

# Tumor Markers - what are they telling us??

Tumor markers are molecules occurring in blood or tissues that are associated with cancer and whose measurement or identification is useful in patient diagnosis or clinical management. Tumor markers can be used for one of four purposes:

1. screening a healthy or high risk population for the presence of cancer
2. making a diagnosis of cancer or a specific type of cancer
3. determining the prognosis in a patient
4. monitoring the course in a patient in remission or while receiving surgery, radiation, or chemotherapy.

The ideal marker would be a "blood test" for cancer in which a positive result would occur only in patients with malignancy, one that would correlate with stage and response to treatment and that was easily and reproducibly measured. Unfortunately no single test meets all of these requirements, but the following tests have been established as tumor markers that are associated with specific cancers or diseases that can be useful in patient diagnosis or clinical management.

## TUMOR MARKER

Alpha-fetoprotein (AFP)  
 Carcinoembryonic antigen (CEA)  
 CA 15-3, BR 27.29  
 CA 125  
 CA 19-9  
 Estrogen/Progesterone receptors  
 Immunoglobulins  
 Prostate Specific Antigen (PSA)  
 Prostatic acid phosphatase (PAP)  
 BRCA 1&2

## ASSOCIATED DISEASE

cancer of liver, ovary, testes  
 cancer of colon, breast, lung  
 cancer of breast  
 cancer of ovary  
 cancer of pancreas  
 cancer of breast  
 multiple myeloma  
 cancer of prostate  
 cancer of prostate  
 genetic markers for breast cancer ♦

Avera St. Luke's, Aberdeen  
 Avera Queen of Peace Health Services, Mitchell  
 Avera McKennan Regional Lab, Sioux Falls  
 Avera Sacred Heart Hospital, Yankton  
 3900 West Avera Drive  
 Sioux Falls, SD 57108



## Editors Notes:

I wanted to take a moment to thank the number of you that returned the Customer Satisfaction survey. It is extremely important to us that we understand our clients needs. This information will prove very helpful as we plan for the future.

April 1, 2003 marked the implementation of new CPT codes and a fee schedule change. We feel confident that even with this small increase on some tests, ALN remains very competitive in the laboratory market. We want to thank you for allowing us to serve your laboratory needs. We continue to grow and expand. One of our recent expansions has been in the area of education. We have employed a person to coordinate and provide educational programs for the Avera Laboratory Network. These programs and tools will be made available to our clients throughout the year.

We are committed to supporting our clients in their own delivery of service. It is through productive and professional relationships that we are able to define the needs of the client and provide the services they need to support the delivery of quality patient care.

April also marks the celebration of National Medical Laboratory Week. We commend all the laboratory professionals that have dedicated themselves to providing a crucial part to the delivery of quality patient care. ALN thanks you !!

Lori Murray ♦

## Prenatal Screening for Risk of Cystic Fibrosis

The American College Of Obstetricians And Gynecologists is calling for widespread screening for cystic fibrosis. This is a simple prenatal screening test parents may elect to have, that it could tell whether their unborn child has a devastating disease.

Cystic fibrosis is the most common inherited disease among Caucasians. CF is an autosomal recessive genetic disorder characterized by chronic lung disease and pancreatic insufficiency. There is a broad range of clinical severity. Most individuals born today with CF are expected to survive into their 30s or 40s. CF occurs in about 1 in 2,500 newborns of European ancestry. It is less frequent among other ethnic and racial groups. About 1 in 25 persons of European ancestry is a carrier, having one normal and one abnormal CF gene. A single mutation, denoted DeltaF508, is found in approximately 70% of carriers of European ancestry. Currently, over 160 other mutations have been identified. Many of these are extremely rare, but a few reach frequencies of 1% -3 % of CF carriers. Current surveys indicate that 85%-90% of CF carriers in the North American white population can be detected by testing for 6-12 mutations. The detection rate is even higher in some populations (e.g., Ashkenazi Jews) but is substantially lower in blacks, Hispanics, and Asians.

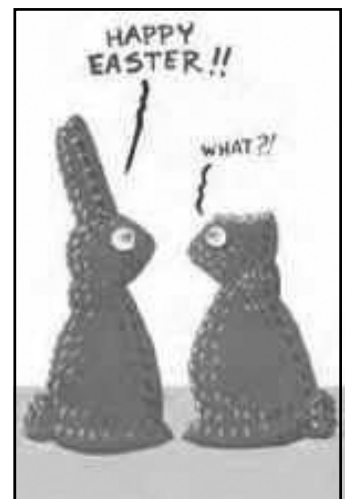
The gene test is to be offered to every Caucasian woman who is pregnant or planning to have a baby, and her partner. People of other races are less likely to carry the mutation, but they should get screening information and the test, if desired. If both test positive, a type of in vitro fertilization is an option they may want to consider.

Generally, the CF test is covered by insurance. Be aware, however, that it's not 100% accurate, since it only screens for the most common mutations in the gene. But widespread testing should drastically lower the incidence of cystic fibrosis. ♦

Avera Laboratory Network *Lab News* is published every other month to provide the latest updates on services from labs of the Avera Laboratory Network.

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## Celebrate National Medical Laboratory Week April 20-26, 2003

The theme for this year's event is Laboratory Professionals: Exceptional People — Exceptional Work.

More than 265,000 medical laboratory personnel are employed in the United States. National Medical Laboratory Week (NMLW) is a special time set aside to recognize medical laboratory professionals. It is a time of celebration for the approximately 265,000 medical laboratory professionals and 15,000 board certified pathologists who perform and interpret medical laboratory tests. NMLW recognizes the vital role these professionals play in every aspect of health care.

### Some interesting Lab week facts:

Beginning in January 1997, on the average, one "baby boomer" is turning 50 years of age every 7 seconds. Almost 13% of the U. S. population is now over 65 years of age, and the over-85 category, which requires the greatest amount of health care services, is growing by more than 3% annually. As Americans continue to age, more testing is required more frequently.

Other reasons for an increasing demand on medical laboratory testing are:

- increases in the population worldwide
- stronger emphasis on preventive medicine including early detection and diagnosis of diseases and increased patient responsibility for maintaining good health. Generally, the earlier a condition is detected, the greater the likelihood of a cure. Early detection also means patients can help prevent a condition with changes in diet and lifestyle; or that treatment is simpler, which greatly reduces costs
- an explosion of new medical technologies such as genetic testing

Expanding medical knowledge and technological developments have increased the need for medical laboratory testing. Twenty-five years ago, few organ transplants were performed. Today, they are becoming routine surgeries in many hospitals. Transplant patients need significant testing before the procedure, must be monitored immediately following, and require some follow up for years after the transplant.

## NCCLS Guidelines for Patient Identification for Phlebotomy

According to NCCLS proper patient identification for outpatients consists of asking patients to give their full name, address, identification number, and/or birth date and to compare this information with the request form. For inpatients, ask for same information, comparing it with the request form, the patient's identification bracelet and the information on the identification card posted outside each room, if possible.

It is critical that the patient be asked to **state** his/her name rather than for the collector to state the patient's name and ask the patient for affirmation. Patients who are hard of hearing or have an altered level of alertness due to illness or medication may affirm a name simply to be accommodating. Without asking inpatients to state their name, an arm bracelet attached to the wrong patient may go unnoticed. With outpatients, asking the patient to state his/her name

New and different pathogens are contributing to increased needs for laboratory testing as well. The identification of new diseases like AIDS, Lyme disease, and hepatitis C and the resurgence of old foes like tuberculosis, pose serious threats to the public health.

Unprecedented increases in international travel and immigration are resulting in the importation of rare or previously unknown diseases - especially parasitic infections and inherited disorders - which increases the need for laboratory testing.

More than 10 billion - that's 10,000,000,000! - laboratory tests are performed in the United States each year. \*

National Medical Laboratory Week is often a time for laboratorians to inform and educate medical colleagues and the public about the medical laboratory. Since medical laboratory professionals often work "behind the scenes," few people know much about the critically important testing that laboratorians perform every day. NMLW is also an excellent opportunity to promote medical laboratory professions, to recruit students to the field, to thank technologists and technicians, build morale, and gain visibility for the laboratory throughout the institution and the community.

The eleven sponsors for this year's celebration are:

- [American Society for Clinical Pathology](#)
- [American Association for Clinical Chemistry](#)
- [American Association of Blood Banks](#)
- [American Medical Technologists](#)
- [American Society for Clinical Laboratory Science](#)
- [American Society of Cytopathology](#)
- [American Society for Microbiology](#)
- [Association of Public Health Laboratories](#)
- [Clinical Laboratory Management Association](#)
- [College of American Pathologists](#)
- [National Society for Histotechnology](#)

Laboratory professionals are to be commended for their commitment to the profession. The Avera Laboratory Network extends our appreciation to the devoted laboratory professionals and thanks you for your commitment to quality patient care.

will screen for patients who were mistakenly given the wrong paper work.

In cases where patients do not have name bands and may not be able to identify themselves, long term care centers, triage situations, it is important that the collector document the name of the staff member who verified the identification. One of the most common problems that phlebotomists face is when an inpatient does not have an identification bracelet attached to their person. The phlebotomist that assumes the bracelet attached to a bedrail or on a bedside table puts the patient at a significant risk of an adverse outcome, including patient death. Many facilities have a policy of not drawing patients who are not properly identified. Often the phlebotomist is the patient's last line of defense against potentially life-threatening complications. ♦

## Group B Strep Website

CDC has developed a website specifically for the prevention of Group B Streptococcal disease at <http://www.cdc.gov/groupBstrep/default.htm>. Check it out for useful educational resources including print materials and slidesets for clinicians/healthcare providers, laboratory personnel, and the general public. ♦

## Rapid HIV-1 Antibody Test Granted Waived Status but Restricted to Clinical Laboratory Use Only

On November 7, 2002 the FDA approved the OraQuick Rapid HIV-1 antibody test. Under pressure from the Bush administration and Health and Human Resources Secretary Tommy Thompson, OraSure Technologies was urged to immediately apply for CLIA waiver. Classification of the new point-of-care test as waived would expand the availability of the test from 38,000 laboratories to more than 100,000 sites which would include physician offices and HIV counseling centers. CLIA granted waived status on January 31, 2003. But in what is believed to be an unprecedented action, the Food and Drug Administration has restricted the purchase and use of CLIA-waived rapid HIV test kit to clinic laboratories. This announcement came last week at the Clinical Laboratory Improvement Advisory Committee meeting. FDA officials say they believe it is the first time the agency has placed a laboratory-only sale and use restriction on a waived test. The finger-stick test is being shipped with a letter to customers stating that sale of the kit is restricted to clinical laboratories with adequate quality assurance programs, that the test is approved for use only by an agent of a clinical laboratory, and that patients must receive and information packet and counseling before testing. There is strong argument that this test be classified as moderate complexity.

The ELISA method has a minimum TAT of 5 hours, and if the testing facility batches testing it can take days for results to be reported. The SUDS (single use diagnostic system) for HIV-1 is faster (48-107 minutes) than ELISA but requires centrifugation. Results are available in 30-45 minutes using the OraQuick method. In the new test a drop of blood is added to a vial and mixed with a developer. The test device, a dipstick, is inserted into the vial and the results are read after 20 minutes. If HIV-1 antibodies are present, 2 reddish bands will be visible on the test device. The sensitivity of the test is 99.6% and the specificity of the test is 100%. The kit is stored at room temperature.

Rapid HIV tests have been in use in Europe for several years and are even available over-the-counter in several European countries. Manufacturers in the United States initially wanted to develop HIV-1,2 rapid tests but the company that holds the patent for the HIV-2 antibody method, Biorad, refuses to license the test to other companies developing point-of-care HIV tests.

In order for a test to qualify for CLIA waiver it must be easy to perform, be highly accurate, and present no adverse outcome for the patient if the result is erroneous. After FDA approval last year, CAP, the Clinical Laboratory Improvement Advisory Committee, and the FDA's own Blood Products Advisory Committee were unsure of the appropriateness of classifying the test as waived. These agencies were concerned that if the test was waived there would be no mechanism to ensure proper oversight, quality control, proficiency testing, or quality assurance. CLIAC reaffirmed its opposition to waived status at last week's meeting, saying that waived tests occur largely in unregulated and unmonitored environments, fail to ensure pre-analytic and post-analytic intervention, and that if performed incorrectly, could have detrimental results.

OraSure feels that several large populations will benefit greatly from the new rapid HIV test: people tested in public health care settings, women in labor who do not know their HIV status, health care workers who are exposed to blood, and military personnel. Faster results in public health care settings may encourage more people to seek HIV testing if they know they can get results the same day. According to the CDC, each year about 8,000 HIV-positive and hundreds of thousands of HIV-negative people did not return the following week for their results. Many obstetricians do not order HIV testing for women in labor citing inability to receive timely results as the main inhibiting factor. Studies show that starting antiretroviral treatment during labor and delivery and administering treatment to the newborn can reduce viral transmission by half.

The US Navy Military Sealift Command recently purchased 10,000 OraQuick tests to screen personnel participating in the smallpox vaccination program. The smallpox vaccine may cause serious complications for those with compromised immune systems and they should not be vaccinated.

The availability of the new rapid test may also increase the volume of routine screening done in hospitals. Since 1992 the CDC has recommended routine HIV screening of hospital admissions in areas of high HIV prevalence. The hospitals had difficulty getting results to discharged patients and did not want to incur liability from knowing a patient had tested HIV-positive and not being able to inform them.

The OraQuick test is not approved for screening blood donors. ♦

## Clarification From Jan/Feb LabNet News:

Page 5, under paragraph "other":

Medicare will not pay for capillary draws, therefore G0001 should be used for Venipuncture draws only. ♦