TENNESSEE DEPARTMENT OF HEALTH
It's About Time!

Tennessee Department of Health Public Health Laboratories Newsletter

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Group A Streptococcus Testing Change

Effective, April 1, 2009, Laboratory Services discontinued routine throat culture testing for Group A Streptococcus. Required (TCA Rule 1200-6-3-.12*) referral testing of Streptococcus Group A cultures isolated from necrotizing fasciitis wound cultures or normally sterile sites will be continued. In the last few years, there have been several advances in Group A Streptococcus point of care (throat culture) latex agglutination tests. The current tests are highly sensitive and specific and provide rapid results for the attending physician. These tests are easy to perform by following the manufacturer's package insert. The positive results obtained from these tests are reliable and can be used for immediate treatment of the patient. Because these tests provide reliable results and immediate validation for patient treatment, the use of these tests is preferred over the traditional culture method that requires 24-48 hours to complete. The use of latex agglutination tests and rapid methods has dramatically reduced the number of tests performed by Laboratory Services.

Any health department that needs assistance in training staff to perform rapid strep testing, may contact Sean O'Connell, 615-262-6318 or sean.oconnell@tn.gov for assistance. If you have any other questions, you may contact:

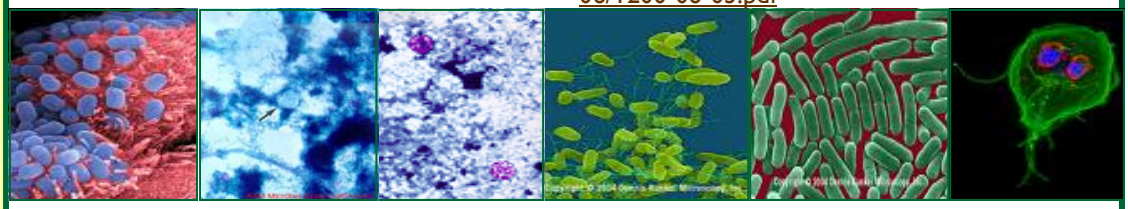
Middle Tennessee - Henrietta Hardin, 615-262-6362 or Henrietta.Hardin@ tn.gov

East Tennessee – Dr. Robyn Atkinson, 865-549-5201or Robyn.Atkinson@ tn.gov

West Tennessee – Dr. Oristyne Walker, 731-426-0686 or Oristyne.E.Walker@ tn.gov

Submitted by Henrietta Hardin, Manager, Bacteriology, Laboratory Services

*http://state.tn.us/sos/rules/1200/1200-06/1200-06-03.pdf



State Public Health Laboratory Workshops Concluded

The *2009 Foodborne Outbreaks and Enteric Illnesses in Tennessee* and the *2009 Packaging and Shipping Category A and Category B Substances* workshops were recently taken across the state to bring current topics and continuing education to laboratory professionals and other healthcare workers in Tennessee and neighboring states. Both workshops were very well received. The *Foodborne Outbreaks* sessions were presented in cooperation with the Communicable and Environmental Disease Services (CEDS) section of state public health. The course was open to hospital and private laboratory professionals, regional and state epidemiologists and hospital infection control personnel who were given an opportunity to network with each other to solve case studies using the principles of epidemiological investigation to respond to various scenarios. The *Packaging and Shipping* workshops provided important information from the primary regulators, including the International Air Transport Association, the Department of Transportation and the U.S. Postal Service. Look for this topic to be available online in the near future. Look for CE opportunities and future training programs at http://health.state.tn.us/Lab/index.htm

Clostridium botulinum Spores; Nature's Little Survival Packages

Botulism is a serious illness that causes paralysis or muscle weakness, including weakness in muscles needed for breathing. It is caused by a poisonous neurotoxin released by bacteria named *Clostridium botulinum*. Spores of *Clostridium* botulinum are metabolically dormant and extremely resistant to acute environmental stresses such as heat, desiccation, ultra violet light and radiation, mechanical disruption, enzymatic digestion and toxic chemicals. In addition to the spore's resistance to acute stress, spores can survive for years, even under harsh conditions. It is thought that spores can survive for thousands of years in some special niches. Botulism is not a common illness but it does occur naturally. Inactive botulism spores are found widely in soils, freshwater and marine sediments. A hard outer coating helps the spores survive. When botulism spores enter the human body, they germinate into actively growing bacteria and begin making deadly botulism neurotoxins.

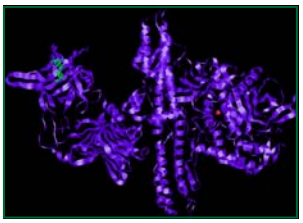
Infant botulism is caused by the ingestion of *C botulinum* spores that germinate, colonize and produce neurotoxin in the intestinal tract of infants under one year of age. Infant botulism was first recognized in 1976 and is now the most common form of botulism in the United States. Honey should never be used to quiet a fussy or colicky baby, or fed to infants under one year of age. The honey may become contaminated with spores of *C. botulinum* carried through the pollination process by honey bees to the honeycomb or directly into the beehive by spores carried on dust in the wind. Spores remain viable even in pasteurized honey. In healthy children and adults, these spores do not cause illness, but infants are particularly susceptible because they have not yet developed healthy immune systems. Ingested spores can germinate and produce neurotoxin because the infant digestive system is not yet able to digest the *C. botulinum* bacterium.

Food-borne botulism is caused by eating food contaminated with preformed botulinum neurotoxin. The causative organism is *Clostridium botulinum*, an anaerobic, rod-shaped bacterium that produces heat resistant spores. For an outbreak of food-borne botulism to occur, the spores must contaminate food, grow and produce neurotoxin. After the contaminated food is consumed, the neurotoxin is absorbed from the digestive system. The characteristic symptoms usually develop in 12 to 36 hours after consumption of the food. In extreme cases symptoms may occur as soon as 2 hours or as long as 14 days after consumption of the food. Symptoms include nausea, vomiting, diarrhea, weakness, dizziness and vertigo, ptosis (drooping of the eyelids), dysphagia (difficulty in swallowing), blurred vision, diplopia (double vision), constipation, dry mouth and others. The neurotoxin affects nerve terminals of the parasympathetic nervous system. Specifically, the neurotoxin inhibits release of the neurotransmitter acetylcholine at the neuromuscular junction. Death may result from asphyxiation caused by paralysis of the diaphragm. The fatality rate has declined from over 60% to less than 10% because antitoxin is administered promptly in suspected cases and because mechanical respirators can be used to manage patient breathing.

Control of food-borne botulism is based almost entirely on thermal destruction of the spores or inhibition of spore germination and bacterial cell growth in foods. Through the establishment and enforcement of strict, standardized time-temperature treatments of canned foods, the commercial food-canning industry has been successful in

preventing botulism. Home canning may lead to botulism because the time-temperature treatment of foods may be insufficient to kill spores, especially in "low-acid" foods (e.g., corn, peppers, green beans, asparagus, mushrooms, eggplant). Home canners should use approved pressure-cooker processes for such products and follow instructions carefully, including adding sufficient amounts of salt and/or vinegar. Foods other than canned foods have been implicated in botulism outbreaks. Foods with instructions for refrigeration must be kept refrigerated to reduce the risk of botulism poisoning.

Two forms of botulism could arise from deliberate release of botulinum toxin—foodborne and inhalation botulism. In contrast, gastrointestinal (infant) and wound botulism arise from infection with *C. botulinum*, rather than ingestion or inhalation of toxin, and are unlikely to occur in a biological attack. Botulism after inhalation of aerosolized toxin is an unnatural, man-made form of the disease and would be considered deliberate. Botulinum neurotoxin producing species of *Clostridium* is a select agent. Select agents are classified by the Centers for Disease Control and Prevention



Crystal structure of Clostridium botulinum Neurotoxin B

Continued on next page

Clostridium botulinum Spores; Nature's Little Survival Packages (Continued)

and the United States Department of Agriculture as organisms that could potentially be used in a bioterror attack. Possession and culture of *Clostridium botulinum* is strictly regulated.

Submitted by A. Sean O'Connell
State Training Coordinator, Laboratory Services

BabyBIG®— Botulinum Immune Globulin Made From Botulism Antitoxin Antibodies

BabyBIG® or Botulinum Immune Globulin Intravenous (Human) is an orphan drug that consists of human-derived botulism antitoxin antibodies, approved by the U.S. Food and Drug Administration for the treatment of infant botulism types A and B. BabyBIG is the only medication specifically indicated for treating infant botulism (infants 12 months of age or younger) and is considered the standard of care for such patients. Infant botulism is a very rare disease, but remains the most common form of human botulism in the United States and results from colonization of the infant's intestine by *Clostridium botulinum* and subsequent toxin production. The clinical spectrum of laboratory-confirmed cases ranges from mild, outpatient illness to sudden fatal respiratory arrest. Almost all of the 80 to 110 cases identified in the United States each year are recognized because their severity necessitates hospital admission. Botulinum toxin is one of the most poisonous substances known, and occurs in seven antigenically distinct types (A through G). More than 99% of infant botulism cases in the United States have resulted from toxin type A or B. Historically, untreated patients with infant botulism caused by toxin type A toxin had a mean length of hospital stay that was significantly longer than that of untreated patients with infant botulism caused by toxin type B toxin, and treatment was limited to supportive care.

When administered in the first 7 days of hospitalization, BabyBIG® has been shown to significantly reduce length of hospital stay and hospital cost. (N Engl J Med 2006; 354:462-71) For all suspect cases of infant botulism, clinicians may procure BabyBIG® by calling the Infant Botulism Treatment and Prevention Program at the California Department of Public Health, 510-231-7600 available 24/7/365. Clinical specialists are available to consult on the infant's clinical condition. Additional information about BabyBIG® may be found on their website at www.infantbotulism.org

The Tennessee Department of Health (TDH) Division of Laboratory Services confirmation of infant botulism is available by calling 615-262-6362 or 615-262-6363 during the day or 615-262-6300 for 24/7/365 calls. Symptoms such as poor feeding, droopy eyelids, constipation and general lethargy prompt physicians to seek a diagnosis and to rule-out botulinum toxin as the causative agent. It is necessary for prompt laboratory analysis to be performed to establish the diagnosis. Direct toxin analysis and culture of *Clostridium botulinum* is performed for the laboratory diagnosis of infant botulism. The specimen required for the definitive diagnosis of infant botulism is stool or enema (serum not needed from infant). Collect and submit the raw fecal specimen in a sterile container such as a urine collection cup with a tight, screw-capped lid. Botulism has been confirmed in infants with only "pea-sized" stools. However as much fecal sample as possible should be collected, preferably before antitoxin treatment. If an enema must be given because of constipation, a minimal amount of fluid (preferably non-bacteriostatic, sterile water) should be used to obtain the specimen so the toxin will not be unnecessarily diluted. All fecal specimens (stool or enema) collected for infant botulism testing require refrigeration only. **Do not freeze**. Transport the specimen to the laboratory on cold packs with same day or over-night delivery to:

Tennessee Department of Health
Division of Laboratory Services
General Bacteriology
630 Hart Lane
Nashville, TN 37216.

If the patient has been taking antibiotics or other medications that may interfere with toxin assays or culture, the laboratory should be notified. The specimen should be placed in a sterile, leak proof container, then in an insulated shipping container with cold packs. Follow all recommendations for proper shipment of specimens including IATA and DOT regulations. Complete Lab Request Form PH 1573 with patient information and include a phone number and contact information for notification of test results. Remember to notify the laboratory of this test request. In 2008 and 2009, one case per year of infant botulism was reported in Tennessee, both cases were positive for *Clostridium botulinum* type B.

Contact the TDH Epidemiologist for infant botulism, Dr. L. Rand Carpenter at 615-741-7247 during the day or 24/7/365 for on-call EPI assistance at the first sign of infant botulism.

Submitted by Henrietta Hardin, Manager, Bacteriology Section, Laboratory Services

Charge for Required Testing of Microbiological Parameters for Drinking Water Samples

Effective July 1, 2009, the Division of Laboratory Services is charging a fee for all microbiological compliance testing on drinking water samples received from both community and non-community water systems. The routine compliance test, Total Coliform, will cost $13.00 per sample.

Historically, the Tennessee Department of Health, Division of Laboratory Services has received water samples from both community and non-community water systems for microbiological compliance testing using the total coliform test. This compliance testing has been performed at no cost to the water system. While the Division of Laboratory Services has provided this testing service, it has not received additional State funding during any budget year to offset the increasing costs associated with testing. Given the costs associated with testing a large number of yearly samples, and continuing State budgetary constraints, the Division of Laboratory Services can no longer provide microbiological compliance testing at no charge.

Currently, there are no State regulations that require community and non-community water systems to send their microbiological compliance samples to the Division of Laboratory Services for testing. Water systems in Tennessee have three options for analysis of microbiological samples; (1) the water system may receive certification from the State Certification Office and perform their own compliance testing, (2) they may send microbiological compliance samples to the certified state laboratory (Nashville, Jackson, Knoxville, or Memphis); or (3) they may send microbiological compliance samples to a commercial laboratory approved for microbiological drinking water analyses. Section 1200-5-.14 of the Regulations states that for the purpose of determining compliance with the regulations regarding maximum contaminant levels, samples may be considered only if they have been analyzed by a laboratory certified by the Department. The following link is a current (12-2-2008) listing of commercial laboratories certified by Tennessee Department of Environment and Conservation (TDEC) for microbiological analysis:

http://www.state.tn.us/environment/dws/pdf/micro_labs.pdf

Please note that not all commercial laboratories are certified for the analysis of drinking water samples for levels of microbiological contamination.

Effective July 1, 2009, the Division of Laboratory Services will only provide water sample bottles to the water systems that continue to send their compliance samples to one of the four certified state public health laboratories (Nashville, Jackson, Knoxville, or Memphis). A fee of $13.00 will be charged by invoice for each routine compliance sample received.

Background Information

The Division of Water Supply Regulations, Rule 1200-5-1, provide the rules and regulations that agents, employees or representatives of public water systems must meet. The rules apply to all public water supply systems that provide water for human consumption through pipes or other constructed conveyances, if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year. A public water supply system is either a community water system or a non–community water system. A **community water system** is a public water supply system that serves at least 15 service connections used by year-round residents or regularly serves at least 25 year–round residents. A **non–community water system** is a public water supply system that is not a community water system and which generally serves a transient population such as hotels, motels, restaurants, camps, service stations, churches, industry, etc.

Municipal swimming pools, water fountains and residential water systems should be checked routinely for bacterial contamination.

Rule 1200-5-1-.06(4) (a-e) describes the maximum levels for microbiological contaminants that are applicable to both community and non-community water systems. The maximum contaminant level (MCL) is based on the presence or absence of total coliforms in a sample, rather than coliform density.

If you have any questions concerning this change in policy, please contact the following individuals:

Bob Read, PhD, Environmental Laboratory Director, (615)262-6300, bob.read@tn.gov

Jim Gibson, Director, Clinical Services, (615)262-6300, jim.gibson@tn.gov

Adjustment in Newborn Screening Fee Policy Began May 1, 2009

Historically, the Newborn Screening Program has charged only for the first specimen submitted for testing regardless of subsequent repeat samples submitted on the same patient for retesting. In addition, we test all specimens, including unsuitable/ unsatisfactory samples. Due to the high number of unsuitable/unsatisfactory samples, we have begun charging for repeat sample testing. As prescribed in the Department of Health rules Chapter 1200-15-1, the birth facility is responsible for submitting a satisfactory specimen on all babies born in their facility. Therefore, as of May 1, 2009, we have started charging the **birth facility** $75.00 for every newborn screening specimen submitted for testing including specimens submitted for retesting. This includes the following:

1. Specimens resubmitted for testing because the initial specimen or subsequent specimens are deemed unsatisfactory,
2. Specimens collected at a different site than the birth facility on an infant born at that birth facility because the first specimen as determined to be unsatisfactory,
3. Specimens resubmitted for testing due to the initial collection at <24 hours,
4. Specimens resubmitted for testing due to TPN/Lipid Therapy,
5. Specimens resubmitted for testing due to infant transfusion.

In addition, the **submitting facility** will be charged $75.00 for every specimen submitted for PKU monitoring or Galactose Challenge.

There will be no charge if any of the following applies:

1. Forms are submitted without blood to document refusal of the parent for testing based on religious beliefs or in the event of the death of a newborn prior to collection of the sample.
2. The Laboratory requests another specimen be resubmitted due to a prior abnormal result.
3. The Laboratory requests that another specimen be resubmitted due to a laboratory accident.

For proper sample collection information or to request a copy of the CD-ROM entitled "Let's Do It Right the First Time" go to our webpage, http://health.state.tn.us/lab/directory.htm or the Newborn Screening webpage, http://health.state.tn.us/NBS/index.htm or call 615-262-3604 to request a copy.

Submitted by Christine McKeever, Manager, Newborn Screening Tandem Mass Spec, Laboratory Services

Newborn Screening for CF Institutes New Floating Cut-Off and Timing Changes

Early detection is key in treating cystic fibrosis (SIS-tik fi-BRO-sis). After more than a year of screening for cystic fibrosis (CF) with the test measure Immunoreactive Trypsinogen (IRT), a few changes have been made in the screening protocol. The lab is changing from a set cut off to a floating cut off that will change daily. The new protocol will identify all infants less than 8 days of age that are in the upper 2% of that day's run. Those results will be sent to Newborn Screening Follow Up as presumed positives and a case will be opened for follow up. The timing of the repeat collection is also being changed. Now, instructions given for a presumed positive IRT for CF will be to repeat the screen prior to 14 days of age. Do not wait until the infant is 2 weeks old to collect a repeat sample.

How will the changes affect the follow up of testing for CF?

- The number of presumed positives on infants less than 8 days of age will increase.
- The repeat needs to be collected before the infant is 2 weeks old.

CF is an inherited disease of the secretory glands, including the glands that make mucus and sweat. "Inherited" means that the disease is passed through the genes from parents to children. People who have CF inherit two faulty CF genes—one from each parent.

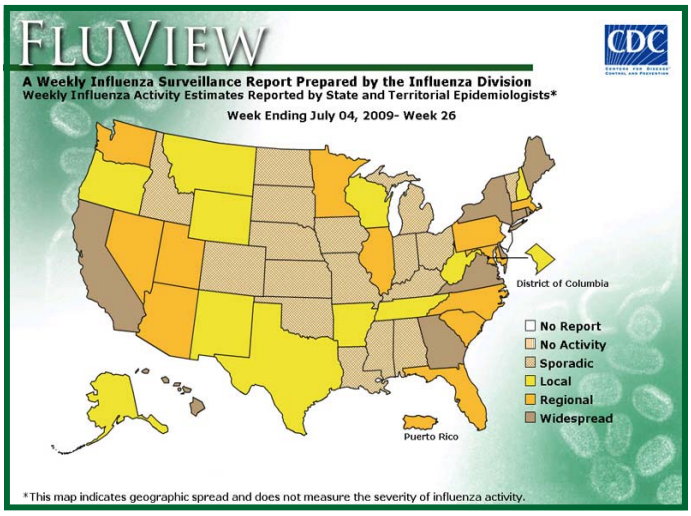
The parents of children with CF likely don't have the disease themselves. CF mostly affects the lungs, pancreas, liver, intestines, sinuses and sex organs. For example, mucus is a substance made by the lining of some body tissues. Normally, mucus is a slippery, watery substance. It keeps the linings of certain organs moist and prevents them from drying out or getting infected. However, if you have CF, your mucus becomes thick and sticky. The mucus builds up in the lungs and blocks the airways—the tubes that carry air in and out of the lungs. The buildup of mucus makes it easy for bacteria to grow, leading to repeated, serious lung infections.

Over time, these infections can severely damage your lungs. Early treatment for CF is vital and can improve both the quality of life and lifespan of an individual. Such early treatment includes nutritional and respiratory therapies, medicines, exercise, and other treatments.

For more information about Cystic Fibrosis go to http://www.nhlbi.nih.gov/health/dci/Diseases/cf/cf_what.html or for Tennessee specifics go to http://health.state.tn.us/NBS

Submitted by Christine McKeever, Manager, Newborn Screening Tandem Mass Spec, Laboratory Services

A Global Pandemic of Novel Influenza A (H1N1) Is Declared



On June 11, 2009, the World Health Organization (WHO) signaled that a global pandemic of novel influenza A (H1N1) was underway by raising the worldwide pandemic alert level to Phase 6*. This action was a reflection of the spread of the new H1N1 virus, not the severity of illness caused by the virus. At the time, more than 70 countries had reported cases of novel influenza A (H1N1) infection and there were ongoing community level outbreaks of novel H1N1 in multiple parts of the world.

Since the WHO declaration of a pandemic, the new H1N1 virus has continued to spread, with the number of countries reporting cases of novel H1N1 nearly doubling. The Southern Hemisphere's regular influenza season has begun and countries there are reporting that the new H1N1 virus is spreading and causing illness along with regular seasonal influenza viruses. The Southern Hemisphere includes South American, Africa and Australia. In the United States, significant novel H1N1 illness has continued into the summer, with localized and in some cases intense outbreaks occurring. The United States continues to report the largest number of novel H1N1 cases of any country worldwide, however, most people who have become ill have recovered without requiring medical treatment.

Given ongoing novel H1N1 activity to date, CDC anticipates that there will be more cases, more hospitalizations and more deaths associated with this pandemic in the United States over the summer and into the fall and winter. The novel H1N1 virus, in conjunction with regular seasonal influenza viruses, poses the potential to cause significant illness with associated hospitalizations and deaths during the U.S. influenza season.

By June 19, 2009, all 50 states in the United States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands have reported novel H1N1 infection. While nationwide U.S. influenza surveillance systems indicate that overall influenza activity is decreasing in the country at this time, novel H1N1 outbreaks are ongoing in parts of the U.S., in some cases with intense activity.

CDC is continuing to watch the situation carefully, to support the public health response and to gather information about this virus and its characteristics. The Southern Hemisphere is just beginning its influenza season and the experience there may provide valuable clues about what may occur in the Northern Hemisphere this fall and winter.

Vaccines are a very important part of a response to novel H1N1 influenza and the U.S. Government is aggressively taking early steps in the process to manufacture a novel H1N1 vaccine, working closely with manufacturers. CDC isolated the new H1N1 virus, made a candidate vaccine virus strain that can be used to create vaccine, and is working with other agencies and industry to begin scaling up for testing and production of a vaccine. Making vaccine is a long multi-step process requiring several months to complete. CDC has developed guidance** state and local public health departments to assist them in planning for a novel H1N1 influenza vaccination campaign. Additional guidance is forthcoming.

The Department of Health continues to work with federal and local officials to respond to the outbreak in Tennessee and inform residents of ways to prevent the flu. The raising of the influenza pandemic alert level reflects the spread of the illness, not its severity. As new information develops, it is important that we all remain aware and be informed of updates for the health of ourselves and our loved ones. For up-to-date information on novel influenza A H1N1 in Tennessee go to http://health.state.tn.us/H1N1.htm

Reprinted information from the Department of Health and Human Services, Center for Disease Control and Prevention, July 2009

*Phase 6 description available at:
http://www.cdc.gov/ncidod/ EID/vol12no01/05-1371_app1.htm

Labeling Reminder for Clinical Laboratories and County Health Departments

The State Laboratory system is making every effort to ensure that all patient test requests and specimens are processed in an accurate and timely manner for the ultimate benefit of the patients seeking care at your facility. In order for us to do this, the test request form and the specimens must be labeled accurately. Please remember the following:

- Sample Labeling

Samples should be labeled with the patient's name or chart number in addition to the test request form number (i.e. "tear strip number"). The sticker with the test request form number may be displaced during shipping and receiving. The addition of specific patient identifiers to the sample allows the laboratory to process the specimen without delay. Specimens received without patient identifiers and/or the test request number will be reported as "unsatisfactory" and will not be tested.

- Test Request Form Must Be Complete

The "Send Report To" section of the test request form must be completed for each sample submitted. Please ensure that all copies of the request form are completed. Test requests received without the "Send Report To" section completed will be processed but the reports will be held until the State Laboratory receives written documentation that the patient's specimen in question belongs to your facility.

Submitted by Robyn Atkinson, PhD, Director, Knoxville Regional Laboratory