THE FOOD AND DRUG ADMINISTRATION (FDA) UPDATES

From: http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/default.htm

“The Food and Drug Administration (FDA), is a regulatory agency that enforces the Food, Drug, and Cosmetic Act and the Public Health Service Act, assuring that drugs and biologics are safe and effective for their intended uses, and properly labeled. FDA’s activities help protect all consumers in the United States, regulating some trillion dollars worth of products.

The FDA sets standards for, and monitors:
• all prescription and non-prescription drugs;
• all blood products, vaccines, and tissues for transplantation;
• all medical devices and equipment, and all radiation emitting devices;
• all animal drugs and feed;
• nearly all domestic and imported foods except for meat and poultry;
• and all cosmetics.”

Because of this, the FDA plays a major role in the personal and professional lives of all medical laboratory professionals. The following articles highlight a few examples of this impact.

FDA Approves Rapid Test for Antibodies to Hepatitis C Virus

For Immediate Release: June 25, 2010
Consumer Inquiries: 888-INFO-FDA

The U.S. Food and Drug Administration today announced approval of the first rapid blood test for antibodies to the hepatitis C virus (HCV) for individuals 15 years and older.

The OraQuick HCV Rapid Antibody Test is used to test individuals who are at risk for infection with HCV and people with signs or symptoms of hepatitis. HCV is transmitted through exposure to infected blood, which, for example, can occur during intravenous drug use. The virus can also be transferred from an infected mother to her child. Hepatitis C can lead to liver inflammation and dysfunction and, over time, to liver disease and liver cancer.

OraQuick is a test strip and does not require an instrument for diagnosis. It takes about 20 minutes to obtain results from the test.

"Approval of OraQuick means that more patients can be notified of their HCV infection faster so that they can consult with their physicians for appropriate health measures," said Jeffrey Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health. "Getting faster treatment is an important public health step to control this dangerous disease."

OraQuick is not approved for HCV screening of the general population.

According to the U.S. Centers for Disease Control and Prevention, there are approximately 3.2 million people in the United States chronically infected with HCV.
July 4th weekend, innovations are bursting in the air over the United States and HIV is associated with an estimated 12,000 deaths annually. Approximately 75 to 85 percent of people who become infected with the hepatitis C virus develop chronic infection. OraQuick is manufactured by Bethlehem, PA-based OraSure Technologies Inc. For more information:

- FDA: Medical Devices: http://www.fda.gov/MedicalDevices/default.htm
- NIH: Hepatitis C: http://health.nih.gov/topics/HepatitisC

Article reprinted from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm177118.htm See website for more information.

FDA Approves First Diagnostic Assay to detect both HIV Antigens and Antibodies

For Immediate Release: June 21, 2010
Consumer Inquiries: 888-INFO-FDA

Test advances ability to detect HIV infection earlier

The U.S. Food and Drug Administration today approved the first assay to detect both antigen and antibodies to Human Immunodeficiency Virus (HIV). This assay is approved for use as an aid in the diagnosis of HIV-1/HIV-2 infection in adults including pregnant women. It is also the first assay for use as an aid in the diagnosis of HIV-1/HIV-2 infection in children as young as two years old.

The highly sensitive assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. Since it actually detects the HIV-1 virus (specifically the p24 antigen) in addition to antibodies to HIV, the ARCHITECT HIV Ag/Ab Combo assay can be used to diagnose HIV infection prior to the emergence of antibodies. Most tests used today in the diagnostic setting detect HIV antibodies only. Although direct detection of the virus itself by nucleic acid testing is available, it is not widely used in diagnostic settings.

HIV is the virus that can lead to acquired immune deficiency syndrome, or AIDS. HIV damages a person’s body by destroying specific blood cells, called CD4+ T cells, which are crucial to helping the body fight diseases. Two types of HIV have been identified: HIV-1 and HIV-2. HIV-1 is responsible for most HIV infections throughout the world. HIV-2 is found primarily in West Africa; however, cases of HIV-2 infection have been reported in North America and Europe.

The Centers for Disease Control and Prevention report that approximately 18 million people in the United States are tested for HIV each year. Most recent CDC estimates are that there are about 56,000 new HIV infections in the United States each year. In addition, there are more than 1 million people living with HIV in the United States, according to CDC.

“The approval of this assay represents an advancement in our ability to better diagnose HIV infection in diagnostic settings where nucleic acid testing to detect the virus itself is not routinely used,” said Karen Midthun, M.D., acting director of FDA’s Center for Biologics Evaluation and Research. “It provides for more sensitive detection of recent HIV infections compared with antibody tests alone.”

The ARCHITECT HIV Ag/Ab Combo assay is not intended to be used for routine screening of blood donors. However, it is approved as a donor screening assay for HIV-1/HIV-2 infection in urgent situations where licensed blood donor screening tests are unavailable or their use is impractical.

The ARCHITECT HIV Ag/Ab Combo assay will be used in clinical laboratories and in public health laboratories, and is the first assay approved in the United States to detect HIV antigen and antibodies simultaneously.

The ARCHITECT HIV Ag/Ab Combo assay is manufactured by Abbott Laboratories, Abbott Park, IL.

For more information:

- HIV Testing: http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/default.htm
- HIV and AIDS Activities: http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/default.htm

Article reprinted from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm126375.htm. See website for more information.

Defibtech LLC, DBP-2800 Battery Pack for Revive! AED® and Lifeline AED® Semi-automatic External Defibrillators Recall Class: Class I

Date Recall Initiated: May 20, 2010

Product(s): DBP-2800 Battery Pack for the Defibtech Revive! AED® and Lifeline AED® semi-automatic external defibrillators

Affects only DBP-2800 battery packs distributed prior to June 4, 2007 and used with the Revive! AED® and Lifeline AED® devices.

Affected battery pack serial numbers range:

- Between 200200105 and 200200196, or,
- Between 200600101 and 200600387

In a letter to customers dated May 20, 2010, Defibtech states that the company is mailing to all affected customers a battery pack update data card that will allow customers to update device software to correct the problem while allowing the devices to remain in their locations.

To view the Defibtech notification and instructions on determining whether a battery pack is affected visit http://www.defibtech.com/Battery-FA-usa.html.

Reason for Recall: If the AED is used with an affected battery pack, the AED may falsely detect an error condition, cancel charge and not provide therapy.

Recalling Firm: Defibtech LLC

741 Boston Post Road, Suite 201
Guilford, Connecticut 06478-3921

Verlin K. Janzen, MD, F.A.A.P.
Chair, COLA Board of Directors
The serial number is located on the underside of the device and contains only numbers.

Approximately 42,943 devices were distributed worldwide between September 16, 2002 and September 27, 2007. These devices were manufactured from July 31, 2002 to September 19, 2007.

Recalling Firm: Physio-Control, Inc. 11811 Willows Road NE Redmond, Washington 98052-2003

Reason for Recall: A failure on the power supply assembly can result in either “No DC power” or “No DC or AC power.” A failure of DC (battery) power can result in the inability to deliver defibrillation therapy if the device will not turn on using DC (battery) power and no AC (line) power is available.

Public Contact: Physio-Control Technical Support at techsupport@defibtech.com or call 1-800-442-1142, Monday – Friday between 6:00 AM and 4:00 PM (Pacific Time).

FDA Comments: The firm began mailing notification letters to affected customers on May 26, 2010. All affected power supplies will be updated. Customers are advised to keep the defibrillators in service and follow recommended daily Operator Checklist steps while service updates are scheduled.

Useful Links:

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

Useful Links:
• MedWatch: The FDA Safety Information and Adverse Event Reporting Program: http://www.fda.gov/Safety/MedWatch/default.htm

INCORPORATING PATIENT SAFETY BY DECREASING HOSPITAL-ACQUIRED INFECTIONS

A recent article (released by PR Newswire) documented how infections may be spread via lab coats and scrubs worn by medical personnel.

“Lab coats or scrubs can be the source of some serious bacterial hazards like MRSA,” said Charles P. Gerba, PhD, a professor of Environmental Microbiology in the Department of Microbiology and Immunology at the University of Arizona. “When doctors or nurses lean over the beds of patients who are carrying organisms, their clothing can become contaminated. Hours later that bacteria can still be alive and passed on through incidental contact with other patients.”

The article mentioned recent studies done at the University of Maryland and Virginia Commonwealth University, but the American Medical Association (AMA) feels more studies should be conducted. According to a report issued by the AMA Board of Trustees, better hygiene, not dress codes, appears to provide the greatest hope in reducing hospital-acquired-infections. The AMA report encourages more research and validation of the research results before advocating changes in dress code policies.

Whether or not clothing is a major means of transmission of nosocomial infection, steps have already been taken to combat this form of bacterial spread. The PR Newswire article mentions the creation of lab coats and scrubs “embroidered with Tri-Active, an FDA approved silver-based antimicrobial compound that can kill resistant microorganisms such as MRSA, E. coli and Salmonella.”

An alternative approach, mentioned in an article on the AMA website, is clothing that “when washed in bleach, maintains the chlorine until the next wash, continually working to kill bacteria.” This article also mentions other possible transmission vehicles: the stethoscope and cell phones as well as the invention of sterile or anti-bacterial covers for both.

See the following sites for more information:


FDA FINES AMERICAN RED CROSS $16 MILLION FOR PRIOR FAILURES TO MEET BLOOD SAFETY LAWS

For Immediate Release: June 17, 2010
Consumer Inquiries: 888-INFO-FDA

The FDA announced today that the American Red Cross has been fined $16 million for prior failures to comply with federal laws and regulations related to the collection and manufacture of blood products.

Despite the compliance failures, the FDA found no evidence that the Red Cross violations endangered any patients and the blood supply is believed to be safe. Multiple layers of safeguards are in place to protect and enhance the safety of blood products. However, these types of violations decrease the assurance that blood products manufactured by the American Red Cross will continue to be safe and have the potential to compromise the safety of the blood supply.

The FDA assessed fines totaling $16.18 million – $9.79 million for violations related to mismanagement of certain blood products and $6.39 million for Good Manufacturing Practice violations. Blood products include red cells, plasma and platelets.

The fines announced today were assessed under an amended 2003 consent decree that outlines requirements for the American Red Cross to ensure safety of the nation’s blood supply. The original 1993 decree was amended in 2003 to allow the FDA to impose significant fines for failure to comply with agency regulations and provisions designed to ensure the safety of the nation’s blood supply. Since 2003, the American Red Cross has made progress addressing some of its quality issues, including standardizing procedures, upgrading its National Testing Laboratories, and increasing oversight of the organization. However, to fully comply with federal regulations and consent decree provisions, the American Red Cross must make swift, additional progress on all of the issues the FDA has identified.

The agency has previously sent 12 similar letters to the American Red Cross and imposed a total of more than $21 million in fines under terms of the amended 2003 consent decree. The American Red Cross is one of several organizations that is responsible for the nation’s blood supply. For more information: http://www.fda.gov/AboutFDA/Centersoffices/ODA/ODAElectronicReadingRoom_UCM188299.htm

FDA Fines American Red Cross $16 Million For Prior Failures to Meet Blood Safety Laws

DON’T WORRY ABOUT FOLLOWING THE TIMING ON THE DIPSTICK CHART. JUST LOOK FOR A COLOR CHANGE.

“I didn’t know that I was supposed to run daily QC, but I was told it was okay because it’s only been a couple weeks since it was last run.”

“It’s never a good idea to break rules, take short-cuts, or ignore protocol. We’ve always done the test this way and it’s always worked.”

“Don’t worry about following the timing on the dipstick chart. Just look for a color change.”

“I didn’t know that I was supposed to run daily QC, but I was told it was okay because it’s only been a couple weeks since it was last run.”

Yes, it's that easy.
1: Open. 2: Dispense. 3: Run.

Calibration verification/linearity testing doesn't get much easier than VALIDATE®. Our liquid, ready-to-use testing kits minimize the need for manual dilutions, saving you time and making your job easier. Plus, you get our promise of 100% satisfaction, backed by experts who are ready to help you with any questions or concerns.

To learn more about VALIDATE®, call us at 1-800-377-0664 or visit www.mainestandards.com/POL.htm.

For more information: http://www.fda.gov/AboutFDA/CentersOffices/ODA/ODAElectronicReadingRoom_UCM188299.htm

TWO new clinical sessions presented by Toni Clinton (Vice-President, Sonic Healthcare)
• Vitamin D: Analyte of the Moment
• POCT: Issues and Answers

PLUS new sessions of particular interest to those in COLA labs
• COLA Top 10 Citations, Part 1 & Part 2
• COLAcentral Training

AND sessions focused on improving your work environment (so hot we had to bring them back!)
• Want Quality Outcomes? Empowered People are the Most Important Asset
• Improve Quality by Improving Communication (Even With Difficult People)
• Improve Quality by Improving Your Leadership Skills
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