RT results, be sure to select tests with demonstrated quality, precisely follow manufacturer instructions, and ensure strict adherence to all quality assurance practices.

We wish you good health!

RAPID TESTS

- Speed
- Efficiency
- Reliability
- Accessibility

*Click here to view a video demonstration (in French) of the TOYO **rapid test for the detection of HBsAg** (Hepatitis B surface antigens) developed by the Laboratoires Nephrotek.*

*Click here to view a video demonstration (in French) of the TOYO **rapid test for the detection of Hepatitis C antibodies** developed by the Laboratoires Nephrotek.*

We would be happy to hear from you. If you are interested in current diagnostic methods and would like to receive additional information about how rapid tests work, their performance, what role they can play in effective testing algorithms, or how to verify test quality, DiaPrep Systems, Inc. can help.

You can submit queries on our website, http://diaprepsystem.com, or write to us at: admin@diaprepsystem.com, info@diaprepsystem.com; phone: +7 705 181 4342; +1 404 382 9240

DiaPrep System Inc.

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