Nebraska Public Health Laboratory Newsletter

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NPHL Updates

By Peter C. Iwen, PhD, D(ABMM), Director, NPHL

"Science never solves a problem without creating ten *more*" – George Bernard Shaw. The laboratorian today seems to be in a flux of never-ending changes in laboratory practices as technology advances. This month's newsletter provides insight into areas where technological advances are changing how the laboratory operates and intertwines this with the old where we continue on a well-recognized path in testing. In the new technology areas, Dr. Paul Fey, Director of the Clinical Microbiology Laboratory at TNMC, offers some insight into new applications for carbapenemase detection and confirmation. Dr. Timothy Southern, Clinical Microbiology Fellow, presents information on a new molecular assay recently approved by the FDA for the rapid identification of microbial pathogens directly from blood. Finally, Dr. Scott Campbell, IT Consultant, gives insight on the topic of Meaningful Use, federal legislation that will undoubtedly have a large impact on how laboratory tests are ordered and reported in the future.

With the old..... Tony Sambol, Assistant Director of NPHL, gives a summary of the NPHL activities surrounding our continued program for WNV testing in Nebraska while Karen Stiles, Training Coordinator, updates on training opportunities provided through NPHL for ER staff relating to specimen collection during a disaster, and DOT packaging and shipping training of Division 6.2 Infectious Substances. In closing, I would like to highlight that Dr. Steve Hinrichs, former Director of the NPHL, was chosen by the Association of Public Health Laboratories to be this year's recipient of the Lifetime Achievement Award. He will receive his award at the APHL Annual Meeting in Little Rock, Arkansas, in June. Please join me in congratulating Dr. Hinrichs!

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New Testing for Carbapenem Resistance

By Paul Fey, PhD, D(ABMM), Medical Director of Clin Micro
The Nebraska Medical Center

There has been significant discussion in the scientific literature and lay media regarding carbapenem (imipenem/meropenem/ertapenem) resistance in gramnegative rods such as *Klebsiella pneumoniae* and *Escherichia coli*. For the most part, carbapenem resistance is mediated by specific β -lactamases, called carbapenemases, such as KPC (*Klebsiella pneumoniae* carbapenemase) or NDM (New Delhi metallo-beta-lactamase). The prevalence of these β -lactamases in the United States is highly dependent upon region of the country, with the highest prevalence at this time on the East Coast.

The Nebraska Public Health Laboratory, in collaboration with the Centers for Disease Control and Prevention and several regional microbiology laboratories in Nebraska, have recently completed a three-year survey assessing the prevalence of carbapenem-resistance within the *Enterobacteriacae* in Nebraska. Our survey found that carbapenem-resistance was not detected in laboratories outside of Omaha, where KPC has been isolated from *Klebsiella pneumoniae, Enterobacter cloacae*, and *Serratia marcescens*. Nevertheless, laboratories should be aware of *Enterobacteriaceae* isolates with increased resistance to any of the carbapenems ($\geq 2~\mu g/ml$ for imipenem and meropenem or $\geq 1~\mu g/ml$ for ertapenem) that are tested in your laboratory.

If current carbapenem interpretive breakpoints are utilized, CLSI does not recommend the use of additional testing, such as the modified Hodge test, to identify specific carbapenemase producing isolates¹. It should be noted that other resistance mechanisms, such as a porin mutation in the presence of an upregulated AmpC β -lactamase or an extended-spectrum β -lactamase (ESBL), can also mediate carbapenem-resistance.

The NPHL has developed a combination of molecular and phenotypic tests that are designed to identify specific carbapenemeases. If you require consultation about carbapenem-resistance in your laboratory or would like to send an isolate for testing, please contact Drs. Peter Iwen (402-559-7774) or Paul Fey (402 559-2122).

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Rapid Identification of Positive Blood Cultures

By Timothy Southern, PhD, Clinical Microbiology Fellow

Blood stream infections (BSIs), often referred to as sepsis or septicemia, are life threatening infections that can result in permanent cognitive and physical impairment or death. Over a decade ago, an aggressive international campaign was initiated with the goal of improving management of BSIs through early detection, reduced time to appropriate antimicrobial therapy, identification of infection source, and fluid therapy. Despite this effort, hospitalization rates for BSIs in the United States continued to rise. Data from the Centers for Disease Control and Prevention (CDC) indicate that BSIs remain a critical health concern with rates increasing every year, especially among older Americans.

Recent studies show that rapid identification of bacterial and yeast pathogens from positive blood cultures coupled with effective antimicrobial stewardship improved time to effective and optimal antimicrobial therapy⁶ and reduced healthcare costs. Technologies for rapid identification of pathogens from positive blood cultures include mass spectrometry, microarray and polymerase chain reaction (PCR), among others. In 2012, BioFire Diagnostics (bioMerieux, Salt Lake City, UT) released the FilmArray® Blood Culture Identification (BCID) panel, a multiplex PCR test for identification of common bacterial and fungal pathogens directly from positive blood cultures. This rapid, multiplex PCR panel identifies 19 organisms at the species-level including 5 gram-positive bacteria, 9 gram-negative bacteria and 5 yeast (**Table 1**). Additionally, the BCID panel can detect 4 genus-level targets, 1 family-level target and 3 markers of antimicrobial resistance.

Like other FilmArray® products, the BCID panel contains all reagents necessary for sample preparation and PCR. Following reagent rehydration, a blood sample is mixed with Sample Buffer and is injected into the pouch. The pouch is loaded into the FilmArray® instrument where DNA is extracted, purified and two rounds of PCR are performed. In just over an hour, the FilmArray® software generates an Analysis Report that includes a qualitative result (detected, not detected) for each target on the BCID panel.

Two published studies provide performance data for the FilmArray® BCID panel. The first study reported an

overall 91% sensitivity and 77% specificity for the BCID panel using prospectively collected blood culture samples. The authors reported excellent performance for bacterial targets (88-100% sensitivity and 99-100% specificity) but only marginal performance with yeast targets (50-75% sensitivity and 100% specificity). A second study reported excellent performance for most targets including gramnegative bacteria (97.5-100% sensitivity; 100% specificity), gram-positive bacteria (88.9% sensitivity; 93.7-100% specificity), yeast (100% sensitivity; 99.5-100% specificity) and *mecA*, a marker of methicillin resistance (96% sensitivity; 98.9% specificity). 10

These studies indicate that the BCID panel is a rapid and reliable method for early detection of common bacterial and yeast pathogens from positive blood cultures. Future studies will likely examine the impact that the BCID panel has on patient outcomes including healthcare costs, time to effective and optimal antimicrobial therapy, length of hospital stay and mortality.

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 (Continued on page 4)

Table 1. Targets detected by the BioFire FilmArray Blood Culture Identification (BCID) panel.

Gram Positive Bacteria	Gram Negative Bacteria	Yeast	Antibiotic Resistance	
Staphylococcus Staphylococcus aureus Streptococcus Streptococcus pyogenes Streptococcus agalactiae Streptococcus pneumoniae Enterococcus Listeria monocytogenes	Acinetobacter baumannii Haemophilus influenza Neisseria meningitides Pseudomonas aeruginosa Enterobacteriaceae Enterobacter cloacae complex Escherichia coli Klebsiella oxytoca Klebsiella pneumoniae, Serratia marcescens Proteus	Candida albicans Candida glabrata Candida krusei Candida tropicalis Candida parapsilosis	mecA vanA/B bla _{KPC}	

LOINC, SNOWMED CT and Meaningful Use - What's all the fuss? Part II

by W Scott Campbell, MBA, PhD, IT Consultant

Except for those living under rocks and communing with various subclasses of *Oligochaeta* (i.e., Latin for the SNOMED CT term 419540000|earthworm), you most likely have experienced the drastic changes to information technology requirements affecting clinical laboratories across the nation. Specifically, labs, clinics and hospitals are required to use the formal, computable clinical terminology standards, LOINC and SNOMED CT, to receive Meaningful Use financial incentives. However, you may not be quite as aware of the details surrounding seismic shift.

Meaningful Use (MU) refers to legislation included in the American Recovery and Reinvestment Act, namely the Hi Tech Act. The Act incents eligible hospitals (EH) and eligible providers (EP) to adopt certified electronic health record (EHR) software and use the software in a "meaningful way", *ergo* Meaningful Use. EH's and EP's must implement and demonstrate meaningful use of EHR software within a set number of years or be subject to reduced Medicare reimbursement. A particular objective of MU is to use standard, computable terminologies to order and report laboratory tests. Those terminologies are LOINC (logical objects identifiers names and codes) and SNOMED CT (formerly known as systematized nomenclature of medicine, clinical terms). 1,2

LOINC is the product of the Regenstreif Institute based out of Indiana University. The primary use is to define the nature of a laboratory test. A LOINC code communicates six parameters: the analyte being tested, the property of the result (e.g., mass concentration), the body system tested, the time aspect of the test, the scale used for results, and the methodology of the test. For instance, the LOINC code, 11475-1, tells the computer that a microorganism was identified by culture from an unspecified specimen. Therefore, the key information about the test is communicated regardless of the name used for the test in the performing lab or by the interpreting healthcare provider.

SNOMED CT, on the other hand, defines results. This standard is managed by the International Health Terminology Standards Development Organization and the terminology traces its roots back to the College of American Pathology. SNOMED CT is a controlled terminology used to define many aspects of human and animal medicine such as clinical findings, body structures and organisms. It maintains multiple relationships between the terms defined so that inferences about terms can be made by a computer. For example, The SNOMED CT code 407166006|Escherichia coli serogroup O157 represents the organism E. coli O157 which is an gammaproteobacteria and is a gram-negative bacterium which is a prokaryote and so on. Used in conjunction with the LOINC code mentioned above for a culture, 11475-1, the overall code can be interpreted by any number of systems as E. coli O157 found by culture.

While this can be complicated, the positive impact on patient care, public health and research is notable. The use of LOINC and SNOMED CT coding facilitates the transmission of lab orders and results by normalizing the names

and terms used for orders and results preventing misinterpretation and medical error. These standards also simplify the storage and display of lab data in EHR programs further reducing medical error and enabling the use of clinical decision support systems. Finally, LOINC and SNOMED CT allow data to be efficiently mined by computers for epidemiological issues (e.g., disease surveillance) and new discovery (i.e, research). In the long run, the juice may be worth the squeeze.³

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West Nile Virus Testing at NPHL

by Anthony Sambol, MS, M(ASCP), Assistant Director NPHL

West Nile virus is a member of the arbovirus family which consists of over 500 viruses that are carried by arthropod vectors- mainly mosquitos. In Nebraska, West Nile virus (WNV) is carried by members of the *Culex* genus of mosquitos, which are found in fresh waters. Other arthropod viruses carried by *Culex* mosquitos encountered in Nebraska include St. Louis encephalitis virus (SLE) and Western equine encephalitis virus (WEE). Birds and other mammalian animals found in the wild act as reservoirs and amplifying hosts.

Testing for WNV has been carried out in Nebraska since 2000 and is spearheaded by the Nebraska Health and Human Services (NHHS), Department of Epidemiology. Recent results for 2012 and 2013 showed a marked increase from 2011.

Only 20% of infected individuals have symptoms and only 1 % shows any neurological effects. The NHHS Department of Epidemiology pays for testing of paired serum/cerebral spinal fluid (CSF) specimens that is requested for patients displaying neurological symptoms. Both serum and CSF are screened for the IgM antibody which is formed in the first two weeks as a response to an acute infection. The numbers of positive cases, including blood donors, reported in Nebraska were 38 in 2011, 230 in 2012 and 258 in 2013.

In animal testing, both horses and dead birds are tested for the presence of WNV through services provided by the University of Nebraska at Lincoln Veterinary Diagnostic Center (UNL-VDC). UNL-VDC performs both serological testing for IgM and IgG in horses and PCR for the viral antigen in birds. This past season six WNV-positive horses were detected, down from 14 in 2012. With the help of local citizens, the Nebraska Department of Agriculture investigates any occurrence of dead birds. Crows, house sparrows and other birds are susceptible to WNV infection and just recently a large die off of bald eagles in Utah was attributed to this virus. This year 39 counties had dead birds

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Unannounced DOT & FAA Inspections Evident in Nebraska Laboratories - Changes in 2014 to Packing & Shipping Infectious Substances Division 6.2 Materials Stressed

by Karen Stiles SM(ASCP)^{CM}, State Training Coordinator NPHL

Packaging and Shipping Infectious Substances, Division 6.2 training was held in Kearney and Omaha on March 18 & 20th, respectively. Classes were sponsored by APHL and taught by Patricia Payne, Ph.D., MT(ASCP). As always, Dr. Payne brought her laboratory experience to bring what is relevant to the laboratorian and shared what changes are in store for 2014.

Laboratories who ship Category A or Dry Ice are subject to inspection by the Department of Transportation (DOT) or the Federal Aviation Administration (FAA), which can be unannounced. Inspections are performed to ensure laboratory facilities have implemented and are compliant with the most recent federal regulations. The federal hazardous materials law as of 2013 has set \$75,000 as the maximum civil penalty that may be assessed for an intentional violation, with violations related to training has reverted to a minimum of \$450.1

Inspectors inevitably will ask for two items, training records and shipping documentation. Training must be completed every 3 years for DOT, Joint Commission and College of American Pathologist (CAP) and 2 years if you ship by FedEx or other IATA carrier. Copies of any Category A or Dry Ice shipping documentation must be kept accessible in your laboratory for 2 years.

Training is required of anyone who affects the transport of hazardous material or dry ice. This would include the person who classifies the culture or patient specimen, packs, marks, labels or completes the documents for the package (such as shippers declaration form and air waybill). Training certificates must include general awareness, function-specific training, safety and security training and is signed by the employees supervisor. All training and shipping documentation must be readily accessible at a moments notices when the inspector arrives. Don't keep them locked up in the office.

In 2011, the DOT introduced changes to the designs of the Division 6.2 infectious substance and Class 9 miscellaneous hazard labels in 49 CFR 172.432 and 49 CFR 172.446. The DOT made these changes to the hazardous material label designs to correspond with the UN Recommendations on the Transport of Dangerous Goods. If you ship infectious substances or miscellaneous hazardous materials, you must change the old format labels and begin using the new labels by October 1, 2014. The changes in the labels are very subtle so you must look carefully at the labels to ensure that the proper label is applied.²

The new Division 6.2 label has the following changes: Text "In U.S.A. Notify Director-CDC, Atlanta, GA 1-800-232-0124" was removed from the label. The remaining text was moved to below the midpoint of the label (**Image 1**).

The new Class 9 label has the following changes: The horizontal line running across the label below the vertical black bars was removed. The width of the vertical black bars on the left and right corners of the label was decreased so

they are the same width as the other black bars (Image 2).

Image 1 - New Category A Infectious Substance Label

Image 2 - New Dry Ice Label





The NPHL hazardous materials shipping program will start replacing these labels on all shipping materials that are provided for the sentinel laboratories. Initially, packages received will be relabeled before refitting and then returned. As the October 1st deadline draws near, we will contact all sentinel labels to see if any NPHL boxes in storage still need replacement labels. The NPHL shipping notebooks will be updated, as well.

Each sentinel laboratory is encouraged to examine shipping materials from other reference laboratories and request replacements. This would be a good time to do a little house-cleaning and discard any boxes not used, damaged or stained. Word to the wise, be prepared before the inspector shows up, unannounced, at your laboratory door!

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402-559-2440

(Rapid Identification of Positive Blood Cultures, Continued from page 2) Microbiol Immunol. 4(1): 1-25.

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What Emergency Room Staff Need to Know About Specimen Collection During a Disaster

by Karen Stiles SM(ASCP)^{CM}, State Training Coordinator NPHL

The CDC has a key role in protecting the public's health in an emergency involving the release of a harmful chemical. A chemical emergency occurs when a hazardous chemical has been released and the release has the potential for harming people's health. Chemical releases can be unintentional, as in the case of an industrial accident, or intentional, as in the case of a terrorist attack. CDC's Office of Public Health Preparedness and Response works 24/7 with local, state public health partners to provide strategic direction, support and coordination, Therefore when states are prepared to detect or respond rapidly to threats, communities are better protected.²

Dr. Kristi L. Koenig, Professor of Emergency Medicine and Director of Public Health Preparedness, University of California, Irvine recently stated "Preparedness for terrorism in the 21st century includes addressing the management of nuclear, biological and chemical (NBC) events. Familiarity with initial patient care considerations and protective actions for staff including decontamination techniques is essential for front-line clinicians."

To recognizing chemical terrorism-related illnesses, adequate planning and frequent exercising are key to preparedness for terrorism-related events. Healthcare providers, especially in emergency rooms should be alert to illness patterns and reports of chemical exposure that might signal a chemical event. The following clinical, epidemiological and circumstantial clues may suggest a possible chemical terrorist event:³

- An unusual increase in the number of people seeking care, especially with respiratory, neurological, dermatological or gastrointestinal symptoms
- Any clustering of symptoms or unusual age distribution (e.g., chemical exposure in children)
- Location of release not consistent with a chemical's use
- Simultaneous impacts to human, animal and plant populations
- Any unusual clustering of patients in time or location (e.g., persons who attended the same public event)

What if the causative agent is unknown? What if there is no overt incident to define the type of chemical exposure? What if victims first present in the emergency room, with no prior notification? What if initial treatment fails? What then?

At this point, the facility may request assistance from Regional Poison Control and other state resources. Ultimately, the CDC may be notified and may request samples

Save the Dates:

2014 Annual Preparedness Symposia

May 7, 2014 | Gering, NE May 8, 2014 | Kearney, NE June 10, 2014 | Norfolk, NE June 11, 2014 | Omaha, NE be collected on the 40 most affected patients. The CDC, in conjunction with other state health laboratories, through the PHEP cooperative agreement, have capabilities to do the *Rapid Toxin Screen*, which analyzes blood and urine for 150 chemical and biological agents within 36 hours. Once the agent is identified, subsequent results provide individual exposure information that determines who was exposed, how much exposure an individual had, guide clinicians in treatment decisions and help prevent additional exposures.

When this request comes, is your emergency room prepared to collect, store and ship 40 urines and over 160 blood tubes to the CDC, on top of your normal supportive care in this critical time? The Nebraska Public Health Laboratory will discuss the CDC's guidelines concerning specimen collection and Level-3 chemical event preparedness at the 2014 Annual Preparedness Symposia held across Nebraska in May and June. As a follow up, NPHL is eager to take the state's preparedness plan to individual hospital facilities in the form of a table top exercise. This function serves to engage team members to work together to manage potential events, to identify gaps at their facility and improve capabilities to respond in real event. Preparing can be a challenge, but the consequences of being unprepared at your facility could be devastating. For additional information, contact Karen Stiles at kstiles@unmc.edu.

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Upcoming NPHL 2014 Events

What Emergency Room Staff Need to Know About Specimen Collection During a Disaster

NPHL presentation at 2014 Annual Preparedness Symposia (see below)

CDC Specimen Collection Emergency Room Training Guidance

Tabletop Exercise Fall 2014 TBA



Salmonella Alphabet Word Search

by Andi Williams, MS, NPHL Technologist

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newportokog
 rnc s d r n l u s m o p i a
        1 d t
             c b p a r h o
heidelb
          e
           ľ
             g
                a u m a
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 ymeulish fiakhr
      fbtazhngoaa
 nohbgseiiucbotm
     i k n p n d n a t d n m
 intrmuocf
   tantuogrispw 1
 lmntebroiccaac
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unnwm f c q i u j a a e e
 g a 1 1
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          imbimhemr
anaivai
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Agona Benfica Enteritidis Dunkwa Gallinarum Heidelberg Kubacha Javiana Mowanjum Newport Quentin Putten Typhimurium Saintpaul Victoriaborg Wenatchee Yoruba Zigong

Clontarf
Fulica
Infantis
Litchfield
Onderstepoort
Ruzizi
Umbadah

x marks the spot

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Salmonella Alphabet Word Search

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under the NPHL Newsletter tab



Congratulations to Dr. Hinrichs!

by Peter C. Iwen, PhD, D(ABMM), Director, NPHL

Dr. Steve Hinrichs, former Director of the NPHL, was recently chosen as recipient of the Association of Public Health Laboratories (APHL) Lifetime Achievement Award. This award is given annually to an individual who has "established a history of distinguished services to APHL, made significant contributions to the advancement of public health laboratory science or practice, exhibited leadership in the field of public health,



and/or influenced public health policy on a national or global level."

Dr. Hinrichs is to be recognized at the APHL Annual Meeting to be held in Little Rock, Arkansas on June 3rd. Please join me in congratulating Dr. Hinrichs for this prestigious award!

(West Nile Virus, Continued from page 3)

submitted for WNV testing. Nine birds out of 110 (8.2%) tested were WNV-positive, as compared to 15 positive birds out of 85 (17.6%) tested in 2012. Only 2 positive birds out of 114 tested (1.8%) were detected in 2011.

Active surveillance of mosquito's for WNV activity starts in May/June, running through September/October. Mosquito trapping sites have been established in 27 counties in NE and trapping is a coordinated effort through the local public health districts. Test results are relayed from DHHS to the public health districts to officials that work in the mosquito abatement program so that an appropriate public health response is undertaken.

Mosquitos are trapped, frozen and sorted so that the correct genus of mosquitos, *Culex*, can be tested. Mosquitos are placed into batches of 50 (designated as "pools") by collection site, day and time and then sent to the NPHL for analysis. The last two years have resulted in an increase in positivity rate in mosquito pools. A total of 1807 pools were tested in 2012 and 2,215 pools tested in 2013. Total positive pools were 257 and 261 for each year which relates to a 14.2 and 11.8 % positively rate, respectively. In 2013, 24 of the 27 counties that had trapping sites were positive for WNV infected mosquitos. As a comparison, the 2011 season had only a 2.3% rate.

West Nile virus testing is dependent upon funds provided on a yearly basis through the Epidemiology and Laboratory Capacity grant funding by the Centers for Disease Control and Prevention to NHHS. Nebraska, as with all states, continues to receive funding yearly for testing and barring any extreme funding cuts to states. Testing is expected to continue.

Additional information can be found on the Nebraska Health and Human Services website at: http://dhhs.ne.gov/publichealth/Pages/wnv.aspx

Meet the Laboratorian - Dean Taubenheim

by Karen Stiles SM(ASCP)^{CM} State Training Coordinator NPHL

Dean Taubenheim is a familiar name in the central portion of Nebraska and is known by many microbiologists in the state. Dean is currently the Microbiology Supervisor at Mary Lanning Hospital in Hastings. We were fortunate to catch up with Dean to obtain the following interview of this highly regarded medical technologist:



I grew up on a farm near Amherst, NE, and even as a child I was always amazed that scientists were able to diagnose infectious diseases in both humans and animals. My love for science grew through high school, and in college it became even clearer to me that I was leaning towards the medical field, with a side interest in education.

I received a BS in education from the University of Nebraska at Kearney, followed by a degree in medical technology at the St. Elizabeth Community Health Center in Lincoln, NE, in 1972.

In 1973, my first position was in the laboratory at Mary Lanning Health Care, and as the years went on, I developed an interest in microbiology. After about three years, I became the microbiology supervisor and I just celebrated my 40th year at MLHC this past September.

In 1992, I took on the added responsibility as site coordinator for the UNMC (University of Nebraska Medical Center) CLS (Clinical Laboratory Science) program. I've also had students from Central Community College and Mid-Plains Community College. I've helped train at least 70 students in microbiology over the years, and all have gone on to work in the clinical laboratory field.

My job is a behind-the-scenes job, but I take great satisfaction in knowing that I play a role in providing the physician with information needed to help determine a plan of action to provide the best treatment for each patient.

Many of us in the lab have worked together for more than 30 years, and we're more like brothers and sisters than just fellow employees. The atmosphere in the lab is one of dedication and teamwork. I can honestly say that, even after 40 years, I still enjoy going to work every day. Because of technology advances and computerization, when I walk into the lab at the start of my shift, I feel that I'm already 4-5 hours ahead of where I would have been 40 years ago.

The biggest challenge I see for the future of medical technology is that the schools aren't turning out enough students to replace those of us already in the field that are looking at retirement.

Although I do love my work, I'm looking forward to retiring later this spring. My wife, Meda, and I have a lot of similar interests, including camping, fishing, and playing golf. We love spending time with our grandchildren, so that will be at the top of our list of things to do year-round. We also want to see more of this great country we live in, and God willing, we will take at least one trip each year.

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The Nebraska Public Health Laboratory Newsletter is a publication of the Department of Pathology and Microbiology, Steven H. Hinrichs, MD, Professor and Chairman, at the University of Nebraska Medical Center. The views expressed here do not necessarily reflect the opinions of the Nebraska Department of Health and Human Services or the University of Nebraska Medical Center.

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