



Mycobacterium chimaera and *Candida auris*: EMERGING THREATS IN THE SENTINEL LABORATORY

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Mycobacterium chimaera and *Candida auris* have emerged globally in recent years as a threat to both public and patient health. *M. chimaera* is a nontuberculous mycobacterium (NTM) that was first proposed as a novel species in 2004.¹ Previously, the organism was classified as an unnamed *Mycobacterium* sequevar within the *M. avium*–*M. intracellulare*–*M. scrofulaceum* group (MAIS). The name *M. chimaera* was derived from the mythological creature consisting of parts from three different animals. Now the organism is classified as one of eight species in the *Mycobacterium avium* complex (MAC): *M. avium*, *M. intracellulare*, *M. marseillense*, *M. timonense*, *M. bouchodurhonense*, *M. colombiense*, *M. vulneris*, and *M. chimaera*.² The MAC organisms cause chronic lung disease.

Most recently, *M. chimaera* has been associated with infections acquired from contaminated heater-cooler units manufactured by LivaNova PLC.³ These units are used to regulate the body temperature of patients during open-chest, coronary artery bypass grafting. Since 2015, infections have been reported in the United States, United Kingdom, Denmark, Germany, Switzerland, Netherlands, Australia and New Zealand.^{4–6} Infections are presumed to be acquired through airborne transmission of aerosolized bacteria from the unit's water tanks.⁷

The main challenge for the sentinel clinical laboratory is the lack of an identification system to accurately identify

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and differentiate *M. chimaera* from other NTM. Both the Hologic AccuProbe *M. intracellulare* and AccuProbe *M. avium* complex DNA probes cross-react with *M. chimaera*.⁸ Similarly, MALDI-TOF mass spectrometry has been demonstrated to lack specificity in differentiating *M. chimaera*, *M. intracellulare*, *M. colombiense*, *M. marseillense* and *M. yongonense*.⁹

Reliable identification of *M. chimaera* can only be performed using DNA sequencing-based methods, such as 16S rRNA gene, *rpoB*, internal transcribed spacer (ITS) or whole genome sequencing.¹⁰ Other than the largest university-based research hospitals, it is unlikely that sentinel clinical laboratories will have the resources to invest in these high-complex technologies. Therefore, on a case-by-case basis, the Bureau of Public Health Laboratories (BPHL) offers definitive identification of *M. chimaera* through collaboration with the National Jewish Health Mycobacteriology Laboratory in Denver, Colorado.

Candida auris presents another globally emerging pathogen that cannot be easily identified in the sentinel clinical laboratory due to similarities with other organisms. The name *C. auris* is derived from the source from which it was first isolated in 2009: external ear canal discharge of a patient in Japan.¹¹ Since then it has been detected in multiple countries, including 35 cases in the United States, as of February 2017. It causes bloodstream and other invasive infections.

Common biochemical analytical methods most often misidentify the organism as other yeasts, such as *Candida haemulonii*, *C. duobushaemulonii*, *C. famata*, *C. sake*, *Saccharomyces cerevisiae*, and *Rhodotorula glutinis*.¹² Specialized methods are required for accurate identification of *C. auris*. MALDI-TOF has been demonstrated as a useful identification method; however, before a reliable identification could be obtained, laboratories first had to generate and validate spectra of known *C. auris* isolates for systems where spectra were not present in the instrument database.^{13,14} More sophisticated molecular identification methods for yeasts are based on sequencing the D1/D2 region of the large subunit (25-28S) ribosomal DNA.¹⁵ Species identification of *C. auris* has been confirmed by ITS rRNA gene sequencing¹⁶ and whole genome sequencing.¹⁷ Again, the highly complex methods are required to definitively identify *C. auris* and suspect isolates should be sent to public health laboratories for referral to the Centers for Disease Control and Prevention's Mycotic Diseases Division.

From a public health as well as patient health perspective, the importance of an accurate identification of *C. auris* relates to the resistance of the organism to multiple antifungal drugs^{12,17} and its association with outbreaks in health care facilities.¹⁸ The latter necessitating infection control measures where patients infected with, or colonized by, *C. auris*, be placed in single rooms on Standard and Contact Precautions. Some isolates have been found to have elevated minimum inhibitory concentrations (MIC) to drugs in all three major classes of antifungal medications. Specific breakpoints for *C. auris* have been based on those established for closely

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related *Candida* species,¹⁷ but since correlation to clinical outcome is not currently known there is only tentative guidance regarding susceptibility breakpoints.¹⁹

Candida auris should be suspected when the following conditions exist:

1. Traditional biochemical methods for yeast identification result in one of the six commonly misidentified species listed above;
2. Resistance to one or more antifungal drug classes;
3. *Candida* infections (species unknown) where patients are not responding to antifungal therapy;
4. Increase of unidentified *Candida* species infections in a patient care unit, including increases in isolation from urine specimens.

The Bureau of Public Health Laboratories can assist sentinel clinical laboratories in testing for *M. chimaera* and *C. auris* when appropriate. Isolates meeting the acceptance criteria along with any case history information should be provided to BPHL.

Contact Betsy Jones in the Mycobacteriology Laboratory at 904-791-1638 (Betsy.Jones@flhealth.gov) to coordinate testing for suspect *M. chimaera* and *C. auris* isolates.

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BPHL INTRODUCES NEW MOLECULAR ASSAY TO DETECT CARBAPENEM RESISTANT *ENTEROBACTERIACEAE*



The Bureau of Public Health Laboratories (BPHL) is excited to announce additional testing capability for Carbapenem Resistant *Enterobacteriaceae* (CRE) at the Jacksonville laboratory. CRE are a serious public health threat especially in health care settings where these bacterial organisms are transmitted from person to person often via hands of health care personnel or contaminated medical equipment.¹ These bacteria are difficult to treat because they are often resistant to all beta-lactam antibiotics and frequently co-resistant to other antibiotics, leaving very few options.

Infection with CRE has a high rate of mortality. In one report CRE was associated with mortality rates as high as 50 percent.² There is an increased effort to prevent, detect and treat multi-drug resistant organisms, as Antimicrobial Resistance (AR) is becoming a global threat, requiring the most aggressive infection control measures. The Florida Department of Health, as part of this effort, is funded through the Centers for Disease Control and Prevention (CDC), to establish an Antimicrobial Resistance Surveillance Program. In conjunction with this program, BPHL will be expanding its capabilities to perform testing for drug resistant organisms.

BPHL currently uses the Modified Hodge Test to detect CRE. However, the phenotypic test cannot detect all the gene families found in CRE organisms and there is a 48-72-hour turnaround time that involves subjective reading of the test results. BPHL will be changing soon to the modified Carba-R molecular assay.

Implementing the Cepheid Xpert[®] Carba-R molecular assay in addition to the phenotypic test will allow for faster and more accurate identification of CRE and rapid response to outbreaks. This efficient automated testing system is FDA-approved with a run-time of less than one hour and uses real-time PCR to detect and differentiate five of the most common carbapenemase gene families: KPC, NDM, VIM, IMP-1, and OXA-48 (including OXA-181 and OXA-232).

As part of the Antimicrobial Resistance Laboratory Network (ARLN) with public health laboratories around the country, BPHL has performed and validated two CRE diversity panels from the CDC's AR Isolate Bank as well as successfully completing a panel provided by a local hospital of unknown multi-drug resistant enteric organisms. With validations completed, BPHL is building a network of collaborators including its AR Regional Laboratory, the Tennessee State Public Health Laboratory, who can provide additional or confirmatory testing and outbreak support for these pathogens, when needed.³ In addition, BPHL will be performing outreach with hospitals, and other health care facilities in Florida to collect and submit CRE colonization samples and any suspected or questionable CRE organisms for susceptibility testing and, if appropriate, fingerprinting to determine relatedness.

This testing and surveillance will lead to a better understanding of the extent of CRE in our state, improved infection control measures and, ultimately, better patient care. Although some people are at greater risk than others, no one can

BPHL INTRODUCES NEW MOLECULAR ASSAY TO DETECT CARBAPENEM RESISTANT *ENTEROBACTERIACEAE* (CONTINUED)



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completely avoid the risk of antimicrobial-resistant infections. Only through concerted commitment and action will we succeed in reducing this threat.

Please contact Kendra Edwards at kendra.edwards@flhealth.gov or 904-791-1624 if you are interested in submitting CRE for testing.



Kendra Edwards
BPHL Jacksonville

References.

1. <https://www.cdc.gov/hai/organisms/cre/cre-clinicianfaq.html>
2. <https://www.cdc.gov/hai/organisms/cre/index.html>
3. <https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-networks.html>

2017 DIVISION 6.2 INFECTIOUS SUBSTANCES PACKAGING AND SHIPPING TRAINING

Infectious Substances Packaging and Shipping Training is required every two years to maintain certification. Saf-T-Pak has been contracted to conduct 20 live classes throughout the state. **All classes are scheduled from 9:00 am to 4:30 pm local time but may run longer.**

This training covers general awareness/familiarization, function specific, safety, and security awareness as required by the 49CFR 172.704. A hands-on exercise will emphasize how to properly package and ship Category A and Category B infectious substances and other dangerous goods, such as dry ice, by air and ground. Upon successful completion of the written assessment, a certificate of training will be awarded. This course offers five (5) Continuing Education Unit (CEU) contact hours. **Space is limited and advance registration is required.**

To register, please log in to your **FL TRAIN** account <https://fl.train.org/Desktopshell.aspx>. If you do not currently have a FL TRAIN account, click the box "Create Account" and complete the required information. Once registered as a TRAIN user, the course can be found by typing in the search box either "FDOH 2017 Division 6.2 Infectious Substances Packaging and Shipping" or the course identification number 1068198. Click on the registration tab. If you would like to receive CEUs, select credit type and type your license number in the box. If you do not have a license, select "none" and type "none" in the box. Then select the session you wish to attend by clicking on the "Get Approval" button. You will receive an email notification once you are approved only if you elect to receive emails from TRAIN.

If you have questions or problems creating an account with TRAIN, please contact Betty Wheeler at betty.wheeler@flhealth.gov or at 904-791-1568 or Leah Kloss at leah.kloss@flhealth.gov or 813-233-2278.

2017 DIVISION 6.2 INFECTIOUS SUBSTANCES PACKAGING AND SHIPPING TRAINING SCHEDULE



1. Tuesday, March 14, 2017	Florida Department of Health-Escambia - 1295 W. Fairfield Dr, Pensacola, FL 32501 Room #302/303
2. Wednesday, March 15, 2017	Florida Department of Health-Okaloosa – 810 E. James Lee Blvd. Crestview, FL 32539 Room #73 A&B
3. Wednesday, March 29, 2017	Florida Department of Health-Bay– 597 W 11 th St, Panama City, FL 32401 Auditorium
4. Tuesday, April 4, 2017	Florida Department of Health-Marion - 1801 SE 32 nd Ave, Ocala, FL 34471 Auditorium # 1&2
5. Wednesday, April 12, 2017	Department of Agriculture and Consumer Affairs – Conner Administration Building, 3125 Conner Boulevard, Tallahassee, FL 32399 Eyster Auditorium
6. Wednesday, April 26, 2017	Florida Department of Health-Volusia - 1845 Holsonback Drive, Daytona Beach, FL 32117 Main Conference Room 516A
7. Friday, April 28, 2017	Florida Department of Health/Bureau of Laboratories-Jacksonville, 1217 Pearl Street, Jacksonville, FL 32202 2 nd Floor Porter Auditorium
8. Tuesday, May 2, 2017	Florida Department of Health-Lee - 83 Pondella Dr, N Ft Myers, FL 33903 – Large Conference Room
9. Wednesday, May 3, 2017	DeSoto County EOC – 2200 NE Roan Street, Arcadia, FL 34266 – Meeting Room
10. Monday, May 8, 2017	Florida Department of Health/Bureau of Laboratories-Tampa, 3602 Spectrum Blvd, Tampa FL 33612 Conference Ctr
11. Wednesday, May 10, 2017	Florida Department of Health-Miami-Doral - 8600 NW 17th St, Miami, FL 33126 2nd Floor Conference room
12. Thursday, May 11, 2017	Florida Department of Health-Miami-Doral - 8600 NW 17th St, Miami, FL 33126 2nd Floor Conference room
13. Monday, May 15, 2017	Florida Department of Health-Orange - 6101 Lake Ellenor Dr, Orlando, FL 32809 Auditorium
14. Tuesday, May 16, 2017	Florida Department of Health-Orange - 6101 Lake Ellenor Dr, Orlando, FL 32809 Auditorium
15. Friday, May 19, 2017	Florida Department of Health/Bureau of Laboratories-Tampa, 3602 Spectrum Blvd, Tampa FL 33612 Conference Ctr
16. Monday, May 22, 2017	Florida Department of Health-Palm Beach - 800 Clematis St, West Palm Beach, FL 33401 Auditorium
17. Tuesday, May 23, 2017	Florida Department of Health-Palm Beach - 800 Clematis St, West Palm Beach, FL 33401 Auditorium
18. Monday, June 26, 2017	Florida Department of Health-Broward – 780 SW 24th St. FT Lauderdale FL 33315 Administrative Auditorium-2nd floor
19. Tuesday, June 27, 2017	Florida Department of Health-Broward – 780 SW 24th St. FT Lauderdale FL 33315 Administrative Auditorium-2nd floor
20. Thursday, June 29, 2017	Florida Department of Health/Bureau of Laboratories-Jacksonville, 1217 Pearl Street, Jacksonville, 32202 FL 2 nd Floor Porter Auditorium

BIOSAFETY RISK ASSESSMENT AND LAB BIOSAFETY TRAINING



The Bureau of Public Health Laboratories biosafety outreach officer (BOO) is currently offering a course in biosafety risk assessment and laboratory biosafety to clinical laboratory institutions. The training consists of two sessions that are approximately one hour each and offered on-site at no charge to the facility. The first session discusses biosafety risk assessment and the second session focuses on biosafety in the clinical laboratory.

Biosafety risk assessment is a systematic process of evaluating the potential risks involved in a laboratory procedure and determining the measures needed to manage any gaps or risks identified. The BOO has created standard operating procedures and resource documents to assist clinical hospital laboratories in biosafety risk assessment and laboratory biosafety. This session will train clinical laboratory personnel how to use these documents to perform risk assessments in their laboratory.

The second session is for anyone who works in the laboratory or is responsible for a safe working environment. Topics include general laboratory biosafety, the use of biological safety cabinets (BSCs), choosing correct personal protective equipment, proper use and removal of gloves, and spill cleanup. This training awards Florida clinical laboratory and nursing continuing education credits.

For more information or to schedule training, contact Ed Kopp at (813)233-2260 (Edgar.Kopp@flhealth.gov)



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CHEMICAL THREAT (CT) PREPAREDNESS TRAINING



The CT laboratory coordinators continue to reach out to the health and medical community by offering training for CT preparedness at hospitals and county health departments (CHDs). This training covers chemical terrorism awareness and the collection of clinical specimens after a chemical terrorism event. Hospital and CHD staff play an important role in the response to a chemical exposure event since clinical specimens will be collected for analysis. For your convenience and to increase participation, this training can be presented at your facility. Each course lasts approximately one hour with one 15-minute break between courses. Florida clinical laboratory and nursing continuing education credits will be offered. Training manuals, "hands on" exercise materials, and CT preparedness kits will be provided. This training is recommended for physicians, nurses, epidemiologists, emergency department personnel, phlebotomists, hospital and health department laboratory personnel, and others who may collect clinical specimens. Contact the CT laboratory coordinators in your region for more information (see the Bureau of Public Health Laboratories Directory on the back of this document for contact information).

LABORATORY RESPONSE NETWORK (LRN) TRAINING—BIOLOGICAL DEFENSE

The Bureau of Public Health Laboratories is currently offering an LRN sentinel laboratory training course at no cost to you at your facility. This training follows the American Society for Microbiology (ASM) Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases. Scheduling the training at your facility is a relatively easy process.

Determine when you would like to have the training and how many people will be attending. A time will be set up that is convenient for all. The training materials are provided, as well as the biodefense reference manuals for your laboratory.

***"at no cost
to you at
your facility"***

The training syllabus includes: 1) an overview of the LRN; 2) the ASM protocols for ruling out potential bioterrorism agents and how to refer a sample to the state LRN Public Health Reference Laboratory when a bioterrorism agent cannot be ruled out; 3) the role of the sentinel laboratory in responding to pandemic influenza; 4) a brief introduction to packaging and shipping of infectious substances; 5) an introduction to the CDC Select Agent Program; and 6) the College of American Pathologists Laboratory Preparedness Exercise (CAP LPX).

This class awards Florida clinical laboratory continuing education credits based on five hours of instruction. Please contact Betty Wheeler at (904) 791-1568 (Betty.Wheeler@FLhealth.gov) to schedule a class for your facility.

**FLORIDA DEPARTMENT OF HEALTH
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Bioterrorism Events	24/7 – after hours		888-276-4130	
Chem. Threat Events	24/7 – after hours			904-271-1593
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