# Carbapenemase-producing Organism (CPO) Electronic Laboratory Reporting (ELR): Frequently Asked Questions

Title 17, California Code of Regulations, Section 2505[1] requires laboratories to electronically submit reports of all CPO to the California Reportable Disease Information Exchange (CalREDIE). Because the reportable condition includes information on bacteria and genes, markers, or phenotypes, clinical laboratories can encounter challenges when submitting Health Level 7 (HL7) ELR messages to the California Department of Public Health (CDPH). This document is meant to address some of the most commonly asked questions and unique scenarios that laboratories might encounter.

[1] CDPH Reportable Diseases and Conditions (www.cdph.ca.gov/Programs/CID/DCDC/Pages/Reportable-Disease-and-Conditions.aspx)

## Frequently Asked Questions

## 1. What needs to be reported to CalREDIE?

Laboratories should report any:

- Positive phenotypic test result for carbapenemase production, with or without identification of a specific carbapenemase. This includes immunoassays for the phenotypic detection and differentiation of common carbapenemase families, e.g., NG-Test® CARBA 5
- Positive molecular or genotypic test result detecting a carbapenemase gene
- Detection of a carbapenemase gene by whole genome sequencing (WGS)
- Specimen positive for a carbapenemase gene without bacterial species identification, e.g., Xpert® Carba-R rectal swabs, other polymerase chain reaction (PCR)-based culture independent diagnostic tests (CIDT)

All reports must indicate the following:

- Specimen collection date
- Genus and species (when identified)
- Type of specimen tested (e.g., urine)
- Carbapenemase type identified in the CPO (e.g., KPC)
- Facility where the specimen was collected
- Other required patient, provider, and ordering facility demographics listed on page 3, under 'HOW TO REPORT' ELRs on Title 17, California Code of Regulations Section 2505[2]

## 2. My laboratory performs antimicrobial susceptibility testing (AST). Do I need to report AST results when submitting ELR messages for CPO cases?

Laboratories may submit antimicrobial susceptibility testing (AST) results, including minimum inhibitory concentration (MIC) values and interpretation. However, this practice is NOT required.

If submitting AST results, please report using the specialized "parent-child" format of a Health Level 7 (HL7) ELR message to tie susceptibility observations to the initial

[2] Title 17, California Code of Regulations (CCR), Section 2505 (PDF) (https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH Document Library/LabReportableDiseases.pdf)

organism identification observation; e.g., *Klebsiella pneumoniae* would be the parent observation, and the child observations would be the associated AST results.

## 3. My laboratory does not perform carbapenemase testing. Do I need to report carbapenem-resistant organisms (CROs) like imipenem-resistant *E. coli* or meropenem-resistant *Pseudomonas aeruginosa*?

Labs that do not perform carbapenemase-testing do not need to report CRO results, unless mandated to do so by a local health department.

Laboratories should strongly consider submitting isolates for carbapenemase testing at a reference or public health lab.[3] If positive for a carbapenemase, they should be reported via ELR.

## 4. My lab uses a phenotypic test like mCIM or Carba NP to test for the presence of a carbapenemase, but cannot determine the specific type of carbapenemase (e.g., KPC, NDM). How should I submit these results?

Labs that identify carbapenemase production in an isolate but cannot determine the specific type should strongly consider obtaining additional testing to determine carbapenemase type at a reference or public health lab.[4] If not submitting for additional testing, please use the following LOINC[5] and SNOMED[6] codes to submit phenotypic results.

| Analytes | Analytes LOINC | Results | Results SNOMED |
|---|---|---|---|
| Carbapenemase [Presence] in Isolate | 86930-5 | DETECTED | 260373001 |
| Carbapenemase [Type] in Isolate by Carba NP | 74676-8 | DETECTED | 260373001 |

[3] CDPH MDL Carbapenemase Testing Services (www.cdph.ca.gov/Programs/cls/idld/mdl/Pages/MDL-Expanded-Carbapenemase-Testing-Services-FAQs.aspx)
[4] CDPH MDL Carbapenemase Testing Services (www.cdph.ca.gov/Programs/cls/idld/mdl/Pages/MDL-Expanded-Carbapenemase-Testing-Services-FAQs.aspx)
[5] Logical Observation Identifiers Names and Codes (loinc.org)
[6] Systematized Nomenclature of Medicine (www.snomed.org)

Note: Please do *not* use these codes if your lab performs a test for a specific type of carbapenemase. Rather, use the more targeted set of codes for either molecular or immunochromatographic assay tests.

## 5. My laboratory performs carbapenemase testing. Do the results need to be in a parent-child format?

Though this approach is preferred, carbapenemase results are not required to be in the specialized "parent-child" format of a HL7 ELR message relationship to tie carbapenemase identification observations to the organism.

If the carbapenemase result is not in a parent-child format, please ensure that the HL7 ELR message that contains the result shares the same accession number in the SPM2.2.1 segment. See the example HL7 ELR message at the conclusion of this document.

## 6. My laboratory uses a molecular test like the Xpert® Carba-R test to identify carbapenemase type. What LOINC and SNOMED codes should I use?

Labs using a molecular test should use the following LOINC and SNOMED codes to indicate which carbapenemase was detected. Please use the corresponding LOINC code for panel *Carbapenemase resistance genes panel by Molecular genetics method (85502-3)*.[7]

| Analytes | Analytes LOINC | Results | Results SNOMED |
|---|---|---|---|
| blaIMP by Molecular method | 85498-4 | DETECTED | 260373001 |
| blaKPC by Molecular method | 49617-4 | DETECTED | 260373001 |
| blaNDM by Molecular method | 73982-1 | DETECTED | 260373001 |
| blaOXA48 by Molecular method | 85503-1 | DETECTED | 260373001 |
| blaVIM by Molecular method | 85501-5 | DETECTED | 260373001 |
| blaOXA-23 by Molecular method | 85825-8 | DETECTED | 260373001 |
| blaOXA-24 by Molecular method | 85826-6 | DETECTED | 260373001 |

[7] Carbapenemase resistance genes panel by Molecular genetics method (loinc.org/85502-3)

Labs should only submit results for genes which are detected; do not report results for genes that are not detected.

## 7. My laboratory uses an immunochromatographic assay (ICA) like the NG-Test® CARBA 5 test to identify carbapenemase type. How do we report these results?

ICAs that detect the presence of specific carbapenemase types are becoming more common in clinical laboratories. Please use the corresponding LOINC code for *Carbapenemase enzyme panel - Isolate by Rapid immunoassay (RIA)* (101672-4).[8]

| Analytes | Analytes LOINC | Results | Results SNOMED |
|---|---|---|---|
| KPC carbapenemase [Presence] in Isolate by Rapid immunoassay | 101673-2 | POSITIVE | 10828004 |
| NDM Carbapenemase [Presence] in Isolate by Rapid immunoassay | 101677-3 | POSITIVE | 10828004 |
| VIM Carbapenemase [Presence] in Isolate by Rapid immunoassay | 101676-5 | POSITIVE | 10828004 |
| IMP Carbapenemase [Presence] in Isolate by Rapid immunoassay | 101675-7 | POSITIVE | 10828004 |
| OXA-48-like carbapenemase [Presence] Isolate by Rapid immunoassay | 101674-0 | POSITIVE | 10828004 |

## 8. My laboratory uses a test that results carbapenemase type by group, but does not identify the specific carbapenemase type (e.g., OXA without characterizing the specific variant). How should we report these results?

[8] Carbapenemase enzyme panel - Isolate by Rapid immunoassay (loinc.org/101672-4)

Some carbapenemase tests[9] do not distinguish among OXA variants (e.g., groups 23, 40, 48 and 58) or between genes in a given class (e.g., *bla*VIM and *bla*IMP).

The table below summarizes how to report results for the most common tests do not differentiate carbapenemase types. In addition to using the most appropriate LOINC and SNOMED codes, please indicate the test kit in the NTE segment (e.g., "this isolate was tested using Check-Points CPO for BD MAX").

| Method | Analytes | Analytes LOINC | Results | Results SNOMED |
|---|---|---|---|---|
| VERIGENE® Gram-Negative Blood Culture Test | Carbapenem resistance blaOXA gene [Presence] by Molecular method | 86712-7 | DETECTED | 260373001 |
| Cobas® ePlex BCID6 | Carbapenem resistance blaOXA-23-like+blaOXA-48-like genes [Presence] in Isolate or Specimen by Molecular method | 93390-3 | DETECTED | 260373001 |
| Check-Points CPO for BD MAX™ | Carbapenem resistance blaIMP+blaVIM genes [Presence] by Molecular method | 95540-1 | DETECTED | 260373001 |

## 9. My laboratory tests screening specimens (e.g., rectal/perirectal swab) collected for colonization testing. If a carbapenemase type is identified from a screening specimen, how do we report these results? Does it matter if we culture an organism from the screening specimen?

Labs can identify carbapenemases directly from screening specimens, most often collected from the rectal or perirectal swabs. For some pathogens, such as *A. baumannii*, screening swabs might be collected from the skin or another external site.

If a screening specimen is positive for a carbapenemase type, laboratories might obtain a reflexive culture to identify the genus and species of the carbapenemase-positive bacteria. Regardless of whether an organism is identified, use the corresponding LOINC code for either molecular or immunochromatographic assay tests. Please make sure to indicate the specimen source in the SPM-4 segment of the HL7 ELR message using the

[9] CRO Primer Tests for Carbapenemases (www.cdph.ca.gov/Programs/CHCQ/HAI/CDPH Document Library/CRO_PrimerTests_for_Carbapenemases.pdf)

appropriate SNOMED code. The table below shows SNOMED codes that might be most appropriate for screening swabs.

| Specimen Source | Specimen Source SNOMED Code |
|---|---|
| Rectal Swab | 258528007 |
| Skin Swab | 258503004 |
| Swab of axilla | 445364004 |
| Wound swab | 258531008 |

If a reflexive culture *is* performed to obtain a species identification (whether in-house or at a reference lab), please report the organism using the appropriate SNOMED code in the OBX segment. This could either be included in the same HL7 ELR message as the carbapenemase result or sent as a separate message. If sent as a separate message, please use the same accession number in the SPM2.2.1 segment (see the example HL7 ELR message below).

If a reflexive culture *is not* performed, or an organism is not able to be identified (i.e., no growth), please report the carbapenemase result. Labs must report all carbapenemase-producing organisms, even if bacteria are not identified.

## 10. My laboratory performs whole genome sequencing (WGS) on carbapenemase-positive isolates. How should we report these results?

Bacterial sequencing at clinical laboratories is currently uncommon; however, laboratories conducting WGS on CPOs should send results to public health if the carbapenemase result has not already been reported.

Sending WGS results via ELR can be challenging. Clinical labs that perform WGS have two primary options:

1) Submit an ELR with the testing results using the appropriate LOINC and SNOMED codes (e.g., 49617-4, blaKPC by Molecular method), and indicate the allelic variant, sequence type, and NCBI identifier (if applicable) in the NTE segment (e.g., “positive for the KPC-1 gene”, “*E. coli* ST-151 identified”, “SRA: ABCDE123456”).
2) Submit a laboratory report directly to your local public health department. Please ensure these reports have information on the allelic variant and organism sequence type, if available. If the result is uploaded to NCBI, please also include the appropriate accession number or identifier.

## 11. My lab currently does not report CPO results using the proper LOINC and SNOMED codes, but has plans to do so in the future. In the meantime, how should we report CPO results?

If your lab performs carbapenemase testing, but does not currently report using SNOMED and LOINC codes, please update your Laboratory Information Systems (LIS) to be in compliance with Title 17 reporting requirements.

In the meantime, please ensure all HL7 ELR messages report organisms (genus and species), collection date, collection facility and specimen source, using the appropriate LOINC and SNOMED codes. To report carbapenemase results using a local code and a string data type, please use the OBX-3.4 and OBX-3.5 fields.

As a secondary option, please use the NTE segment to indicate the carbapenemase test result; this option should be used to state, *as clearly as possible,* the carbapenemase identified. For example:

- “This isolate has tested positive for a *bla*KPC gene”
- “KPC gene DETECTED”
- “KPC Klebsiella pneumoniae”

## Health Level 7 (HL7) ELR Format and Example

### HL7 ELR Key Fields Table

This table highlights the key segments and fields for a successful CPO message in HL7.

| HL7 Field/ Component | Element Name | Guidance/Description | Example |
|---|---|---|---|
| OBX-3.1 | Observation Identifier | Shows the LOINC code for the test performed | 49617-4 |
| OBX-3.2 | Observation Identifier Text | Shows the text description of the test performed | blaKPC Islt/Spm Ql |
| OBX-5.1 | Observation Value Identifier | Shows the SNOMED code for the result of the test performed | 260373001 |
| OBX-5.2 | Observation Value Text | Shows the text description of the result for the test performed | Detected |
| NTE | Notes and Comments | Note important information such as organism genus and species, Carbapenemase gene detected and the specific specimen type. | This is a multi-drug resistant Klebsiella pneumoniae. This isolate tested positive for the blaKPC gene. |
| SPM-4 .1 | Specimen Type or Material SNOMED code | SNOMED code for the type of specimen | 258528007 |
| SPM-4 .2 | Specimen Type or Material Text Description | Text description of the type of specimen | Urine Specimen or Microbial culture isolate |
| ORC-21 | Ordering Facility Name | Preferably the facility where the specimen was collected; if ordering facility is different from collection facility, please note collection facility in the NTE segment | Fake Hospital |
| ORC-22 | Ordering Facility Address | Street address, city, state and zip code | 123 Fake Street<br>San Jose, CA 95124 |
| ORC-24 | Ordering/ Referring Provider Address | Street address, city, state and zip code of licensed physician ordering the test | 123 Testing Blvd<br>San Jose, CA 95124 |

### Example HL7 ELR Message

This is an example of a successful HL7 ELR message for a *Klebsiella pneumoniae* identified from urine, that has tested positive for the KPC gene. Please note these are two messages, linked together using a common accession number. Some of the key components are highlighted.

The accession number, LOINC and SNOMED codes, and collection facility are in highlighted and **bold** text.

**Separate urine culture result without susceptibilities**

MSH|^~\&|SHC_Epic^2.16.840.1.113883.3.3337^ISO|FakeLab^999999^CLIA|CDPH CALREDIE^2.16.840.1.114222.4.3.3.10.1.1^ISO|CDPH_CID^2.16.840.1.114222.4.1.214104^ISO|20240303144928||ORU^R01^ORU_R01|78G4SBC_1FME_1|P|2.5.1|||AL|AL|USA||||PHLabReport-Ack^^2.16.840.1.113883.9.10^ISO

SFT|SOAPUI^L^^^^ANSI&1.2.840&ISO^XX^^^1.2.840.114350|May 2020|Fake_LIMS|9.3.0.0||20201029203931

PID|1||1003^^^EPI&FakeMRN&ISO^PI||CPOGene^Test3^^^^^L||19541031|F||1002-5^American Indian or Alaska Native^CDCREC|1616 Capitol Ave^UNIT 235^Sacramento^CA^95814^USA^H^^34||||||||||N^Not Hispanic or Latino^CDCREC||||||||||||1^1.2.840.114350.1.13.541.2.7.2.11111^ISO||||

ORC|RE|20212024^Fake_EHR^1.2.840.114350.1.13.541.2.7.2.11111^ISO|ConnectionTest0001^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|01A-123B1234^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|||||||1234567890^Fake^Doctor^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI||^WPN^PH^^1^123^1238181|||||||FakeOrderingFac^D^^^^fakeMD&1.2.840.114350.1.13.541.2.7.2.696570&ISO^XX^^^10|123 Fake Street^^San Jose^CA^95124^^B|^WPN^PH^^1^123^1234800|123 Testing Blvd^^San Jose^CA^95124^^B|||||||

OBR|1|Ob789^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|ConnectionTest0001^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|**630-4**^Bacteria identified Cx Nom (U)^LN^2922077^Urine Culture^L|||20240417200214|||||||||1234567890^Fake^Doctor^^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|^WPN^PH^^1^123^8144095|LAB||||20240417200214||LAB|F|||||||||||||||||||||||

OBX|1|CWE|630-4^Bacteria identified Cx Nom (U)^LN^2922077^Urine Culture^L|1|**56415008**^Klebsiella pneumoniae (organism)^SCT^**56415008**^Klebsiella pneumoniae^L|||A^Abnormal (applies to non-numeric results)^HL70078^^^^2.5.1|||F|||20240417200214|||BD Phoenix M50||20240417200214||||fakeMD^L^^^^CLIA&999999&ISO^XX^^^99999|123 Fake Street^^San Jose^CA^95124^USA^B|||

SPM|1|^**24M-060MI3000**&Beaker&1.2.840.114350.1.13.171.2.7.3.798268.320&ISO||122575003^Urine specimen (specimen)^SCT^^L||||||||||||20240416190700|20240416200214||||||||||

**CPO gene result linked to separate urine culture**

MSH|^~\&|SHC_Epic^2.16.840.1.113883.3.3337^ISO|FakeLab^999999^CLIA|CDPH CALREDIE^2.16.840.1.114222.4.3.3.10.1.1^ISO|CDPH_CID^2.16.840.1.114222.4.1.214104^ISO|20240303144928||ORU^R01^ORU_R01|78G4SBC_1FME_2|P|2.5.1|||AL|AL|USA||||PHLabReport-Ack^^2.16.840.1.113883.9.10^ISO

SFT|SOAPUI^L^^^^ANSI&1.2.840&ISO^XX^^^1.2.840.114350|May 2020|Fake_LIMS|9.3.0.0||20201029203931

PID|1||1003^^^EPI&FakeMRN&ISO^PI||CPOGene^Test3^^^^^L||19541031|F||1002-5^American Indian or Alaska Native^CDCREC|1616 Capitol Ave^UNIT 235^Sacramento^CA^95814^USA^H^^34||||||||||N^Not Hispanic or Latino^CDCREC||||||||||||1^1.2.840.114350.1.13.541.2.7.2.11111^ISO||||

ORC|RE|20212024^Fake_EHR^1.2.840.114350.1.13.541.2.7.2.11111^ISO|ConnectionTest0001^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|01A-123B1234^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|||||||1234567890^Fake^Doctor^^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI||^WPN^PH^^1^123^1238181|||||||**FakeHospital**^D^^^^ fakeMD&1.2.840.114350.1.13.541.2.7.2.696570&ISO^XX^^^10|123 Fake Street^^San Jose^CA^95124^^B|^WPN^PH^^1^123^1234800|123 Testing Blvd^^San Jose^CA^95124^^B|||||||

OBR|4|Ob789^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|ConnectionTest0001^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|**85502-3**^Carbapenemase resistance genes panel Molgen (Islt/Spec)^LN^2922077^Carbapenemase resistance genes panel^L|||20240417200214|||||||||1234567890^Fake^Doctor^^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|^WPN^PH^^1^123^8144095|LAB||||20240417200214||LAB|F|||||||||||||||||||||||

OBX|1|CE|**49617-4**^Carbapenem resistance blaKPC gene Molgen QI (Islt/Spec)^LN^KPC^KPC^L|1|**260373001**^Detected^SCT^Detected^Detected^L|||||F|||20240417200214|||||20240417200214||||fakeMD^L^^^^CLIA&999999&ISO^XX^^^99999|123 Fake Street^^San Jose^CA^95124^USA^B||||||

NTE|1|L|ALERT: This is a multi-drug resistant Klebsiella pneumoniae. This isolate tested positive for the blaKPC gene.

NTE|2|L|Original specimen source was urine.

SPM|1|^**24M-060MI3000**&Beaker&1.2.840.114350.1.13.171.2.7.3.798268.320&ISO||442635007^Microbial culture isolate^^^^2.5.1^^L||||||||||||20240416190700|20240416200214||||||||||