Beyond the SCOPE

A publication of the Missouri State Public Health Laboratory

VOLUME 1, ISSUE 2

INSIDE THIS ISSUE:

MSPHL Embraces Self-Assessment Programs

By: Bill Whitmar, Laboratory Director

Self-Assessment is the practice of examining your processes and operations with the intent of taking stock of what you possess, critically analyzing its worth and determining whether it can be kept, improved or replaced with a superior version. The MSPHL has embarked on this process over the past many months.

We began performing efficiency audits of all the Laboratory units in the MSPHL utilizing internal staff along with our consultant Dr. Ella Swierkosz from St. Louis Cardinal Glennon Hospital. This method uses a cross discipline audit team to document the units' processes from specimen accessioning to final result generation. Along the way, the audit team ensures that laboratorians are following unit-specific procedures and safety protocols, checks for expired reagents and offers suggestions for improved efficiency. The results of these audits show the strengths of each unit and efficiencies that can be achieved in areas of protocol standardization and time and consumables management. A second round of audits will be performed to see how the units have incorporated these efficiencies and get feedback on how units' performances have fared because of them.

Secondly, the MSPHL has embarked on a more ambitious project called the Show-Me Challenge. The Show-Me Challenge is an Excellence in Missouri Program that was established to generate performance excellence among Missouri organizations. Its mission is to drive higher levels of quality in Missouri-produced goods and services.

The Show Me Challenge is an entry-level, organizational, self-assessment tool. An assessment, unlike an audit, is a comprehensive and integrated tool that recognizes the strengths as well as opportunities for improvement within our organization. This allows us to identify existing effective processes to continue building upon, and to identify the appropriate next steps our organization should take in order to improve performance. Thus, this assessment tool seeks to build a comprehensive understanding of our organization's performance and develop actionable steps to improve.

Bill Whitmar, Laboratory Director

The criteria we chose to assess include major categories that address all key systems making up any organization. Those categories were: Leadership; Strategic Planning; Customer Focus; Measurement, Analysis, and Knowledge Management; Workforce Focus; and Operations Focus. The internal self-assessment team interviewed an incredible 90% of the MSPHL employees for the Show Me Challenge. We enthusiastically await the results and recommendations from the Show Me Challenge staff, and will integrate them to enhance our leadership, workforce, customer relations and overall laboratory operations.

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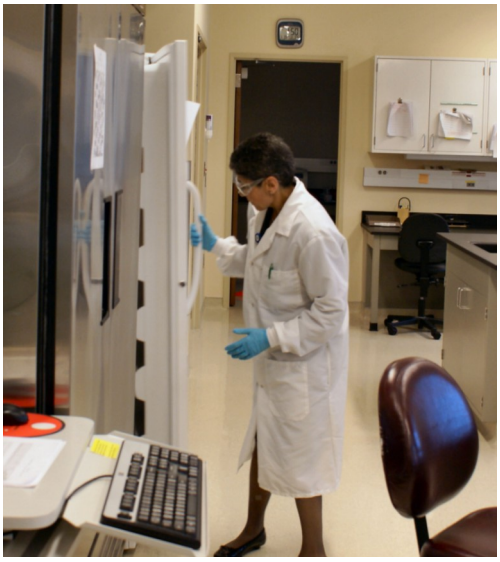
Now, stepping back for a moment and from my standpoint as the director, these self-assessment activities are:

- Time intensive
- Timely
- Absolutely essential

It is **time intensive** from the standpoint that it takes time for the audit team to develop assessment forms, observe processes, question staff, analyze data, formulate a report, and deliver that report back to the staff.

I cite **timely** due the funding situation that looms over us. By means of performing audits and self-assessments we constantly look for ways to work more efficiently and creatively in order to reduce costs and achieve a cost per test that demonstrates our good stewardship of public funds. What's more, by being a service organization, we continuously strive to be more customer-focused and provide superior services. Through performing audits and assessments, we can discover and apply best practices across the Laboratory, sharing knowledge that would otherwise not be known.



Dr. Ella Swierkosz, MSPHL CLIA Director, inspecting a refrigerator during an efficiency audit

The process of self-assessment, a look within one's self, can be enlightening or a bit painful. In the end, however, it is **absolutely essential** so that operations as a whole can be improved. This has absolutely been our experience. Our financial situation has benefitted. The staff feels better connected to the operations overall. The leadership know what challenges lie before them. Now improvements lie just ahead.

Bill Whitmar

LIMS Update

By: Shondra Johnson, LIMS Administrator

The MSPHL is in the process of building a component to the clinical LIMS that will allow the Laboratory to receive electronic test orders from submitting facilities that have EHR systems with HL7 messaging capabilities. The MSPHL will receive the patient and sample data along with the test ordered electronically and load that information into the clinical LIMS for review. Once the sample is received accessioning will occur through the clinical LIMS by the scientist using a work queue screen. The required patient and sample data will already be available in the system for the scientist's review. After testing is complete with the results entered and verified the system will generate an electronic HL7 message that will be sent to the submitting facility. This will decrease the MSPHL reporting turnaround time. The message will also be sent to the DHSS programs so that the information can be loaded into their surveillance system instead of having to enter the information manually.

The MSPHL is also in the process of building an environmental component into the LIMS that will allow for tracking and results reporting of Bioterrorism samples. The information will then be transmitted electronically to the CDC using an HL7 message.

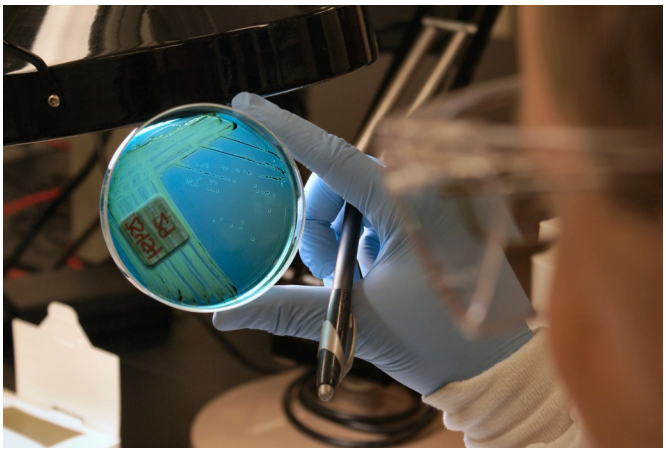
Both of these initiatives support ongoing efforts within the MSPHL to optimize information flow and system interoperability with our internal and external partners.

MSPHL Aids in Investigation of Food-Borne Outbreak in Clay County

By: Steve Gladbach, Microbiology Unit Chief and Pat Shannon, Environmental Bacteriology Unit Chief

On the TV show **CSI: Crime Scene Investigation**, police and laboratory technicians use a combination of in-the-field investigative work and forensic laboratory testing to solve mysterious crimes. Although the MSPHL does not perform forensic testing (that is left to the Missouri Highway Patrol Crime Laboratory), It does have a vital role in investigating the causes of disease outbreaks in our state.

It takes the coordinated efforts of many Missouri Department of Health and Senior Services (DHSS) program staff to perform a successful disease outbreak investigation. These programs include the Bureau of Communicable Disease Control and Prevention, the Bureau of Environmental Health Services, the Bureau of Environmental Epidemiology and the Office of Epidemiology, as well as several testing units in the MSPHL. In addition, the efforts of the staff from local public health agencies including epidemiologists, environmental health specialists and public health nurses are vital to the success of the investigation.

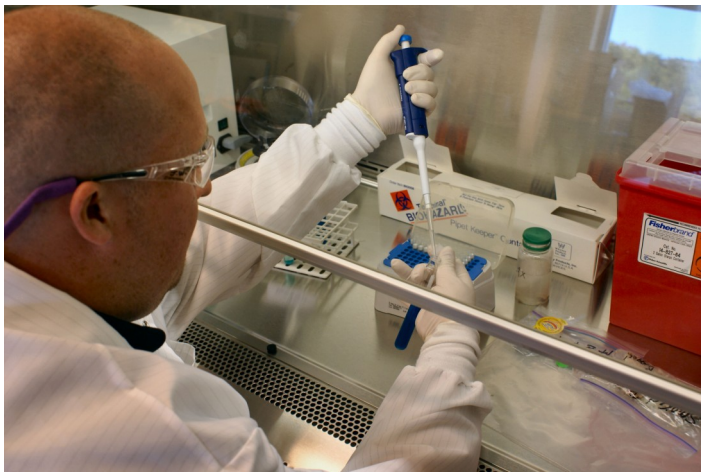


Russ Drury, Microbiology, is reading a HE plate that has been inoculated with Salmonella.

The following case study describes the MSPHL's role in solving the mystery of a food-borne disease outbreak at a recent wedding reception.

On June 9, 2011, the Clay County Health Department notified the MSPHL of a possible food-borne outbreak involving a catered wedding reception in Independence. State and local health agency staff performed the initial epidemiological investigation, including interviewing ill cases and collecting food histories. The family reported that there were 115 guests at the wedding/reception. Eighty-nine interviews were conducted. Twenty of those 89 reported being ill. Of those 20, 13 were male and 7 were female. Their ages ranged from two to 90 with a median age of 44 and a mean age of 40. Stool specimens and food samples were collected and shipped to the MSPHL via overnight courier. Clinical specimens were tested for both enteric bacteria and Norovirus.

On June 14, the MSPHL Microbiology Unit identified *Salmonella* Agona from the stool specimens. The MSPHL Environmental Bacteriology Unit initiated testing for *Salmonella* on seven food samples that same day. Samples of smoked pork and lettuce tested positive for *Salmonella* by PCR the next day. *Salmonella* was isolated by culture from both food samples on June 17. The isolates were referred to the Microbiology Unit for biochemical and serological typing. The food isolates also proved to be serotype Agona.



Jeremy Wilson, Environmental Bacteriology, is preparing food samples for Salmonella testing.

The Microbiology Unit then performed Pulse Field Gel Electrophoresis (PFGE) on the stool and food isolates. PFGE is a process by which isolates can be genotyped and given a DNA "fingerprint" to further characterize them and show relatedness. Those PFGE results indicated that all the *Salmonella* Agona isolates were the same strain. Two more *Salmonella* isolates were received from separate hospitals the following week. Those isolates also serotyped to *Salmonella* Agona and had a very similar PFGE subtype. Upon epidemiological investigation those isolates also appeared to be part of this outbreak.

With the help of all of the key partners the investigation was a success. The Clay County Health Department received the initial inquiry and quickly began investigating and collecting stool and food samples. The Bureaus of Communicable Disease, Environmental Health Services, Environmental Epidemiology and the Office of Epidemiology assisted in the investigation and inspection of the food handlers and participants at the reception. The MSPHL tested the samples in a timely manner and assisted in interpreting laboratory results. It is important to stress that without everyone playing their role effectively this investigation would not have been successful.

Acronyms used in Newsletter

AFB – Acid-fast Bacilli
AIDS – Acquired Immune Deficiency Syndrome
APHL – Association of Public Health Laboratories
ASTPHLD– Assoc. of State and Territorial Public Health Laboratory Directors
CCHD – Clay County Health Department
CDC – Center for Disease Control and Prevention
CERT – Center for Emergency Response and Terrorism
CLIA – Clinical Laboratory Improvement Amendments
CLSI – Clinical and Laboratory Standards Institute
COOP – Continuity of Operations
CST – Civil Support Team
DHSS – Department of Health and Senior Services
DIS – Disease Investigation Specialists
DNA – Deoxyribonucleic Acid
DSR – Department Situation Room
EHR-Electronic Health Record
EIA – Enzyme Immunoassay
EPA – Environmental Protection Agency
EROT – Emergency Response, Outreach and Training
FA – Fluorescent Antibody
FERN– Food Emergency Response Network
FBI – Federal Bureau of Investigation
FDA – Food and Drug Administration
GC-MS– Gas chromatography mass spectrometry
GSP – Genetic Screening Processor
HIV – Human Immunodeficiency Virus
HL-Health Level
IgG – Immunoglobulin G
IgM – Immunoglobulin M
IRB – Institutional Review Board
LED – Light Emitting Diode
LIMS-Laboratory Information Management System
LPHA – Local Public Health Agency
LRN – Laboratory Response Network
LSD – Lysosomal Storage Disorders
MATEC– Midwest AIDS Training + Education Center
MMWR – Morbidity and Mortality Weekly Report
MOLRN – Missouri Laboratory Response Network
MSPHL – Missouri State Public Health Laboratory
MTD – Mycobacterium Tuberculosis Direct
NAA – Nucleic Acid Amplification
NBS – Newborn Screening
OB - Obstetric
PCR – Polymerase Chain Reaction
PFGE – Pulsed Field Gel Electrophoresis
PHEP – Public Health Emergency Preparedness
RNA – Ribonucleic Acid
SCID – Severe Combined Immunodeficiency
SEMA – State Emergency Management Agency
SIDS – Sudden Infant Death Syndrome
TB – Tuberculosis
UV – Ultraviolet

Did You Know?

On the roof of the MSPHL, the Chemistry Unit operates a RadNet air monitoring station for the United States Environmental Protection Agency.

The mission of RadNet is to monitor environmental radioactivity in the United States. The intent is to provide high quality data for assessing public exposure and environmental impacts resulting from nuclear emergencies and to provide baseline data during routine conditions.

Data generated from RadNet provides the information base for making decisions necessary to ensure the protection of public health. The system helps EPA determine whether additional sampling or other actions are needed in response to particular releases of radioactivity to the environment. RadNet can also provide supplementary information on population exposure, radiation trends and other aspects of releases.

The RadNet air monitoring station utilizes two ways to monitor radiation. One way is the use of near-real-time air monitors. These monitors continuously transmit data to the EPA National Air and Radiation Laboratory in Montgomery, Alabama. The second way is air filter sampling. RadNet monitors pass air through a filter which traps particulates. The filter is sent to an EPA laboratory for a sensitive laboratory analysis which can detect radionuclides present. The detailed filter analysis allows the detection of trace amounts of radioactive material that the sensitive near-real-time air monitors don't pick up. The filter analysis identifies the specific radioactive material and its amount. Twice a week, Chemistry Unit personnel collect and change the filter, do a preliminary screening of the filter and then send it to the EPA National Air and Radiation Laboratory in Montgomery, Alabama.

RadNet monitoring device on roof of the MSPHL.

The Emergency Response Outreach and Training Unit (EROT)

By: Steve Hynes, EROT Director

The EROT Unit of the MSPHL was formed shortly after the terrorist attacks on September 11, 2001 and the subsequent anthrax attacks in October of 2001. Laboratory administration had already laid the groundwork for a new unit that would manage a recently funded CDC Bioterrorism Grant prior to the attacks, but these events helped contribute to the establishment of the unit and continue to shape the roles and responsibilities today. EROT's initial mission was to integrate the unit into existing laboratory operations by assembling a cadre of staff members who were able to establish and manage emergency preparedness and response activities as they relate to laboratory functions.

In 2002 EROT established the Missouri Laboratory Response Network (MOLRN). Based on CDC's national Laboratory Response Network (LRN), the MOLRN organizes sentinel hospital and other clinical laboratories across the state into a coordinated network of response laboratories. EROT conducts an annual survey to register contact, capability and capacity information of member laboratories; and routinely provides training and exercise programs to ensure readiness. Today, the MOLRN consists of 136 governmental and private laboratories that work together to improve laboratory support for both routine and emergency situations. The EROT Unit ensures that MOLRN members are provided with up-to-date information regarding testing procedures from CDC and Health Alerts/Advisories from the Missouri Department of Health and Senior Services. The MOLRN is a vital tool in maintaining an integrated state network of laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies.

The EROT Unit provides excellent service to laboratory stakeholders within the preparedness and response community. Through the years, EROT has worked on many diverse projects ranging from establishing laboratory courier services to initiating the development of the MSPHL LIMS, but the overall mission has always been to continue to develop and improve upon effective laboratory response throughout the state to better protect the health of the citizens of Missouri.

The EROT unit, From L to R: Steve Hynes EROT Director, Amy Pierce State Laboratory Training Coordinator and Sandy Jones MOLRN Coordinator

The EROT Unit currently consists of Steve Hynes, Emergency Preparedness and Response Director, Amy Pierce, State Laboratory Training Coordinator, and Sandy Jones, MOLRN Coordinator.

The EROT team can be reached at 573-522-1444, or via e-mail using our new EROT Mailbox at: SPHLEROTUnit@health.mo.gov

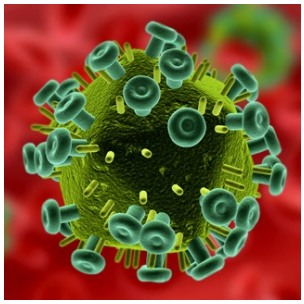
Other Core Responsibilities of the EROT Unit Include:

- Developing and maintaining emergency and safety plans for MSPHL staff and visitors.
- Planning and conducting hazmat and safety drills and exercises.
- Developing and maintaining the Continuity of Operations Plan (COOP) for the MSPHL.
- Managing the Select Agent Program within the MSPHL.
- Providing training and education to laboratory and medical personnel, local health agencies, first responders, HazMat, law enforcement personnel and MSPHL staff.
- Serving as a laboratory liaison to other departmental, state, and federal emergency response and preparedness entities. This list includes the Center for Emergency Response and Terrorism (CERT), various departmental programs, Missouri State Emergency Management Agency (SEMA), First Responders, FBI, CDC, EPA, FDA, Missouri's 7th Civil Support Team (CST), and other state laboratories and agencies.
- Coordinating all MSPHL aspects of the CDC Public Health Emergency Preparedness (PHEP) Grant. This grant has provided the opportunity for the Laboratory to build all current LRN capabilities and is a funding source for Microbiology, Chemistry, Virology, Environmental Bacteriology, EROT, as well as various areas of administration.
- Providing outreach activities and written materials for promotion and education about the MSPHL and its role in serving public health.
- Providing consultation on proper packaging and shipping of specimens, biosafety and biosecurity, reportable diseases and other subjects of interest for sentinel laboratories around the state.

MSPHL Looks Back on 30 years of HIV Testing

By: Dana Strope, Immunology Unit Chief

Thirty years after CDC's first report on the condition that would become known as AIDS, 30 million people around the world have died from this disease, and 33.3 million more are living with HIV.



A depiction f a Human Immuno-deficiency Virus that causes AIDS www.scientificamerica.com

According to the CDC, there are currently more than 1.1 million Americans living with HIV while nearly half of the population knows someone living with the disease. Due to testing availability, 80% of persons living with HIV have been tested and are aware of their infection. This is a sign of progress for HIV prevention because research shows that most individuals reduce behaviors that could transmit HIV when they know they are infected.

Since 2006, CDC recommends "opt-out routine HIV screening in health-care settings for all adults aged 13-64 and repeat screening at least annually for those at high risk." These new recommendations have been developed to decrease the number of new cases.

Rapid HIV tests are available that allow individuals to get results in 10-20 minutes. These tests are performed in clinical laboratories, doctor's offices, HIV counseling centers and at outreach activities. A positive rapid test result must be confirmed with a supplemental assay such as a Western blot.

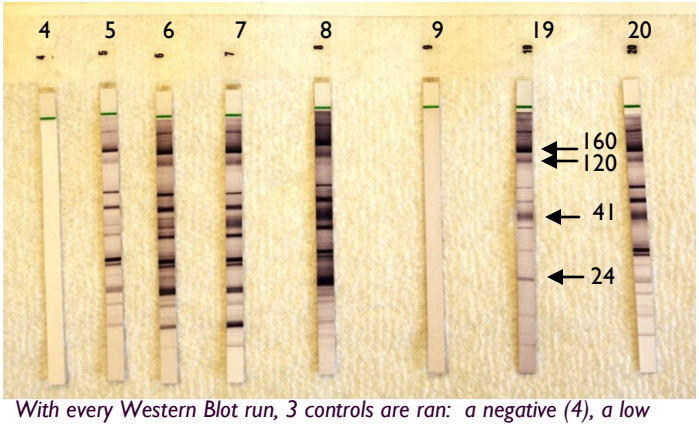
Conventional testing technologies have changed over the 30 year span. The first test available for detecting HIV used beads coated with HIV antigen. Past MSPHL workers talked about chasing the 'runaway' beads around the room if one was dropped. As technology progressed, beads were replaced with microtiter plates or microparticles. The EIA (enzyme immunoassay) test has advanced from a 1st generation test which used HIV-1 viral lysate antigen to a new 4th generation test that can detect HIV-1/HIV-2 IgM and IgG antibodies along with the p24 antigen. Using a 4th generation test, HIV can be detected within 14-16 days post-infection. The EIA test uses an enzyme to produce a signal for detection. Other assays use light emission or fluorescence to generate a signal. Another test available uses RNA to detect acute HIV-1 infection in antibody negative persons as early as 9 days after infection.

Currently at the MSPHL, a 3rd generation test is being used that detects HIV-1 and HIV-2 antibodies. This test detects HIV within 21 days after infection. It is an EIA that uses synthetic and recombinant HIV antigens that are coated on the bottom of a microtiter plate. The patient's plasma or serum is added to the microtiter plate and if it is positive for HIV, the antibody will bind to the antigen in the plate. After the enzyme is added, a color change is detected for reactive samples. Individuals that have a repeatable reactive result will be confirmed using the Western blot. A Western blot strip has HIV-1 proteins electrophoresed according to molecular weight. The patient's sample is added and, if present, the HIV antibodies will bind to the proteins. Oral fluid, called oral mucosal transduate, is also tested at the MSPHL. This sample type is collected using an approved collection device. These collection devices are used by Counseling and Testing sites, Disease Intervention Specialists (DIS), and for outreach activities.

HIV serum/blood testing is performed Monday through Friday excluding state and federal holidays, while the oral fluid specimens are batched and tested once a week. Western Blot testing is usually performed daily.

Missouri Stats

- The first AIDS case was reported in Missouri in June **1982**.
- AIDS was made reportable by Missouri state statute in **1983**.
- The MSPHL began testing serum/plasma for HIV-1 in **1985**. That year it received 1,489 specimens compared to **57,537** specimens received in 2010.
- HIV was made reportable by Missouri state statute in **1988**.
- The MSPHL started testing oral fluids in **1996**.
- Missouri Counseling and Testing sites started rapid HIV testing in **2004**.
- From 1982 to 2010, there have been a total of **17,912** HIV disease cases diagnosed in Missouri and reported to the Missouri Department of Health and Senior Services.
- At the end of **2010** there were **10,862** persons living with HIV disease whose most recent diagnosis occurred in Missouri
- There were **585** persons newly diagnosed with HIV disease in Missouri in **2010.**



With every Western Blot run, 3 controls are ran: a negative (4), a low positive (5) and a high positive (6). Reactive specimens (7, 8, 19, 20). Negative specimen (9). To be considered positive, 2 out of 3 bands are required (p24, gp41, or gp120 and/or gp160). CDC/ASTPHLD criteria are used for result interpretation.

New Sample Storage Process for the Newborn Screening Unit

By: Patrick Hopkins, Newborn Screening Unit Chief

This year will be remembered as a year of change for the NBS Unit, much like in 2005 when 42 disorders were added to the screening panel using tandem mass spectrometry. All of the changes are positive and will greatly benefit Missouri's babies and their families. They will also enhance quality assurance and performance for the NBS laboratory.

Newborn Screening Unit Staff Front Row: Darla Eiken, Miranda Carter, Lacy Vermette, Joel Williams; Second Row: Carlene Campbell, Libby Hicks, Amy Hagenhoff, Keith Bock; Third Row: Debbie Martin, Tracy Klug, Dennis Schmitz; Back Row: Bonnie Ricks, Amy Verslues, Rachel Hardy, Patrick Hopkins.

One of the biggest changes has been the implementation of the NBS Sample Storage Process, which commenced on July 1st, 2011. This process was mandated by a law passed in 2007. However, it has taken over three years to carefully prepare for the proper implementation of the entire process. For the past 10 years leftover samples have been destroyed one month after the NBS has been reported out. Before that time samples were stored for six months to a year, as freezer space would allow. The new statute (Section 191:317) requires the MSPHL to retain the NBS samples for five years after the testing has been completed and then to destroy them. The law allows the DHSS to release the samples for the purpose of anonymous scientific study. It also allows the Department to charge a reasonable fee for the use of such samples for public health research and for preparing and supplying samples for research proposals approved by the Department.

This same law provides three opt-out/dissent options for the parent or legal guardian if they do NOT wish the Department to release their child's leftover NBS sample for anonymous scientific study. These options must be made aware to them at the time of sample collection. The options made available to the parent when their child's NBS testing is completed are:

1). Return the leftover sample to the parents

2). Destroy the leftover sample in a scientifically acceptable manner

3). Store the leftover sample, but do not release it for scientific study

To opt-out of the sample storage, the parent must contact the MSPHL and request the opt-out choice in writing. They may do so at any time during the five year storage process. If the parent does not choose one of these options the specimen will, by default, be stored and can be released for anonymous scientific studies. Leftover samples will be stored in the NBS Unit in freezers at -20 to -30 degrees Celsius.

Other States' experiences have shown that the sample storage process must not begin until parents know that their child's sample is being stored, why they are stored and what their options are. This type of informed dissent required the NBS Unit to add a sheet to the sample collection form that provides this information in easy to understand language for the parents (also provided in three additional languages). The OB nurses are simply required to detach the information sheet and hand it to the mother of the baby when the newborn screen is collected.

Continued on page 8...

The main benefits to NBS sample storage

- Research for new technologies and for detecting new disorders.
- Research for new treatments and cures for major childhood diseases.
- Population incidence studies on disorders and environmental contaminant exposures.
- Parents can recall the specimens to help determine the cause of their child's unexplained death (SIDS).
- Parents can recall the specimens to aid law enforcement in the DNA matching of their missing child.
- Proof the NBS was performed accurately (ability to re-test if questioned).
- Quality control and improvement for the NBS laboratory.
- Ability to save rare case specimens, even those diagnosed clinically months later such as with LSD or SCID.
- Calibration of instruments using real specimens of known values, both borderline and high risk levels.
- New testing method development and instrument validation in the NBS laboratory.

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This opportunity is also used to educate parents about NBS in general as currently many parents do not know their child was screened at all.

The benefits to public health in retaining residual NBS samples are undisputable. Residual NBS samples are the only available opportunity for a complete population study to be conducted as there is a sample on virtually every baby born. In addition to this, the NBS sample is sometimes the only DNA from the child available to the family if their child goes missing.

By providing education, communication and transparency the MSPHL has devised NBS sample storage and release policies and protocols that will maintain the trust of parents and preserve the utmost protection of their privacy. With the aid of the Newborn Screening and Genetics Advisory Committee, strict research request processes and approval protocols have been formulated that can weed out and prioritize research requests before they are sent to the Department's IRB. Not only is sample retention supported by the law, but recommendations from many national organizations, including APHL, state that residual NBS samples are a valuable national resource that can contribute significantly to the health of our children.

MSPHL Employee Spotlight — A Joplin Response

By: Steve Hynes, EROT Director and Mike Massman, Deputy Director

Staff at the MSPHL are accustomed to responding to public health emergencies that occur across the state of Missouri. Usually, they have to do with rapid identification of bacterial or viral infectious disease outbreaks or public and private drinking water testing during floods or other natural disasters. Shortly following the May 22, 2011, Joplin, Missouri tornado disaster, MSPHL staff members responded in varying degrees; either by providing laboratory related support or by volunteering their personal time to assist those affected by this event.

Various MSPHL Central Service staff worked to coordinate and arrange the use of the MSPHL courier system for the timely transport of death certificates from Joplin to the MSPHL for the DHSS Bureau of Vital Records. This statewide laboratory courier system proved to be an additional asset for DHSS and the citizens of Joplin during this tragedy. It expedited the transport of these documents so that they could be processed more efficiently.

During the initial DHSS response to this disaster, rapid and effective communication was necessary to facilitate an appropriate public health response. Elizabeth Weyrauch of the MSPHL Fiscal Unit provided support to this important endeavor by volunteering to operate a work station within the DHSS DSR as a part of the Community Agency Management Team. Elizabeth ensured that appropriate community outreach was available.

In the weeks following the Joplin disaster, the MSPHL provided a more traditional role by facilitating the testing of samples submitted as a part of an investigation into a potential fungal infection outbreak. The Microbiology Unit provided laboratory support by serving as a liaison between Joplin hospital laboratories, DHSS epidemiologists, and the CDC. Samples were routed through the MSPHL to the CDC for testing. This response helped ensure that important laboratory information was available for key public health decision-makers.

Destruction from the Joplin tornado.

Employee Service Spotlight continued on page 13…

Molecular Unit Begin Operations

By: Stephanie Schildknecht, Molecular Unit Chief

This is an exciting time for the MSPHL. Molecular testing is the wave of the future and the MSPHL is following suit with the formation of the Molecular Unit.

The next year will be a transition period for everyone involved. With a lot of hard work and dedication the Molecular Unit will move in the right direction. As the transition is made into the Molecular Unit testing from the Microbiology and the Virology Units will be moved. Some of the proposed testing to be moved as soon as possible are bioterrorism testing, influenza testing, and *Bordetella pertussis* PCR just to name a few.

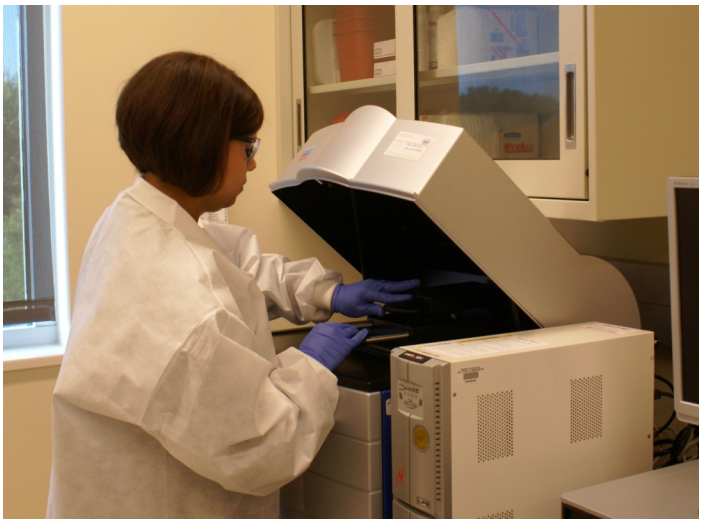
Having a knowledgeable hardworking staff is vital to the Molecular Unit's success. Initially, MSPHL scientists that possess competencies and authorizations in transferable molecular testing procedures will be reorganized into the Molecular Unit to eliminate any disruption of services.

Recently the MSPHL purchased a Capillary Gene

QST 3130XL Capillary Gene Analyzer

Sequencer as well as a Pyrosequencer. These purchases will allow the MSPHL to keep up with new and developing technologies. Initially, the Pyrosequencer will be used to test for markers associated with resistance to antiviral drugs in Influenza A viruses. The procedure detects a specific mutation in a specific subtype (e.g. H275Y mutation in 2009 H1N1 viruses). Pyrosequencing can be performed directly on original clinical specimens and will be able to provide results within days. Pyrosequencing is not limited to just influenza testing. There are other tests that can be performed and hopefully one day the Molecular Unit will be able to explore those options.

Gene Sequencing procedures are available for 16s



Stephanie Schildnecht using the PryoMark Q96 ID for performing a pyrosequencing reaction.

bacterial identification as well as norovirus. The16s rRNA gene sequence is the basis for bacterial identification because it is present in most bacteria. Initially the gene sequencer will be used for sequencing norovirus. Sequencing of norovirus strains is very helpful in conducting epidemiologic investigations. Cases can be linked to each other and to a common source. Outbreaks that may have been mistakenly connected can be distinguished. Sequences can be entered into CaliciNet, a national network of public health laboratories that tracks the different sequences of noroviruses. This system allows public health officials to detect and investigate norovirus outbreaks quickly and identify new strains as they emerge.

Currently the microbiology laboratory sends all of the isolates that cannot be identified to the CDC for identification. The CDC performs 16s bacterial identification on these isolates. The goal one day is to be able to run all of the 16s bacterial identifications with the gene sequencer in the Molecular Unit and eliminate the need to send the unidentified isolates to the CDC for testing.

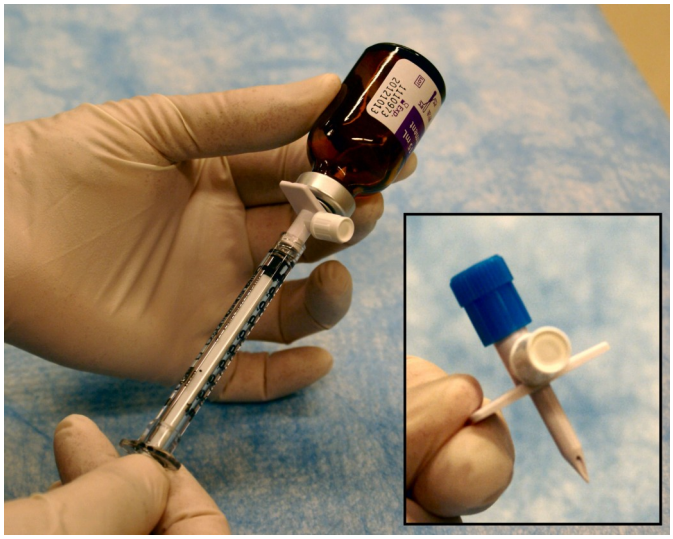
Enhancement of TB Laboratory Procedures

By: Tuberculosis Unit

In 2009 the MSPHL moved the State TB Laboratory from Mount Vernon to the main State Laboratory located in Jefferson City. This event provided a unique opportunity to review and update all TB laboratory procedures in light of current *state of the art* laboratory procedures. The goal was to change laboratory procedures that were not clinically relevant or needed improvement based on current standards. The following four examples represent enhancements to laboratory procedures.

Decontamination and Digestion Procedure

The appropriate decontamination and digestion of clinical respiratory specimens are critical to the detection and culture of *Mycobacterium tuberculosis* complex. The N-Acetyl-L-Cysteine-Sodium Hydroxide method has been and is the standard for processing clinical specimens for TB. As practiced, this method can present cross- contamination issues, notably during addition of buffer from a multi-use source or addition of bovine albumin solution prior to culture. The MSPHL has evaluated the Alpha-Tec NAC-PAC EA3 processing system for the past two years as a replacement to the standard method. During this time, there have been no episodes of cross-contamination. This may be due to the individually packaged neutralization and pellet buffers designed for single use. The Alpha-Tec system also provides visual confirmation, changing from pink to clear, of a neutral pH. This provides greater control over sample pH throughout the process. Reproducibility of results using reagents from lot-to-lot is excellent and scientists like the user-friendly procedure, especially the cell -bond slides which do not require bovine albumin to fix material.



Mini-Spike Dispensing Pin (see photo insert) being used to transfer supplement from a sterile vial

NAA Testing

The ordering of NAA testing is restricted to one respiratory specimen from each patient with a positive acid-fast smear, an elevated suspicion of pulmonary tuberculosis and not having received antitubercular therapy in the past twelve months (or on antitubercular therapy for less than seven days). Bloody specimens and previously processed samples are not acceptable for testing. These restrictions are based on GenProbe MTD package inserts and the January 16, 2009 MMWR publication *Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis*.

As a result of these restrictions, NAA testing has been more effectively utilized when healthcare providers are asked to justify requests for testing. When compared to NAA testing data before initiation of restrictions, NAA testing with restrictions showed a reduction of 60% in the number of tests performed. In the instances where NAA tests were requested but not performed because of restrictions, no *M. tuberculosis* complex was cultured from these specimens. This reduction in the number of NAA tests performed since March 2010 represents substantial cost savings.

Replacement of Needle with Mini-Spike Dispensing Pin

In order to reduce needle stick injuries, the TB laboratory began using Mini-Spike Dispensing Pins (see picture) in place of needles. These devices allow aseptic transfer of fluid reagents or specimens with a syringe – no needle required. The Mini-Spike pin's design reduces the possibility of a stick injury to almost zero.

Replacement of FA Microscope with LED Microscope

The TB laboratory replaced FA microscopes with LED microscopes. Among the advantages of the LED microscopes are:

- LED bulb has 15,000 hours of life
- No bulb warm up or cool down
- AFB fluorescence is bright and clean
- Can also be used for light microscopy (Kinyoun)
- No mercury bulb; no UV light

The above changes (enhancements) have improved TB laboratory operations. Please share your comments and suggestions with TB staff at 573-751-3334 or email the MSPHL at labweb1@health.mo.gov.

Employee Spotlight: Stephanie (Barnhart) Schildknecht

By: Mike Massman, Deputy Director

Stephanie Schildknecht, MSPHL Molecular Unit Chief

The MSPHL has recently established a Molecular Unit. This new unit will be responsible for conducting laboratory molecular testing as well as developing and expanding new Laboratory methodologies in gene sequencing. The initial member of this unit and first Unit Manager is Stephanie Schildknecht (formerly Stephanie Barnhart). Stephanie had previously been a Senior Public Health Laboratory Scientist conducting molecular testing in the Microbiology Unit of the MSPHL.

Stephanie began her career at the MSPHL in 2002 when she was hired as an Associate Public Health Laboratory Scientist to help conduct some of the initial LRN bioterrorism methods in the Microbiology Unit. She continued to expand her responsibilities and knowledge of molecular and microbiological laboratory techniques in her most recent position as Senior Public Health Laboratory Scientist.

Stephanie was born in Charleston, South Carolina and traveled around the United States most of her childhood while her father was with the U.S Air Force. Part of this time she lived on Edwards Air Force Base in California and witnessed numerous space shuttle landings. After leaving the military her father worked on the design and development of the B2 Bomber. Her family finally settled in Warrensburg, Missouri, where she finished high school and graduated from the University of Central Missouri with a degree in Biology.

Stephanie now resides in Jefferson City and was recently married to Aaron Schildknecht on September 9, 2011. Aaron is a Car Audio Specialist in Warrensburg. The Schildknects plan to make their permanent residence in the Jefferson City area.

2011 MSPHL 'Lab Animals' Softball Team

The MSPHL softball team, the Lab Animals, had a great season playing in the Jefferson City Parks and Recreation co-ed softball league. Pictured to the left are only some of the softball team members that was composed of laboratory staff and their families.

From left to right are; Elizabeth Weyrauch, Fiscal Unit; Adam Perkins, Microbiology Unit; Debbie Burnette, Fiscal Unit; Pat Shannon, Environmental Bacteriology Unit; Rachel Hardy, Newborn Screening Unit; and Katy Morgan, Microbiology Unit. Not pictured are: Ashley Mehmert, Environmental Bacteriology, Casey Dickey, Summer Intern, Sarah Miller, Immunology, Brad Morgan, Harold Burnette, Brad Grant, Skip Hardy and Emma Shannon.

The Lab Animals ended their softball season 6-4 and finished third in the standings. The Lab Animals have already started their volleyball season and will be back on the ball field next summer.

Lab Blab

Staff happenings in the Laboratory

New Employees

Elizabeth Hicks-Newborn Screening, **Alicia Luebbering**-Central Services, **Paige Pointer**-Virology, **Melissa Reynolds**-Environmental Bacteriology, **Sarah Robertson**-PART, **Cege Rowlett** -PART, **Frances Thompson**-Chemistry and **Elizabeth Weyrauch**-Fiscal Services

Promotions

Stephanie (Barnhart) Schildknecht, Molecular Unit Chief

Keith Bock, Newborn Screening, Senior Public Health Laboratory Scientist

Conferences and Trainings

Shondra Johnson, LIMS Administrator, received her global Project Management Professional (PMP) certification through the Project Management Institute

Sarah Miller, Immunology Unit, attended the HIV/AIDS/STDs and Human Sexuality Education Regional Conference in Kansas City, MO

Nicole Ayres, Immunology, attended the Expanded Testing Conference—MATEC MO Program in St. Louis, MO

Roy Tu'ua, Tuberculosis, attended the National TB Conference in Atlanta, GA

Steve Hynes, EROT Director, attended the Select Agent Workshop in Ames, IA and the APHL National Meeting in Omaha, NE

Julie Buckley, Chemistry, attended FDA-FERN GC-MS training in Cincinnati, OH

Jeremy Wilson, Environmental Bacteriology, attended FERN Food PCR Methods Course in Phoenix, AZ

Leon Luebbering, Environmental Bacteriology, attended FDA Lab Evaluation officers National Workshop in San Antonio, TX

Ashley Mehmert, Environmental Bacteriology attended the International Association of Food Protection Conference in Milwaukee, WI

Russ Drury, Microbiology, attended a Methods for Isolation Class from the CDC in Atlanta, GA

Congratulations!

Thank you for your years of service

30 years

Jessica Connell

25 Years

Belinda Luadzers

20 years

David Byrd, Mike Massman, and Jackie Pfenenger

10 Years

Matt Renner, Randy Schillers, and Phil Schott

5 Years

Erin Hart, Sarah Miller and Tina Nutter

Years of service as of July 1, 2010 through July 1, 2011.

The MSPHL would also like to congratulate Stan Carrender and James Dean Robinson on their retirements. Stan Carrender began working for the MSPHL in 1981, repairing and maintaining breath alcohol equipment. He soon moved to the Chemistry Unit where he became the radiological chemistry expert. He was a Senior Scientist when he retired this July after 30 years of service.

James Dean Robinson started his career in the laboratory at the SW Branch Laboratory in Springfield, MO. He moved to the MSPHL in 2004 and was a Medical Technologist III for the Environmental Bacteriology Unit. He retired at the end of April with 33 years of service.

Their expertise will be missed but we wish them all the best in their next endeavors.

...employee service spotlight continued from page 8

Other MSPHL staff volunteered personal time to support the ongoing recovery efforts in Joplin. Some personal accounts are provided as follows:

Several weeks after the tornado hit Joplin, Susan Randall (Fiscal unit) along with her husband, son and a friend decided to go down and offer assistance. Susan spent the day assisting with clean up and sorting items in a warehouse. ***"It was amazing to see the power of the wind…you could recognize nothing"****. In all Susan's family took three trips to Joplin to help clean up. Her husband went down 3 times, her son went down twice and Susan, her daughter and son's friend went down one time. When asked why she chose to go down to Joplin, Susan replied* ***"they needed the help and we knew we could help them!"***

Debbie Burnette, Chief of Operations at the MSPHL, travelled to Joplin on Sunday May 29th and volunteered at the Joplin Humane Society where they had taken in over 600 pets following the storm. In all there were over 1,300 animals left homeless. When asked what made her decide to volunteer Debbie replied, ***"I was watching the news of the devastation and started thinking about emergency response and how so many organizations, agencies and individuals were en route to help with rescue and cleanup. Being an animal rescue mom, I wondered what coordinated response might be in place for pets, strays and wildlife. I Googled "Humane Society Joplin, MO" and saw they were requesting assistance…originally food, leashes, kennels, etc. but with the numbers they were taking in, we knew it was where we needed to be."***

American Humane Society Animal Emergency Response vehicle

While the MSPHL was only a small part of the overall response to this devastating disaster, the Laboratory continues to plan and ensure that all laboratory systems are in place to provide appropriate response in emergency situations. The MSPHL staff is truly dedicated and compassionate and continue to keep the people of Joplin in their thoughts and prayers.

Editorial Board for *Beyond The Scope*

Steve Hynes, Shondra Johnson, Sandy Jones, Laura Naught, Mike Massman,

Mary Menges, Amy Pierce and Bill Whitmar

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