



**Expanded Carbapenemase Testing Services Frequently Asked Questions (FAQ)  
05/06/2021 Update**

**1. What types of samples should we send?**

- a. Carbapenem-resistant Enterobacterales (CRE): Submit carbapenem-resistant *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, and *Enterobacter* spp. that are resistant to imipenem, meropenem, doripenem, or ertapenem by standard antimicrobial susceptibility testing (AST) methods (i.e., minimum inhibitory concentrations (MIC) of  $\geq 4$   $\mu\text{g}/\text{mL}$  for doripenem, imipenem or meropenem, or  $\geq 2$   $\mu\text{g}/\text{mL}$  for ertapenem).
  - If your institution uses nonstandard AST, we will review the provided AST results and perform testing on a case-by-case basis.
- b. Carbapenem-resistant *Pseudomonas aeruginosa* (CRPA): Submit carbapenem-resistant *P. aeruginosa* isolates, defined by resistance to imipenem, meropenem, or doripenem by standard AST methods (i.e., MIC of  $\geq 8$   $\mu\text{g}/\text{mL}$ ) **and** nonsusceptible (i.e., intermediate or resistant MIC  $\geq 16$   $\mu\text{g}/\text{mL}$ ) to cefepime or ceftazidime.
  - If your institution uses nonstandard AST or does not test all of the requested drugs, we will review the provided AST results and perform testing on a case-by-case basis.
- c. Other CRE not listed in (1.a): At this time, the CDPH Healthcare-Associated Infections (HAI) Program will provide approval on a case-by-case basis for testing of other CRE, including *Providencia*, *Proteus*, *Morganella*, *Citrobacter*, and *Serratia* spp. Please contact the HAI Program at [HAIprogram@cdph.ca.gov](mailto:HAIprogram@cdph.ca.gov) prior to submission. If accepted, these isolates will either be tested at MDL or the Antibiotic Resistance Laboratory Network (AR Lab Network) regional laboratory. CRE isolates not listed in (1.a.) that are submitted without prior approval will not be tested.
- d. Pan-nonsusceptible CRE and CRPA isolates: A pan-nonsusceptible (pan-NS) isolate is defined as an isolate nonsusceptible to all drugs tested to date. Submit all pan-nonsusceptible CRE (regardless of species) and CRPA to MDL for surveillance purposes. These isolates will either be tested at MDL or an AR Lab Network regional laboratory. If these isolates are not included in 1a or 1b, please contact the HAI Program at [HAIProgram@cdph.ca.gov](mailto:HAIProgram@cdph.ca.gov) and MDL Bacterial Diseases Section (BDS) at [Hillary.Berman-Watson@cdph.ca.gov](mailto:Hillary.Berman-Watson@cdph.ca.gov) prior to submitting isolates for submittal criteria, forms, and shipping instructions.
- e. Pan-nonsusceptible and carbapenem-resistant *Acinetobacter baumannii*: Carbapenem-resistant *Acinetobacter baumannii* (CRAB) isolates are defined by resistance to imipenem, meropenem, or doripenem by standard susceptibility testing methods (i.e., MIC of  $\geq 8$   $\mu\text{g}/\text{mL}$ ). Pan-NS *A. baumannii* and CRAB isolates may be submitted directly to the AR Lab



Network regional lab for testing as a part of their Targeted Surveillance program with coordination of the HAI program and MDL. The AR Lab Network performs bacterial identification and confirmation, AST, and PCR testing to detect carbapenemase genes for CRAB isolates. Slants and shipping materials can be provided to submitting clinical laboratories at no charge. Detailed information for submittal criteria, forms, and shipping instructions can be found at the [AR Lab Network site](https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthLaboratories/ARLNLabTestMenu) (https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthLaboratories/ARLNLabTestMenu). Please contact the HAI Program at [HAIprogram@cdph.ca.gov](mailto:HAIprogram@cdph.ca.gov) and BDS/MDL at [Hillary.Berman-Watson@cdph.ca.gov](mailto:Hillary.Berman-Watson@cdph.ca.gov) for any assistance.

- f. Isolates from patients being investigated as part of a cluster or outbreak, or containing novel resistance mechanisms may be referred for Whole Genome Sequencing (WGS) by the CDPH HAI Program. In general, approval is required by the HAI Program and the MDL Molecular Characterization Unit (MCU) prior to submission. Contact the HAI Program at [HAIprogram@cdph.ca.gov](mailto:HAIprogram@cdph.ca.gov) and MDL MCU at [Rituparna.Mukhopadhyay@cdph.ca.gov](mailto:Rituparna.Mukhopadhyay@cdph.ca.gov) or [Matthew.Sylvester@cdph.ca.gov](mailto:Matthew.Sylvester@cdph.ca.gov) prior to submitting isolates for submittal instructions.
- g. Isolates must be identified to at least the genus level by the submitter.
- h. Mixed cultures received by MDL will not be tested.

## 2. How should samples be sent in for the laboratory testing?

- a. For CRE and CRPA isolates submitted for modified Carbapenem Inactivation Method (mCIM) for detection of carbapenemase production, polymerase chain reaction (PCR) for detection of carbapenemase genes, and routine submittal of pan-NS isolates for surveillance purposes, submit isolates to MDL BDS.
  - Use the MDL barcode submittal form 'MDL\_General\_Electronic\_Submission\_Form'. Under the 'Select Test Requisition' field select the 'Antimicrobial Susceptibility Testing-AST' form. Please type in the relevant information into the form. Information written in by hand is not coded into the barcode. This barcode submittal form can be found at [CDPH's Microbial Diseases Laboratory webpage](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/MDLSubmissionInstructionsandForms.aspx) (https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/MDLSubmissionInstructionsandForms.aspx).
  - Type in the genus, and the species if available, on the submittal form. Provide identification (ID), AST results, phenotypic carbapenemase testing results, and any available molecular testing results. Attach printouts from ID and AST systems to the submittal form.
  - Type in the full name of **the healthcare facility of origin** on the submittal form under "Submitting Facility".
  - Type in the test(s) requested: Phenotypic (mCIM), Molecular (carbapenemase gene detection by PCR), or both.
  - If isolate is pan-NS or being submitted for further testing available through the

- AR Lab Network, please indicate this in the comments section.
- Shipping instructions and submittal forms for testing only available through the AR Lab Network and not MDL will be provided by the HAI Program when testing is approved. Shipping to MDL instead of the AR Lab Network regional lab may result in delays in testing.
- Transport medium: Agar slant or motility deep.
- Ship at ambient temperature.

- b. For WGS, contact MDL MCU for consultation and the appropriate submittal form by emailing [Rituparna.Mukhopadhyay@cdph.ca.gov](mailto:Rituparna.Mukhopadhyay@cdph.ca.gov) or [Matthew.Sylvester@cdph.ca.gov](mailto:Matthew.Sylvester@cdph.ca.gov). Consultation and approval is required prior to submission. Submittal forms and shipping instructions will be provided after approval.

### 3. What is the shipping address?

California Department of Public Health Microbial Diseases Laboratory  
850 Marina Bay Parkway MS B106  
Richmond, CA 94804

### 4. Who can submit isolates for testing?

Isolates will be accepted from the Local Public Health Laboratories **only**. Isolates **will not** be accepted directly from hospitals or other healthcare facilities unless prior arrangements have been made by MDL, and the Local Public Health Laboratories or CDPH HAI Program.

### 5. If I already have molecular testing results can I submit my sample?

**Yes.** CRE and CRPA isolates that have tested negative for known carbapenemase genes by a validated molecular test method can be submitted to MDL for mCIM testing. CRE or CRPA isolates that have tested negative for known carbapenemase genes but positive by a phenotypic test may indicate a novel or unusual carbapenemase; such isolates may be forwarded to the AR Lab Network regional lab for additional characterization. Molecular testing of these isolates will not be repeated at MDL.

### 6. Can isolates be submitted for only real-time PCR testing?

**Yes.** CRE and CRPA isolates determined to be carbapenemase-producers by a phenotypic test but with no PCR performed may be submitted to MDL for carbapenemase gene testing by real-time PCR.

### 7. Can Enterobacterales be submitted for Expanded AST (ExAST) for hard-to-treat infections?

**Yes.** With approval from the HAI Program and MDL, ExAST on CRE isolates that are highly resistant (**non-susceptible to all beta-lactams**) or possess metallo beta-lactamase genes (NDM, VIM, IMP) for

clinical-decision making purposes is available directly through the AR Lab Network regional lab. Detailed information for submittal criteria, forms, and shipping instructions can be found at the [AR Lab Network site](https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthLaboratories/ARLNLabTestMenu) (<https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthLaboratories/ARLNLabTestMenu>). Contact the HAI Program at [HAIProgram@cdph.ca.gov](mailto:HAIProgram@cdph.ca.gov) and BDS/MDL at [Hillary.Berman-Watson@cdph.ca.gov](mailto:Hillary.Berman-Watson@cdph.ca.gov) prior to submitting isolates. Submitting isolates to MDL may result in delays in testing.

#### 8. Can duplicate isolates be submitted for testing?

**No.** Isolates obtained within a 30-day timeframe that are from the same patient, and of the same species, specimen source, and AST profile are considered duplicates. However, if there is a special need to test the duplicate isolates, please contact [HAIprogram@cdph.ca.gov](mailto:HAIprogram@cdph.ca.gov) for approval prior to submission.

#### 9. Can isolates be submitted for WGS only?

**Yes.** Prior approval is required by the HAI Program and MDL prior to submission. Please contact the HAI Program at [HAIProgram@cdph.ca.gov](mailto:HAIProgram@cdph.ca.gov), and MCU/MDL at [Rituparna.Mukhopadhyay@cdph.ca.gov](mailto:Rituparna.Mukhopadhyay@cdph.ca.gov) or [Matthew.Sylvester@cdph.ca.gov](mailto:Matthew.Sylvester@cdph.ca.gov) to get approval to submit isolates for WGS. Once the submission has been approved, the submittal form and shipping instructions will be provided.

#### 10. What is the turn-around-time?

- Results of real-time PCR testing will be available within 7 business days after isolate receipt for genotypic testing; if mCIM testing is performed prior to genotypic testing, PCR results will be available within 7 business days after mCIM testing is completed.
- Results of mCIM testing will be available within 14 business days after isolate receipt for phenotypic testing; if PCR testing is performed prior to phenotypic testing, mCIM results will be available within 14 working days after PCR testing is completed.
- WGS results will be available between within 14 business days after receipt by MCU/MDL.
- Results for isolates forwarded to the AR Lab Network regional lab for further testing will be available by 3 business days for CRE, CRPA and CRAB, and 3 business days for ExAST from time of receipt at that lab.