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Director, Bureau of Laboratories Sandip Shah, PhD, HCLD(ABB)

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BOL Announces New Bioinformatics Section and Section Manager BOL Offers On-line Packaging and Shipping Recertification Course Whole Genome Sequencing of SARS CoV-2 **BOL Becomes National Hepatitis C Virus NAT Reference Center**

Bureau Vision

The Bureau of Laboratories is a stronger, more diverse team within an integrated public health system. We utilize advanced technology and innovative leadership to provide comprehensive public health services in our dynamic global community.

Bureau Mission

We are dedicated to continuing leadership in providing quality laboratory science for healthier people and communities through partnerships, communication and technical innovation.



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BOL Announces New Bioinformatics Section and Section Manager

The Bureau of Laboratories (BOL) advocated for a laboratory section that would combine next generation sequencing with the power of bioinformatics computing to benefit state and local communities with rapid outbreak and surveillance data for emerging and evolving disease threats. This new section would transform public health laboratory practices and provide an impressive tool designed to monitor and track specific biologic changes discovered during genetic sequencing along with associated patterns of organism adaptation and spread. The overarching goal of a



Bioinformatics Section would be to integrate with the Virology and Microbiology laboratory sections while providing a future support structure for the Newborn Screening Section, depending on national developments in all realms. This year, the BOL gained approval to establish the Bioinformatics Section and are pleased to introduce Dr. Heather Blankenship as the Section Manager.

Heather received her BS in Biology from George Mason University and her Ph.D. from Michigan State University (MSU). She gained expertise for her career through study of human and prokaryotic genetics. Her post graduate studies focused on molecular genetics, epidemiology, biotechnology, and bioinformatics. While completing her studies at MSU, Dr. Blankenship worked within the BOL as a National Institute of Health "Broadening Experiences in Scientific Training," (NIH "BEST" program) extern in 2018 and 2019. This unique opportunity has given her the expertise to manage this novel and versatile technology. Dr. Blankenship has authored publications on bioinformatics technology, shared her expertise with colleagues through national conference presentations, and has published several national-level laboratory protocols. Congratulations, Dr Blankenship.

BOL Offers On-line Packaging and Shipping Recertification Course

The Bureau of Laboratories (BOL) is pleased to offer an online, self-serve, Packaging and Shipping Recertification Course.

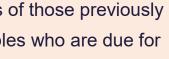
This course is designed to meet the needs of those previously certified to package and ship clinical samples who are due for recertification. PACE continuing education credits will be available with this 2-hour course.

This intermediate level course will provide a comprehensive overview of Federal (DOT & USPS), and International (IATA) Regulations applicable to the packaging and shipping of laboratory specimens.

The course will provide an understanding of terminology, packaging, marking, labeling, and documentation required for shipping under these regulations. Successful completion of this course will meet requirements for employer certification.

After course completion, participants will complete an evaluation and a quiz. Successful participants must achieve at least 80% passing score on their quiz, before they will be able to print out their training certificate. The training certificate must be signed by the participant's supervisor in order to be valid. Continuing education credits are available for participants that are ASCP or NCA certified.

To sign up for this course, access your MITRAIN account and search for course ID 1094582. If you have not previously trained for packaging and shipping certification, please wait to register for a virtual course using course ID 1062236. Virtual courses will be offered in late spring 2021. For questions, please contact Julie Kusey at (517) 335-9604 or by email at kuseyj@michigan.gov.





Whole Genome Sequencing of SARS-CoV-2

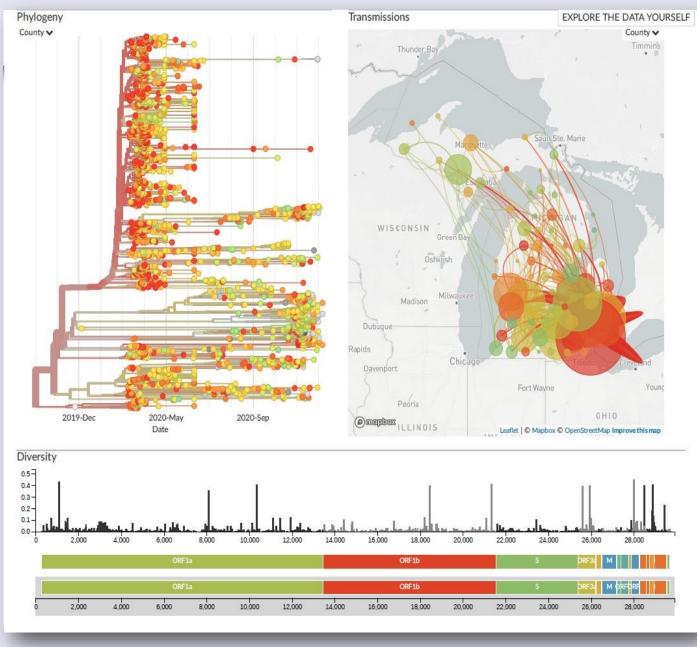
Author: Heather Blankenship, PhD, Bioinformatics Section Manager

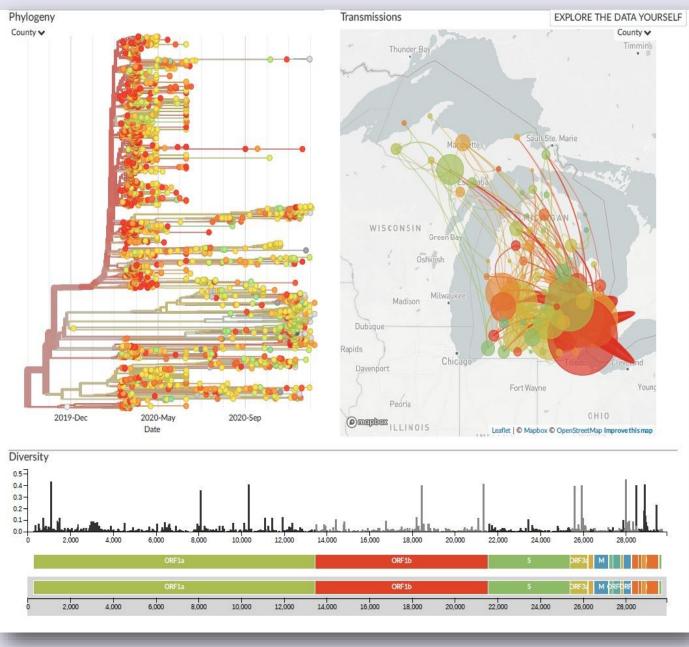
Since the first case of SARS-CoV-2 was detected at MDHHS Bureau of Laboratories (BOL) in mid-March, three laboratory sections (Microbiology, Virology, and Bioinformatics) have worked together as part of a sequencing group to bring high throughput sequencing protocols online, analyze the data, and provide support to our epidemiology partners in response to the pandemic. In the past 9 months, the group has been able to sequence 5,070 SARS-CoV-2 samples that were either tested by BOL or submitted by clinical partners around the state for surveillance.

SARS-CoV-2 is an RNA virus that belongs to the coronavirus family, it also includes other notable viruses such as SARS, MERS, and the common cold. The genome for SARS-CoV-2 is small at 29,900 nucleotides in length and only 11 genes. While the mutation rate for RNA viruses tends to be very high, SARS-CoV-2 only generates 2 mutations per month on average, which is half the rate of influenza and a guarter the rate of HIV. However, not every mutation will provide an advantage to the virus and most mutations will go undetected since they result in either no changes or a non-viable virus. These mutations allow us to generate a picture of how viruses from different people or regions may be related, how the virus is moving, where it came from, or how it is changing. For instance, through whole genome sequencing, researchers were able to identify that the closest related coronaviruses to SARS-CoV-2 were found in bats and pangolins.

Within Michigan, whole genome sequencing of SARS-CoV-2 has helped to understand the virus and provide support to the pandemic response. By examining the virus at the genomic level along with the date of infections, we can generate broad transmission dynamics to watch how the virus might be moving around the state or across state borders.

On a smaller scale, we can examine and provide support to epidemiologists as they investigate cluster outbreaks within different facilities by examining slight differences in the genome. While examining the SARS-CoV-2 genomes, we also monitor and track variants that may be of important clinical or diagnostic importance. Specifically, variants that may result in more severe clinical outcomes or affect our ability to accurately identify a positive specimen. As we continue to respond to the SARS-CoV-2 pandemic, whole genome sequencing will help to provide insight on changes that we see within the virus and how that might affect the response.





Transmission dynamics and genomic differences that can be observed in Michigan through whole genome sequencing analysis of SARS-CoV-2 Courtesy of MDHHS BOL

BOL Becomes National Hepatitis C Virus NAT Reference Center

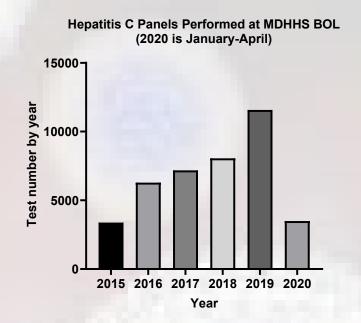
Author: Diana K. Riner, MS, PhD, Virology and Immunology Section Manager

The Bureau of Laboratories (BOL) was awarded a 5-year contract to act as a Hepatitis C Virus (HCV) Nucleic Acid Amplification Testing (NAT) Reference Center by the Association of Public Health Laboratories, in cooperation with the Centers for Disease Control and Prevention. The HCV NAT Reference Center will provide United States public health laboratories access to HCV NAT to identify current HCV infection. The testing algorithm for diagnosis of current HCV infection recommends all persons who test positive for an HCV antibody (anti-HCV) test should receive an HCV NAT to detect HCV RNA. If HCV RNA is detected, the case is considered to have current HCV infection and should be linked to care.

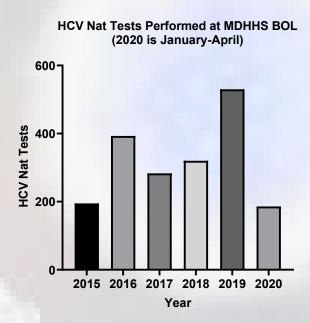
HCV specimens received by the BOL are tested for HCV IgG antibodies. If the specimen is reactive for HCV antibody and there is sufficient specimen quantity (≥ 500 µl) the specimen is run on the Roche COBAS® AmpliPrep/COBAS® TaqMan® HCV test for detection and quantification of HCV viral RNA. This platform allows for quantitative detection of HCV virus from plasma or serum with a quantitative limit of detection of 15 to 100,000,000 IU/ml and a lower limit of detection of < 15 IU/ml HCV. If specimen volume is not sufficient for running on the COBAS® platform BOL has a qualitative HCV NAT laboratory developed real-time PCR assay that was validated for clinical use.

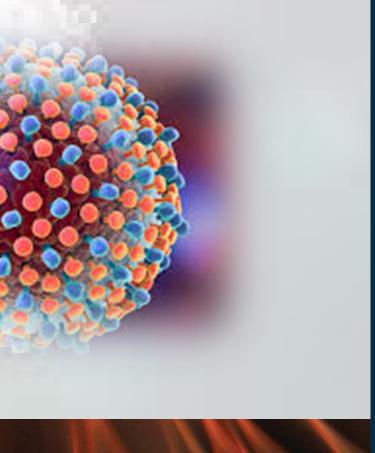
At BOL, the annual testing volume for HCV screening panel has steadily increased over the past five years (Figure 1). This illustrates BOL ability to increase its testing capacity to meet the needs of Michigan's public health efforts to expand testing and provide treatment for HCV with the goal of eliminating this disease.

Figure 1. HCV testing volumes for 2015 -2019 and the first 5 months of 2020











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