

LabLink

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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

Bureau Mission

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

LabLink is published quarterly by the Michigan Department of Health and Human Services Bureau of Laboratories, to provide laboratory information to Michigan health professionals and the public health community.

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Developing New Capabilities for Surveillance Testing of Metals in Drinking Water

In response to Michigan Executive Directive 2021-9, which underscores the critical importance of providing safe drinking water to all Michiganders, the BOL Chemistry and Toxicology Division, Environmental Inorganic Unit (EIU) has been working diligently to enhance surveillance testing capabilities by validating methods for the analysis of metals in drinking water. Specifically, we are focusing on quantification of various metals using United States Environmental Protection Agency (EPA) Methods 200.7 and 200.8 (modified) with collision gas technology.

Both EPA methods are designed to analyze drinking water samples for the presence of metals. For EPA Method 200.7, we will be analyzing for the presence of sodium and iron employing inductively coupled plasma-optical emission spectrometry (ICP-OES). For EPA Method 200.8 (modified), we expand our surveillance capabilities by detecting a broader range of metals such as Aluminum, Arsenic, Silver, Barium, Beryllium, Cadmium, Chromium, Copper, Manganese, Nickel, Lead, Antimony, Selenium, Thallium and Vanadium employing inductively coupled plasma mass spectrometry with collision gas technology (ICP-MSMS). The modified version of EPA Method 200.8 allows for improved sensitivity and selectivity during the analysis.

As an overview of the method, water samples are collected by our partners and submitted to BOL for analysis. Prior to analysis, all water samples require the measurement of turbidity, a measurement of the water sample clarity. This dictates if the sample can be analyzed directly or needs to be digested using a mixture of acids to break down the matrix and release the metals of interest which are then are quantified using ICP-MS or ICP-OES.

As part of our commitment to excellence, we are actively preparing for accreditation through the National Environmental Laboratory Accreditation Program (NELAP). This accreditation will further validate our testing capabilities and ensure compliance with rigorous standards.

Our commitment to water safety drives us to develop cutting-edge capabilities for surveillance testing. Together with the Department of Environmental Health (DEH), we are working to safeguard Michigan's water resources and protect public health. If you have any questions or need further information, please reach out to:

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Jerry Tiernan, Chemical Preparedness & Response Section Manager (DEH): 517-338-7471 or email Tiernang@michigan.gov



My Association of Public Health Laboratories Internship with the Bureau of Laboratories

by Allyssea Smith

My name is Allyssea Smith, an Association of Public Health Laboratories (APHL) intern working in the Bureau of Laboratories Outreach section. I am from Michigamme, located in Michigan's Upper Peninsula. I graduated from Westwood High School, am currently working on earning a Bachelor's of Natural Science degree majoring in Medical Laboratory Science at Michigan State University (MSU), and will be a senior fall semester of 2024. Previous work experience includes a cook for a senior living center and a prep cook at a pasty shop. This summer I have a position as a Home Health Aide from an individual family hire in Michigamme where I am able to continue to enjoy the beautiful view of Lake Michigamme. The family who hired me as a home health aide has given me the opportunity to job shadow with their daughter, who is a Family Practice physician in Marquette. I have also volunteered with "Tower Guard," which is an Honors Student Organization through the Resource Center for Persons with Disabilities at MSU in which an opportunity to tutor, participate in adaptive sports and recreation club, convert pdf course books into Microsoft accessible documents, and collaborate with other students in organized activities. Also, I volunteer to tutor fourth grade students through the RAMS Tutoring program, am a member of MSU Running Club, the Biomedical Laboratory Diagnostics (BLD) Student Association, and am a recipient of the "STARR Charitable Foundation Scholarship" from MSU.

My recent Internship at the Michigan Department of Health and Human Services Bureau of Laboratories has been a great experience to learn about various laboratory career paths in Public Health. I have had the amazing opportunity to work closely with Jason Wholehan, Bioterrorism Training Coordinator from Outreach in the Laboratory Systems Section, where I have gained valuable skills from many different areas. This includes creating and editing on-line courses with Lectora Software such as, Packaging & Shipping for the Clinical Laboratory and Recognize, Rule-Out, and Refer for Detecting Biothreat Agents. I also helped create PowerPoint presentations and other educational material for an in-person, Wet-Mount Laboratory Workshop for Detecting Biothreat

Agents. This workshop occurred the end of May and was designed for Michigan sentinel laboratories. I have had the great pleasure to assist the Outreach section with the smallest tasks, like printing and labeling, to the bigger tasks, like putting together microscopes and preparing a Packing and Shipping Exercise for Henry Ford Hospital. I have also been given multiple opportunities to network and meet other professionals in Public Health such as, job shadowing in Genomics and Virology Sections of the BOL, and attending the APHL 2024 Annual Conference held in Milwaukee, Wisconsin.

I have had the opportunity to gain first-hand experience and insight for various career paths and am seriously considering Public Health as a future option. This internship has shown me that there are many career opportunities, not only in Public Health but in the greater healthcare system that I have never considered pursuing prior to this internship. I plan to pursue a Medical Laboratory Science (MLS) internship at a hospital in Michigan, then hope to work at a hospital in the Upper Peninsula. Dependent upon these experiences, I may choose to continue post graduate education and pursue a career in public health laboratory science.



Allyssea Smith,
APHL Intern 2024

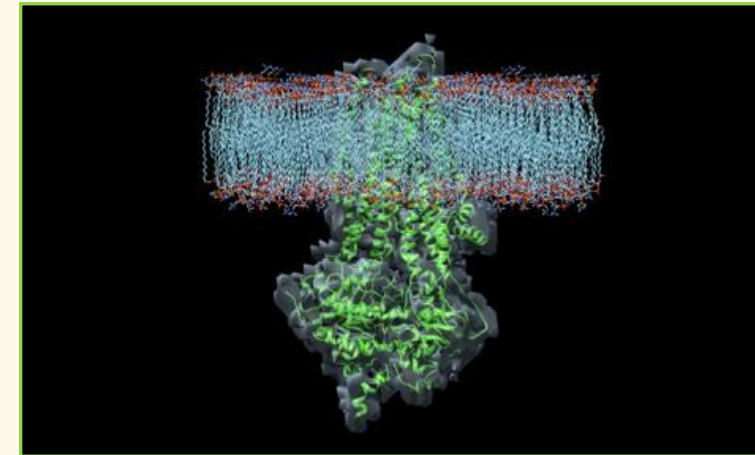
Cystic Fibrosis Newborn Screening by Next Generation Sequencing

by Joseph Hill and Erika Jackson

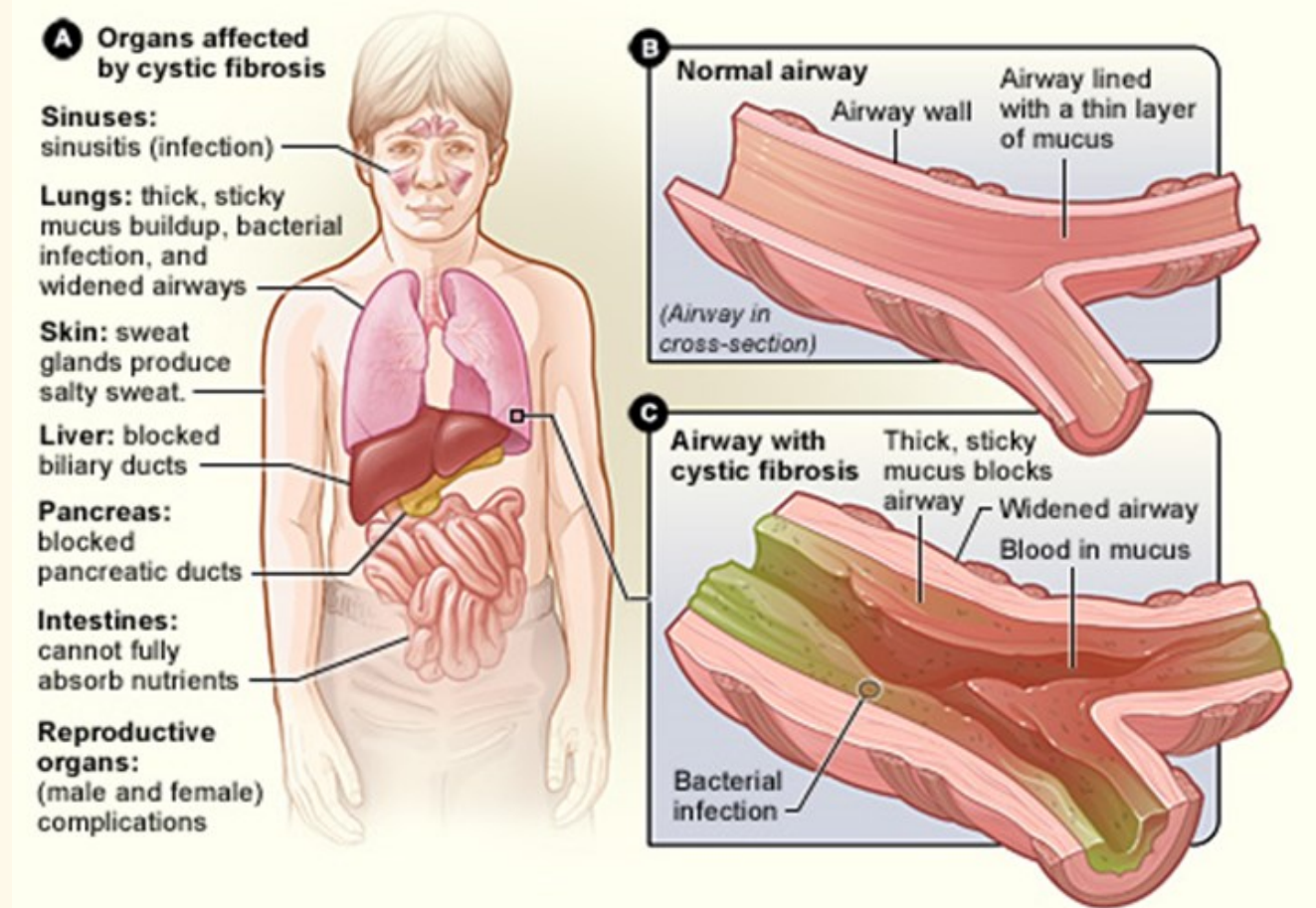
Cystic fibrosis (CF) is a progressive, genetic disease caused by mutations in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene. *CFTR* is a membrane protein anion channel that regulates the electrolyte composition of mucus. With mucus homeostasis disrupted, CF patients experience digestive issues that reduce nutrient absorption and respiratory complications with frequent lung infections, to name a few symptoms. Early diagnosis, facilitated by a positive newborn screening, results in substantially improved outcomes through various proactive treatments – unfortunately, there is no cure.

CF is inherited in an autosomal recessive fashion and affects all racial and ethnic groups at varying rates and with varied mutations but, is most prevalent in Caucasians. In 2007, Michigan's Newborn Screening (NBS) laboratory screened for CF using a 1st tier Immunoreactive Trypsinogen (IRT) assay, which is elevated in the blood of CF patients. Then, as a 2nd tier test, the top 4% of elevated IRT samples are reflexed to a DNA assay for mutations in *CFTR*. Since 2017, the NBS laboratory has utilized a 60-variant *CFTR* panel as the 2nd tier DNA assay however, there are over 2000 known CF variants. To improve screening for Michigan newborns, we are currently validating a Next Generation Sequencing (NGS) method. This new assay replaces the 60-variant panel with an 139-variant panel.

Optimization was necessary for the 139-variant panel because dried blood spot specimens (DBS) yield less DNA than whole blood specimens. Additionally, the assay has been adapted for automation on the NBS laboratory's Eppendorf epMotion[®] liquid handling robots to increase work flow efficiency and reduce the possibility of analytical errors. These adaptations have resulted in a robust and accurate sequencing method for the analysis of *CFTR* in NBS specimens. The expansion of our panel to 139 variants through transition to this NGS-based assay for 2nd tier CF screening will increase detection rates, reduce false negatives, and improve health equity for Michigan's newborns.



CFTR gene
Image provided by the Cystic Fibrosis Foundation



Health problems associated with cystic fibrosis
https://en.wikipedia.org/wiki/Cystic_fibrosis

What is a Laboratory Developed Test?

On April 29, 2024, the U.S. Food and Drug Administration (FDA) announced a final rule amending regulations regarding enforcement surrounding the use of Laboratory Developed Tests (LDTs) including a policy to phase out LDTs (with certain enforcement discretion) over the course of the next four years.

This has laboratory submitters asking the question “What is a Laboratory Developed Test”?

The FDA defines LDTs as “in vitro diagnostic products (IVDs) that are intended for clinical use and designed, manufactured, and used within a single clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meets the regulatory requirements under CLIA to perform high complexity testing.” ([source](#))

In short, LDTs are tests designed, developed, and performed by a single laboratory.

Another way to understand LDTs is to understand their opposite. In other words, if a test isn't an LDT, what is it? Laboratory tests that are not LDTs are tests that have been submitted to the FDA by their manufacturers for approval, clearance, or exemption as determined by the FDA prior to being sold to laboratories for implementation. The process of submission for these tests is extensive and, often, very costly. Frequently, tests that are submitted to the FDA are those that will be manufactured for sale to many laboratories to recoup those costs.

Why would a laboratory develop a LDT and not use an FDA approved, cleared, or exempt test?

There are many reasons a laboratory may choose to implement an LDT. One example is that the laboratory is serving a patient population that would benefit or requires a test that isn't available commercially (in other words, there isn't FDA approved/cleared test). A second example would be when the available FDA approved-cleared tests includes a condition of use that does not fit the needs of the laboratory's patient population

(i.e., patient age, specimen stability from collection to testing). In this instance, the laboratory may choose to make changes to the use of the test. An FDA approved-cleared test that is run outside of the conditions of use originally submitted to the FDA is also a LDT.

More information on the FDA's final rule regarding laboratory tests and their intent to phase out their use (with enforcement discretion) is available through the links in the first paragraph of this article.

