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









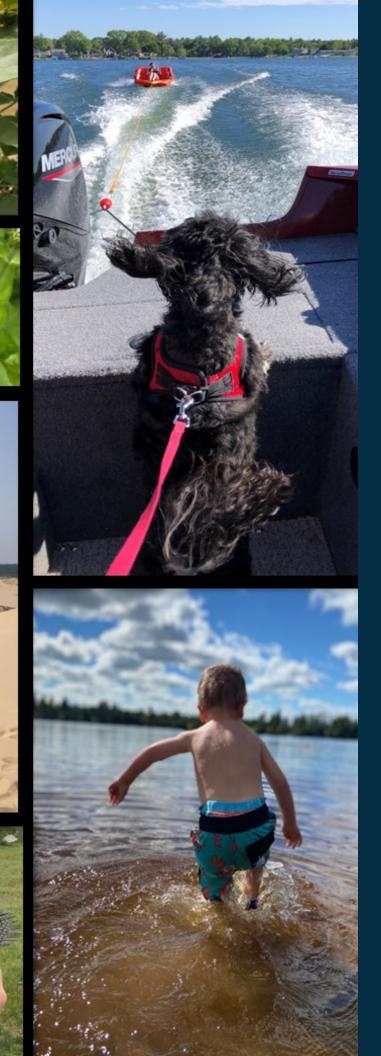


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Bureau Vision

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 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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Editor: Teresa Miler



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Stay Current Visit our webpage at Michigan.gov/MDHHSLab and click on "What's New?"

New Internal Audit Tool Available

Every laboratory is required to perform routine assessments to ensure activities across the entire path of workflow (pre-examination, examination, and post-examination phases) are meeting expectations. Assessments include many items, such as, but not limited to, proficiency testing, competency assessments, and both internal and external inspections or audits.

Internal audits, while an essential part of the assessment process, can be daunting to organize.

In 2018, the Association of Public Health Laboratories (APHL) Laboratory and System Standards Committee organized a subcommittee to enhance a guidance document, provided by the Centers for Disease Control and Prevention (CDC), aimed at making the internal audit process easier for high-complexity testing laboratories.

This now updated document has multiple features to ease the process of internal auditing. These include an interactive table

of contents, a summation of each requirement with a direct link to the Code of Federal Regulations, evidence of compliance examples, an area to take notes, an editable header so portions of the document can be used for target audits, and requirements that are color coded based on their specific Clinical Laboratory Improvement Amendments (CLIA) role.

The <u>APHL Guide for CLIA Internal Audits Related to High Complexity Testing</u> is now complete and available for all laboratories to utilize.

Spotlight on Mental Wellness

Not feeling like yourself? "Stay Well" may be able to help.

It's fair to say the pandemic has taken an emotional toll on all of us. As a society, we are still recovering from cultural, economic, and personal upheaval brought about by COVID-19 and many of us are now struggling with fluctuations of anxiety or sadness we never experienced before.

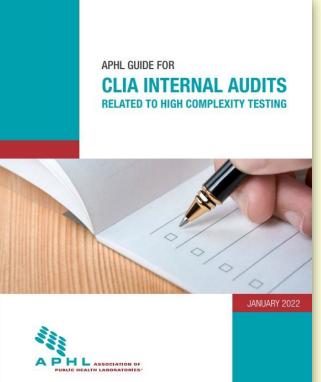
Good news: there is help available from Stay Well, a program created by MDHHS behavioral health professionals at the start of the pandemic. Stay Well offers a variety of services and educational opportunities to help Michiganders cope with the emotional challenges of COVID-19.

One of the program's longest-running services is the Stay Well counseling line. Free, confidential, emotional support is available 24 hours a day, 7 days a week on the Stay Well line. Just dial **1-888-535-6136 and press "8"** at the prompt. Stay Well counselors help callers understand their feelings and reactions to a disaster like the COVID-19 pandemic. Counselors are taught to listen, not judge, and help callers develop coping strategies.

Learn about your mind – and how to help others

Why do I feel so burned out? What does a panic attack feel like? How will I know if my teenager is depressed? How can I deal with my ongoing grief?





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Spotlight on Mental Wellness

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Stay Well answers these questions and others during educational webinars presented by staff outreach specialists. These can be single, one-hour Zoom presentations, such Addressing Burnout or Psychological First Aid *for Teachers,* or they can be weekly online workshops such as, *Staying Well: an emotional health workshop for teens*. A long-running webinar series called <u>Coping with Grief and Loss</u> has attracted regular participants who discuss the day's topic and share stories of support. To register for an upcoming webinar or series, or to view a recording of a past webinar, visit Michigan.gov/StayWell.

Gaining support from like-minded people

Another mainstay of the Stay Well program: online discussion groups that meet weekly on Zoom. Would it feel good to talk to others who've gone through COVID experiences similar to yours? Stay Well counselors conduct support groups for older adults, parents, teens and those who are grieving. Or you can join the *<u>Be Kind to your Mind</u>* support group, which is open to anyone. To register, visit Michigan.gov/StayWell and click the button for Online Discussion Groups.

Coming soon from Stay Well

Beyond the Plate: A "non-diet" workshop series to expand your perspective of food and wellness. Presented by a registered dietitian and certified intuitive eating counselor, this series will focus on the physical, mental and emotional health implications of what we eat. This series starts mid-August: Watch for a registration link on Michigan.gov/StayWell.

Additional things to browse on the Stay Well website

 An animated video series called <u>"Cultivating Joy:"</u>full of feelbetter tips and insights.



- ◆ <u>*T.A.P. (Take a Pause)*</u> brief videos demonstrating mindfulness exercises, for whenever you need to restore calm and focus.
- Stay Well's "Summer Resilience Series" recordings, on practices designed to restore mental well-being (good nutrition, yoga, meditation, exercise for depression, healing arts and music).
- Other video resources to learn more about managing emotional distress.
- <u>Behavioral health guides</u> for all populations.



Kimberly McCullor, PhD and Carrie Anglewicz, MS

In March 2022, the Bureau of Laboratories (BOL) surveyed Michigan clinical laboratories that perform Gram stains and antimicrobial susceptibility testing on specimens from at least one of the following: lower respiratory tract, wound, or blood cultures. Of the 52 sites surveyed, 22 sites responded (42% response rate).

The purpose of the survey was to understand antimicrobial susceptibility testing (AST) capacity within Michigan and to identify needs based on systems and methodologies which BOL can provide resources and training on best practices.

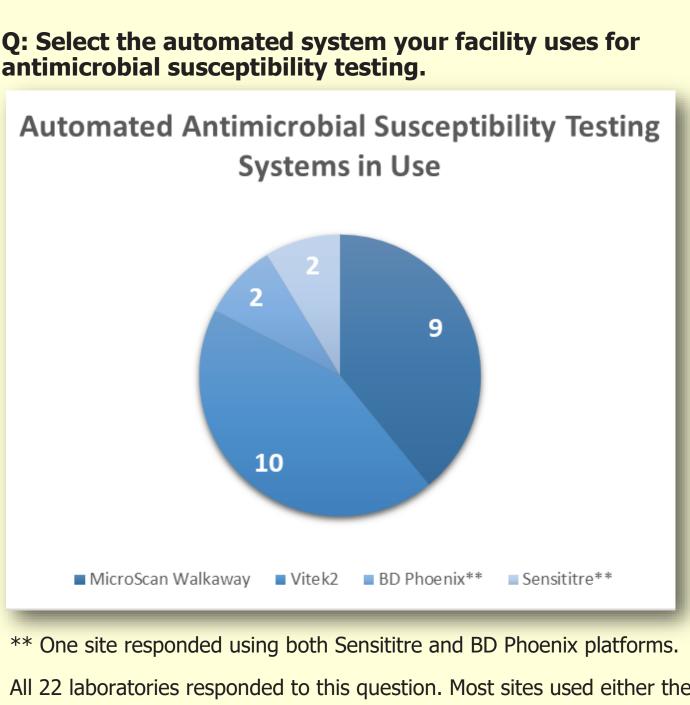
The scope of the questions included growth-based (automated and manual) methodologies and molecular platforms. The survey also assessed the readiness of clinical laboratories to implement upcoming accreditation changes regarding AST.

Excerpts from the survey are as follows:







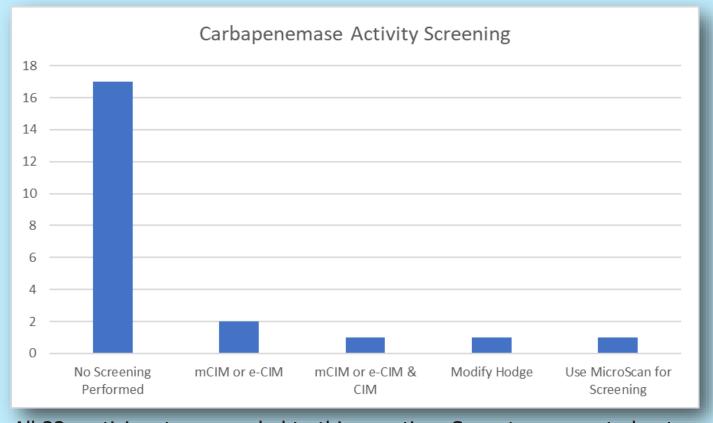


All 22 laboratories responded to this question. Most sites used either the MicroScan Walkaway or Vitek2 system for automated susceptibility testing. One site listed using BD Phoenix and Sensititre.

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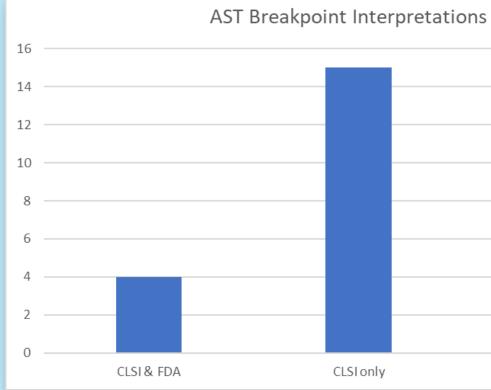
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Q: What phenotypic test (if any) is your facility using to screen for carbapenemase activity?



All 22 participants responded to this question. Seventeen reported not screening for carbapenemase activity. Two sites reported using the Modified Carbapenem Inactivation Method (mCIM) or EDTA-Modified Carbapenem Inactivation Method (e-CIM) and one site reported using the mCIM or e-CIM and Carbapenem Inactivation Method (CIM) screening method. One lab responded to relying upon their MicroScan Automated system to alert to carbapenemase activity and one lab responded to using the Modified Hodge Method to screen. No laboratories reported using the NG-Test Carba 5, Carba NP, nor the Rapid CARB Blue assays. No laboratories reported using the E-test for metallo-beta lactamase screening.

Q: Which antimicrobial susceptibility testing breakpoints does your facility use and from what year?



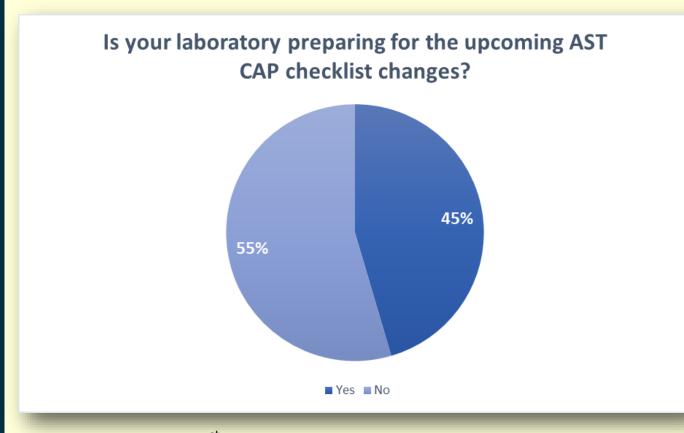
This question was included to assess which guidelines sites were using (Clinical Laboratory Standard Institutes' (CLSI) or FDA) and if they were using the most current interpretation guidelines.

All participants answered the first portion of the question asking which interpretations are used for AST. Majority of respondents reported using the CLSI breakpoint interpretations alone (n=15). Few sites reported using both (n=4) or FDA only (n=3). When asked for the publication year, half did not provide a response.

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Q: Is your laboratory preparing for the 2024 changes to CAP requirements involving annual AST testing reviews?

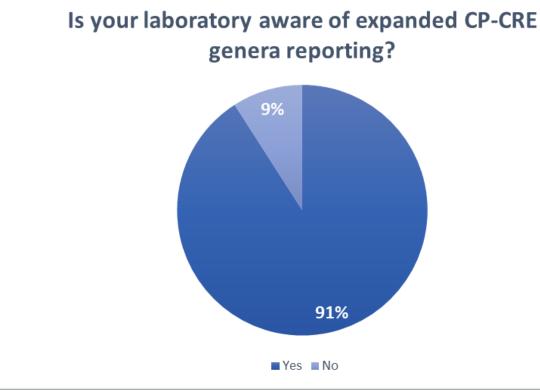


Beginning January 1st, 2024, new College of American Pathologists (CAP) guidelines will go into effect requiring clinical laboratories to update interpretations and to ensure appropriate validation and verification studies have been performed. The changes will help improve quality of AST by ensuring sites are assessing which guidelines are being used but will require a substantial amount of effort and knowledge.

We posed this question to learn whether sites are undergoing preparations for the CAP checklist changes. The survey data is to be used to determine whether it would be of benefit for Bureau of Laboratories to provide additional materials or training on the updated CAP checklist.

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Q: Are you aware of changes to the Michigan Reportable Disease list to now include mandatory submissions to Bureau of Laboratories of Carbapenemase Producing-Carbapenem **Resistant Enterobacterales (CP-CRE) all genera?**



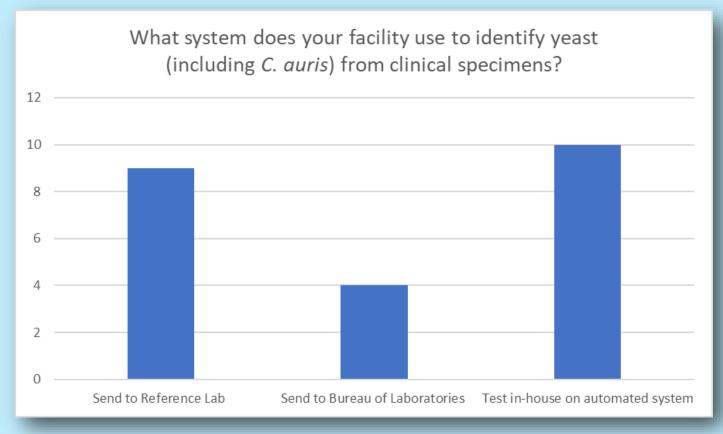
All sites responded to this question with the majority stating that their laboratory was aware of the CP-CRE expanded genera requirements for reporting and isolate submission.





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Q: What system does your facility use to identify yeast (including *C. auris*) from clinical specimens?



Twenty-one sites responded to this survey question. The majority of respondents report to using automated systems for the identification of yeast isolates. Two labs reported performing in house automated identification and sending to the Bureau of Laboratories for confirmatory testing.

Of the ten sites reporting automated identification, the majority reported to using mass spectrometry assays (MALDI-TOF) for yeast identification (2 reported using the Vitek MS and 5 using the Bruker Biotyper). Two sites reported using the Vitek 2 and one reported using MicroScan. According to Continued from page 7...

the CDC, MALDI-TOF is the standard for species level identification of yeast as other assays reliant upon biochemical characteristics tend to mis-ID *Candida auris* as other species.

The BOL will use the results of the survey to outline opportunities for outreach on AST best practices including E-test and Kirby-Bauer. Training and support for implementing the CAP accreditation changes is also planned.

Contact Carrie Anglewicz at <u>anglewiczc@michigan.gov</u> for a copy of the results of the full survey or for questions or suggestions for AST related issues.



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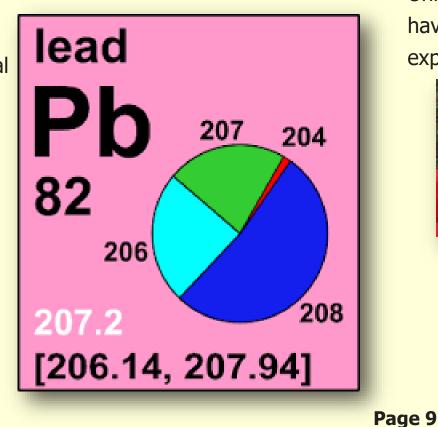
A New Tool to Identify Household Sources of Lead Exposure

Bureau of Laboratories, Chemistry & Toxicology Division, Trace Metals Unit

Lead is a non-essential constituent of the body and is present because of its existence in our environment due to its use in manufacturing of ammunition, metal alloys, and batteries. Exposure to lead can have serious health effects for both children and adults. Children under the age of six, pregnant women, or a developing fetus can experience particularly dangerous health effects from lead exposure.

The Analytical Chemistry section at the Bureau of Laboratories (BOL) recently validated a new methodology to assist in identifying household sources of lead exposure in children. The methodology examines lead

isotopic ratios on clinical specimens and environmental samples to differentiate sources of environmental lead. This is carried out by associating the isotope ratio present in the child's blood with that of environmental sources. This methodology makes it possible to further investigate sources of lead poisoning and lend a degree of confidence towards the source responsible for the poisoning when there may be multiple sources present.





When a child has been identified as having an elevated blood lead level, the goals are to identify the source of lead and stop the lead exposure. A vast majority of the time this is accomplished through the analysis of lead in blood specimens and environmental samples, e.g., settled dust, soil, spices, teas, and supplements. At times, lead is still present in the child's environment even after mitigation techniques have been employed. Lead isotope ratio analysis can supplement lead hazard evaluations in identifying sources of lead exposure in children when the current mitigation techniques have been exhausted. The Trace Metals Unit is excited this tool identifies household sources of lead, and we have the ability to assist Michigan citizens with prevention of lead exposure.



