Council of State and Territorial Epidemiologists (CSTE)

Interim Operational Guidance for PS 22-ID-04 (CPO)

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1. Objectives

This document serves as a complementary, practical guide to the implementation of recommendations for the surveillance of carbapenemase-producing organisms (CPO) provided in the <u>Council of State and Territorial</u> <u>Epidemiologists (CSTE) Position Statement 22-ID-04, Change in Case Definition from Carbapenemase-Producing</u> <u>Carbapenem-Resistant Enterobacteriaceae (CP-CRE) to CPO</u> (www.cste.org/resource/resmgr/ps/ps2022/22-ID-04_CPO.pdf). The document is targeted at state, territorial, local, and tribal (STLT) public health agencies. Sections addressing clinical or laboratory practices are not intended to provide guidance for those settings and are included to support STLT public health staff when collaborating with laboratories and clinicians. The objectives of this document are as follows:

- To provide guidance for applying case definitions, including considerations for testing and data collection
- To provide guidance for reporting case counts and epidemiologic data to Centers for Disease Control and Prevention (CDC)
- To present resources and examples for surveillance and public health response

2. Implementation of the case definition

2.1 Case classification

Confirmed cases of CPO are defined as any specimen that meets the following laboratory evidence. There are no probable or suspect case classifications for CPO.

- Positive phenotypic test* result for carbapenemase production in a specimen, OR
- Positive molecular test** result detecting a carbapenemase gene*** (with or without organism identification), OR
- Detection of carbapenemase gene*** by next-generation sequencing (NGS)[‡]
- * Phenotypic testing methods include but are not limited to: metallo-8-lactamase test, modified Hodge test, Carba NP, carbapenem inactivation method (CIM), modified carbapenem inactivation method (mCIM), EDTA-modified carbapenem inactivation method (eCIM), or immunochromatography tests (ICT).

- ** Molecular tests for carbapenemase genes include but are not limited to: Xpert Carba-R, VERIGENE, Streck ARM-D, Cepheid, validated laboratory-developed NAAT.
- *** Common carbapenemase genes include: bla_{KPC}, bla_{NDM}, bla_{VIM}, bla_{IMP}, bla_{OXA-48}, but other carbapenemase genes include but are not limited to: bla_{SIM}, bla_{GIM}, bla_{SPM}, other OXA genes, etc.
- ⁺ It is not necessary to report organisms with known chromosomal carbapenemase genes, including but not limited to SME+ Serratia marcescens, unless they have additional non-chromosomal carbapenemase genes.

2.2 Clinical vs. screening case classifications

The CPO case definition distinguishes between screening and clinical case sub-classifications. This differentiation is determined by the purpose of the collected specimen, whether that be for screening or diagnosis and treatment.

<u>Screening</u> – A screening case is a person with a CPO identified in a swab collected **for the purpose of screening** regardless of the site of collection, however the most common site for CPO screening is a rectal swab. These specimens are collected for the purpose of surveillance and not to identify the source of infection. Because it can be difficult to differentiate screening specimens from clinical specimens based on microbiology records, screening cases should generally be limited to CPO identified in rectal, peri-rectal, axilla, groin, or stool specimens. Specimens from such sites can be assumed to be for screening unless specifically noted otherwise. Laboratories may also note screening specimens from other sites (e.g., wound, tracheostomy or central line) but this is uncommon.

<u>Clinical</u> – A clinical case is a person with a CPO identified from a clinical specimen collected **for the purpose of diagnosing or treating disease during the normal course of care**. The most common examples are blood, wound, urine, sputum, and tissue. A CPO identified in a non-invasive site (e.g., urine) could be an indication of colonization and not true infection; however, when collected during the normal course of care, it should be classified as a clinical case.

2.3 Counting cases

Enumeration criteria

A specific organism/carbapenemase combination in a person should be counted as a separate case from other organism/carbapenemase combinations in the same person (e.g., KPC+ *K. pneumoniae* vs. NDM+ *E. coli*). A specific organism/carbapenemase combination can include a carbapenemase gene(s) without an organism detected (e.g., NDM+ no organism vs. NDM+ *E. coli*). A patient who is colonized or infected with a CPO is considered to be colonized indefinitely. A person is counted as a case when a CPO is identified for the first time in a specimen, whether that be a screening or clinical specimen. If the person later has another positive screening specimen, they are not counted again. However, if a person was identified as a screening case first and later developed clinical infection, the individual would be counted twice: once as a screening case and once as a clinical case. Multiple screening positives or multiple clinical positives from the same patient, even if years apart, are not counted again if they are the same organism/carbapenemase combination. Only the first instance per patient (for an organism/carbapenemase combination. Only the first instance per patient (for an organism/carbapenemase combination) is counted. (See **Table 1**)

Note that CPO cases should be counted by jurisdiction of residence (as with all other nationally notifiable conditions); however, they should still only be counted once in their lifetime (or twice if first as a screening case, and later as clinical case), regardless of residence at time of CPO identification.

Initial CPO specimen	Additional CPO specimen(s)	How Classified and counted
NDM+ E. cloacae	NDM+ E. cloacae	Twice: once as screening NDM+ E. cloacae case
Screening swab	Clinical specimen	and once as clinical NDM+ E. cloacae case
NDM+ E. cloacae	NDM+ E. cloacae	Once: clinical NDM+ E. cloacae case at time of
Clinical specimen	Screening swab	first positive specimen
NDM+ (no organism recovered)	NDM+ E. cloacae	Twice: once as screening NDM+ case and once
Screening swab	Screening swab	as screening NDM+ E. cloacae case
NDM+ E. cloacae	NDM+ E. coli	Twice: once as clinical NDM+ E. cloacae case
Clinical specimen	Clinical specimen	and once as clinical NDM+ E. coli case

Example scenarios demonstrating implementation (e.g., screening vs clinical, duplicate cases) can be found in Appendix B.

3. Clinical Testing

This section provides information for STLT public health agencies regarding clinical testing. Distinguishing CPO from gram-negative organisms that are carbapenem resistant due to non-carbapenemase-mediated mechanisms is important, as CPO disseminate between patients more readily than non-CPO and warrant implementation of more intensive infection prevention and control measures that would be employed in the absence of carbapenemase production. (Ref: www.ncbi.nlm.nih.gov/pmc/articles/PMC5241781/)

3.1 Testing methods to identify carbapenemase-producing organisms

The selection of a carbapenemase detection test is contingent upon several factors, including local carbapenemase prevalence, regional molecular epidemiology, diagnostic performance characteristics, labor intensity, cost, and turnaround time of the test. The most common laboratory protocols for identifying carbapenemase production first rely on culturing an organism and then performing antimicrobial susceptibility testing (AST) to determine if the isolate is carbapenem-resistant. Select carbapenem-resistant organisms will then undergo phenotypic testing and molecular testing to further characterize the resistant genes.

While culture-dependent methods are still the mainstay of identifying a carbapenemase-producing organism in a clinical specimen, some laboratories might perform culture-independent diagnostic testing methods (CIDT) on clinical isolates. Public health guidance on follow-up of cases identified through CIDT methods is still evolving.

Culture-dependent diagnostic testing methods

- 1. Testing to define carbapenem-resistant organisms
 - AST alone will not reliably distinguish carbapenemase producers from non-carbapenemase producers but does help identify isolates that should be tested further for carbapenemase production.
 - Clinical laboratories should follow Clinical and Laboratory Standards Institute (CLSI) guidance (M100) regarding which antimicrobials should be tested for each organism. <u>M100Ed32 | Performance Standards for Antimicrobial Susceptibility Testing, 32nd Edition</u> (<u>www.em100.edaptivedocs.net/Login.aspx? ga=2.224561170.948929043.1663873824-2118344032.1660842784).</u>
 - Carbapenem-resistant organisms (CRO) are defined by CLSI breakpoints for ertapenem, doripenem, imipenem and meropenem.
 - Pseudomonas aeruginosa and Acinetobacter baumannii are intrinsically resistant to ertapenem. minimum inhibitory concentration (MIC) breakpoints for doripenem, imipenem, and/or meropenem should be used.
 - Morganella spp., Proteus spp., and Providencia spp. have intrinsic elevated MIC to imipenem.
 MIC results for meropenem, doripenem, and/or ertapenem should be used.

2. Testing to define carbapenemase-producing organisms

Laboratories without the capacity for phenotypic or molecular detection of carbapenemases should submit CRO specimens to state public health labs. Section 3.2 outlines the isolates that should be prioritized for each testing method.

- Phenotypic tests: Most of these tests identify carbapenemase production but in their traditional forms lack guidance regarding the specific carbapenemase being produced. Sensitivity and specificity vary by method (Ref: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6204673/). Of Note: Immunochromatography Tests (ICT) are an emerging technology that shows promise in identifying carbapenemases. Refer to Appendix A for examples of phenotypic testing methods.
- Molecular tests: These tests identify the specific type of carbapenemase gene target(s). They will only detect gene targets available on the specified panel/probe. Refer to **Appendix A** for examples of molecular tests for carbapenemase genes.
 - Figure 1 includes an example lab report. This is for an *Acinetobacter baumannii* isolate from a wound culture. OXA 24-40 gene was detected and should be counted as a case.
- Next generation sequencing: These tests identify the specific type of carbapenemase gene target(s) but are not limited based on a panel or probe and can determine relatedness of isolates.

Figure 1. Example lab report

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Culture-independent diagnostic testing (CIDT) methods

CIDT uses molecular technology to detect the presence of specific gene targets. This only detects microorganisms and antibiotic resistance genes specified in the panel. Antibiotic resistance genes are detected in the specimen and are not specific to a detected pathogen. Resistance genes may be detected in bacterial strains not tested for in the panel.

Figure 2 provides an example lab report from a wound specimen. In this example, NDM was detected and should be counted as a case. Both *Morganella morganii* and *Proteus mirabilis* were identified but it is not indicated which organism contains NDM. This case would therefore have no organism identified for case counting purposes. The lab report also indicates the presence of additional carbapenemases that are not typical PCR testing targets, such as OXA-1 and GES. Jurisdictions will need to determine the significance of these carbapenemases by taking into consideration the ability of the carbapenemase gene to easily transfer to other organisms (i.e., plasmid-mediated) and the epidemiological significance.

Figure 2. Example Culture-Independent Lab Report

Facility Information	Specimen Information	
Ordering Provider:	ACC:	
Facility:	Collection Date: 02-26-2021	Report Date: 03-03-2021
Facility Phone:	Received Date: 03-01-2021	Sample Type: Wound Swab
Facility Fax:	Notes:	

PATHOGENS DETECTED			
Staphylococcus aureus, enterotoxins A/B	1 x 10^6 Cells/mL	47.366%	
Proteus mirabilis	1 x 10^6	47.366%	
Morganella morganii	Cells/ml 1 x 10^5 Cells/mL	4.737%	
Enterococcus faecalis, faecium	1 x 10^4 Cells/mL	0.474%	
Corynebacterium jeikeium, striatum	1 x 10^3 Cells/mL	0.047%	
Peptoniphilus harei, ivorii	1 x 10^2 Cells/mL	0.005%	
Peptostreptococcus prevotii, anaerobius, asaccharolyticus,	1 x 10^2 Cells/mL	0.005%	
magnus	Gelis/IIIL		

POTENTIAL MED	CLASS AFFEC	TED
VEB, blaNDM-1, OXA-1, GES	Beta-lactams	
ermB	Macrolides	
mecA	Methicillin	
tetM	Tetracycline	
ampC, ACC, DHA, ACT/MIR	Ampicillin	
aac6-1b/aacA4, ant(3), aph(A6), aac6-1b-cr	Aminoglycosides	
SULL, DFRA	Bactrim	

RESISTANCE GENES DETECTED &

3.2 Isolate submission criteria

Jurisdictions should work with their state public health lab and regional antimicrobial resistance (AR) laboratory on prioritization based on laboratory capacity. Several examples of state health department guidance for isolate submission can be found in **Appendix C**.

Recommended isolates for carbapenemase testing

• Carbapenem-resistant Enterobacterales (CRE)

- All CRE isolates should be tested for carbapenemase production. If prioritization is needed due to lab capacity, consider the local epidemiology of CRE and/or consider a focus on the following:
 - Citrobacter spp.
 - Enterobacter spp.
 - Escherichia coli
 - Klebsiella oxytoca
 - Klebsiella pneumonia
 - Any CRE isolate from a patient with a high suspicion of being a carbapenemase-producer (e.g., epidemiologically linked isolate)

- Any CRE isolate submitted from a patient with a history of infection or colonization with *C. auris*
- Carbapenem-resistant Pseudomonas aeruginosa (CRPA)
 - Prioritize the following CRPA isolates for carbapenemase testing:
 - Non-susceptible (i.e., intermediate, or resistant MIC ≥16µg/ml) to cefepime and/or ceftazidime
 - Any CRPA isolate submitted from a patient with a high suspicion of being a carbapenemase producer (e.g., epidemiologically linked isolate)
 - Any CRPA isolate that is non-susceptible to all antibiotics tested
 - Any CRPA isolate submitted from a patient with a history of infection or colonization with *C. auris*
- Carbapenem-resistant Acinetobacter baumannii (CRAB)
 - All CRAB isolates should be tested for carbapenemase gene targets. Phenotypic testing is not routinely performed on CRAB isolates and often gene targets are identified through molecular methods or NGS. Some states may perform a modified (molecular) panel on CRAB isolates while others may perform the same (full) panel used on other organisms, depending on internal lab workflow and capacity. If prioritization is needed due to lab capacity, focus on the following:
 - Any CRAB isolate submitted from a patient with a high suspicion of being a carbapenemase producer (e.g., epidemiologically linked isolate)
 - Any CRAB isolate submitted from a patient with a history of infection or colonization with *C. auris*

Organism(s)	Recommended Carbapenemase Gene Testing Targets	Most Common Gene in US*
CRE	KPC, NDM, VIM, IMP, OXA-48	КРС
CRPA	KPC, NDM, VIM, IMP, OXA-48	VIM
CRAB	KPC, NDM, VIM, IMP, OXA-48, OXA-23, OXA-24-40, OXA-58, OXA-235-like	OXA-type^

Recommended carbapenemase gene testing targets by organism

Metallo-beta-lactamase (IMP), Oxacillinase-48-like beta-lactamase (OXA-48), Oxacillinase-23-like beta-lactamase (OXA-23), Oxacillinase-24/40-like beta-lactamase (OXA-24/40), Oxacillinase-58-like beta-lactamase (OXA-58), Oxacillinase-235-like beta-lactamase (OXA-235-like)

*This may vary by region. Refer to the <u>CDC Antibiotic Resistance & Patient Safety Portal</u> (arpsp.cdc.gov/profile/antibioticresistance?tab=ar-lab-network) for more information.

^CDC Antibiotic Resistance & Patient Safety Portal (arpsp.cdc.gov/profile/antibiotic-resistance?tab=ar-lab-network) lists NDM as the most common gene based on testing data, however, OXA-type carbapenemases have not been routinely tested through the AR Lab Network. OXA-23 is far more common, present in ~80% of isolates tested for the gene. More information can be found in the CDC's featured document on CRAB. (arpsp.cdc.gov/story/cra-urgent-public-health-threat)

Recommended isolates for NGS

Utilization of NGS can be helpful to identify novel gene targets, identify disease transmission, and characterize virulence factors. <u>CDC AR Lab Network - General-Guidance-for-WGS-of-HAI-AR-Pathogens v2.pdf - All Documents</u> (sharepoint.com) (Login required) As of April 2023, prioritization for NGS conducted by the CDC's AR Lab Network focuses on rapid detection of emerging, rare, and novel carbapenemases and is as follows:

- 1. Carbapenemase-producing/carbapenemase-gene-negative CRE/CRPA isolates
- 2. CRAB carrying Class A, Class B, or blaOXA-48-like carbapenemase genes
- 3. Carbapenemase-producing/carbapenemase-gene positive CRPA
- 4. Carbapenemase-producing/carbapenemase-gene positive CRE
- 5. Other CRAB with clinically or epidemiologically significant profiles
 - a. Generally, the order of precedence:
 - i. resistant to all beta-lactams tested;
 - ii. resistant to all carbapenems, but not all beta-lactams tested;
 - iii. positive for other Class D carbapenemase genes (e.g., blaOXA-23-like, blaOXA-24/40-like, blaOXA-58-like) that are NOT common in the submitting jurisdiction.
- If funding remains, NGS may be directed to support other epidemiological investigation priorities, particularly:

 a. CRE/CRPA. Although many of the top NGS priorities listed above include CRE/CRPA that are the focus
 of many epidemiological investigations, there are additional situations that may be supported, including:
 - i. ongoing investigations with newly associated locations within a facility, new CRE species (carbapenemases in less common Enterobacterales, organisms not frequently identified in that jurisdiction, etc.), new strains, or newly discovered epidemiology exposures (e.g., large proportion of case-patients have received care from the same healthcare worker, or a history of exposure to the same medical device);
 - ii. continued problems or suspected transmission at a facility after the initial infection control assessment and interventions have been implemented.
 - b. CRAB. The following situations increase the value of NGS for CRAB investigations:
 - i. inform a regional response;
 - ii. initial interventions in a facility are not successful;
 - iii. define local epidemiology if this has not been done recently or ever (e.g., test a subset periodically).

3.3 Role of testing at public health laboratories

Public health laboratories in the US have developed substantial capacity to test organisms for carbapenemase genes. In particular, the AR Lab Network can provide confirmatory organism identification, AST, carbapenemase gene detection, supplemental AST, surveillance testing, and NGS. AST, carbapenemase gene detection, and NGS are covered above. Surveillance testing is covered below in Section 4. More information about expanded AST (ExAST) can be found on the CDC ExAST website (www.cdc.gov/drugresistance/ar-lab-networks/domestic/expandedast.html).

4. Colonization testing (screening)

• Individuals with clinical multi-drug resistant organism (MDRO) infections represent only a small fraction of total individuals with a targeted MDRO as many more are colonized. Colonized individuals can still be a source of transmission to others within healthcare settings, particularly when their colonization status is

unknown and, as a result, recommended infection prevention and control (IPC) interventions are not applied. MDROs may spread from colonized individuals in a facility or region before the first clinical infection is detected. Prevention-driven and responsive point prevalence surveys (PPS) as well as admission screening are several strategies that can be used to detect colonized individuals.

- Screening recommendations- <u>Containment Strategy | HAI | CDC</u> (www.cdc.gov/hai/mdroguides/containment-strategy.html)
- and <u>Guidance for Control of Carbapenem-Resistant Enterobacteriaceae, 2012 CRE Toolkit (cdc.gov)</u> (www.cdc.gov/hai/pdfs/cre/CRE-guidance-508.pdf) and <u>Request CDC's AR Lab Network Test to Prevent the</u> <u>Spread of Emerging Carbapenem Resistance (www.cdc.gov/drugresistance/pdf/CRE-lab-test-508.pdf)</u>

4.1 Types of screening

The different characteristics of each screening type are listed in the table below.

5 //				
Prevention-based point prevalence surveys (PPS)				
Definition	Screening everyone in a facility or a specified unit on a specific date and time			
	regardless and possibly prior to the identification of CPO			
Screening	Jurisdictions can find new CDC guidance regarding prevention activities			
Recommendations	including prevention-based PPS here: MDRO Guides HAI CDC			
	(www.cdc.gov/hai/mdro-guides/prevention-strategy.html)			
Considerations/	Should be considered for influential facilities (ventilator-capable skilled			
Additional	nursing facilities and long-term acute care hospitals) based on testing			
Information	resources in the jurisdiction			
	 PPS frequency will vary depending on prevalence 			
	Response-based targeted screening			
Definition	Screening conducted on people who are considered close healthcare contacts			
	with someone newly identified with CPO infection or colonization			
Screening	Refer to the following guidance document for more information on response-			
Recommendations based screening:				
	 <u>Containment Strategy HAI CDC</u> (www.cdc.gov/hai/mdro- 			
	guides/containment-strategy.html)			
Considerations/	Response-based screenings should be prioritized over prevention-based			
Additional screening				
Information				
Response-based PPS				
Definition	A PPS conducted in response to the new identification of a CPO case or multiple			
	cases in a facility			
Screening	Refer to the following guidance document for more information on response-			
Recommendations	based screening:			
	 <u>Containment Strategy HAI CDC</u> (www.cdc.gov/hai/mdro- 			
	guides/containment-strategy.html)			

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Considerations/	 Might be conducted instead of a response-based targeted screening 		
Additional due to the difficulty or delay in identifying close contacts to a			
Information	case or concern for larger spread due to additional cases being		
	identified or concerns related to infection prevention and control		
	practices at the facility		
	 Frequency of PPS will vary; early on in an outbreak more frequent 		
	screening might be necessary but eventually facilities should transition		
	to a "maintenance phase" where PPS might be conducted every 6-12		
	months		
	Admission screening		
Definition	Individuals screened upon admission to a facility		
Screening	Will depend based upon laboratory capacity and feasibility. Example		
Recommendations	approaches to admission screening include:		
	• Ventilator-capable Skilled Nursing Facility (vSNF) screens all admissions		
	to their ventilator unit		
	 Long-term Acute Care Hospital (LTACH) screens all admissions 		
	Acute Care Hospital (ACH) screens all admissions from certain facilities		
	or facility types		
	ACH only screens admissions with MDRO risk factors from certain		
	facilities or facility types		
	ACH screens all admission to their ICUs		
	• Patients admitted to healthcare facilities after an overnight stay in a		
	healthcare facility outside of the United States in the prior 6 months		
Considerations/	More useful to facilities that do not already have many cases or spread		
Additional	where a novel introduction is the chief concern		
Information	Consider conducting a proactive PPS beforehand to ensure transmission		
	is not occurring in the facility.		
	Discharge screening		
Definition	Individuals screened prior to discharge to another unit or healthcare facility		
Screening	Will depend on feasibility and lab capacity but could include:		
Recommendations	• Those transferring to other healthcare facilities, especially to units that		
	house many people with risk of MDRO colonization		
	• Those transferring to other units in a healthcare facility, especially to		
	units that house many with risk of MDRO colonization		
Considerations/	Particularly useful during a current outbreak on a unit or if the facility has many		
Additional			
Information	take into consideration the following:		
	Laboratory capacity		
	 Turnaround time for results 		
•	 Timing: screening at discharge vs. right before discharge 		
	 Results communication: decide who will be responsible for 		
	communicating results if patient/resident is discharged prior to results		
	being released		

٠	Discharge screening results should not be used to determine whether a
	facility will accept a patient; transfers should be based on clinical need
	and not MDRO status.

4.2 Screening recommendations

Identifying those to screen

Prevention-based

• Jurisdictions can find new CDC guidance regarding prevention activities including prevention-based PPS on the SharePoint site (Login required)

Response-based

• <u>Containment Strategy | HAI | CDC</u> (www.cdc.gov/hai/mdro-guides/containment-strategy.html)

Admission screening

- Will depend based upon laboratory resources and what is feasible for the jurisdiction
- Example approaches to admission screening:
 - vSNF screens all admissions to ventilator unit(s)
 - o LTACH screens all admissions
 - o ACH screens all admissions from certain facilities or facility types
 - o ACH only screens admissions with MDRO risk factors from certain facilities or facility types
 - ACH screens all admission to their ICUs
 - Facility screens any patients admitted after an overnight stay in a healthcare facility outside of the United States in the prior 6 months

Discharge screening

- Particularly useful during a current outbreak on a unit or if the facility has many people with a particular MDRO/CPO
- Requires a well thought out implementation plan that should take into consideration the following:
 - Laboratory capacity
 - Turnaround time for results
 - Timing: Screening at discharge vs. just prior to discharge
 - Those to be screened may include:
 - Patients/residents transferring to other healthcare facilities, especially to units that house many people at risk of MDRO colonization
 - Patients/residents transferring to other units within the same healthcare facility
 - Results communication
 - Decide who will be responsible for communicating results if patient/resident is discharged prior to results being released

Identification methods

• PCR is the preferred method for colonization screening.

4.3 Additional screening resources

Sample consent script and screening FAQs (CDC) <u>MDRO Guides | HAI | CDC</u> under colonization screening resources (www.cdc.gov/hai/mdro-guides/index.html)

ARLN Shipping and sample collection guidance examples:

- Central ARLN-Minnesota DPH Infectious Disease Laboratory Guidance for Carbapenem-Resistant organism (CRO) Colonization Test Sampling and Specimen Handling Methods (state.mn.us) (www.health.state.mn.us/diseases/idlab/mdhcroguidance.pdf)
- Mid-Atlantic ARLN-Maryland Public Health Laboratory Instructions for CRE colonization testing request_updated 6_19_18.pdf (maryland.gov) (health.maryland.gov/laboratories/docs/Instructions%20for%20CRE%20colonization%20testing%20req uest_updated%206_19_18.pdf)
- Midwest ARLN-Wisconsin State Laboratory of Hygiene <u>http://www.slh.wisc.edu/wp-content/uploads/2021/10/Instructions-for-colonization-swab-collection.pdf</u> (www.slh.wisc.edu/wp-content/uploads/2021/10/Instructions-for-colonization-swab-collection.pdf)
- Mountain ARLN-Utah Public Health Laboratory ARLN Utah | Utah Public Health Laboratory (uphl.utah.gov/arln-utah/)
- Northeast ARLN-Wadsworth Laboratory NYS DOH CROSampling-Shiping Instructions_2016Final_1 (wadsworth.org) (www.wadsworth.org/sites/default/files/WebDoc/CRO%20Colonization%20Sampling-Shipping%20Instructions_%20Final.pdf)
- Southeast ARLN-Tennessee State Public Health Laboratory TN_ARLN_Shipping_Information.pdf (www.tn.gov/content/dam/tn/health/program-areas/lab/TN_ARLN_Shipping_Information.pdf)
- West ARLN-Washington State Public Health Laboratories SCSI-CRE-Testing-V2.pdf (wa.gov) (doh.wa.gov/sites/default/files/legacy/Documents/5240//SCSI-CRE-Testing-V2.pdf)

5. Making CPO reportable

The CSTE Position Statement recommends that STLT public health agencies make CPO reportable and conduct surveillance and CPO remains nationally notifiable to CDC using the revised case definition.

5.1 Example language from CDC to guide laboratories reporting CPO to public health

While the following is an example of language that could be used (e.g., in reporting laws, clinical alerts, etc.) to guide laboratories or facilities on when to report confirmed CPO: "*Report to the public health department, any organism from a human specimen (including screening or surveillance swabs) that is found to be carbapenemase-producing (or contains a carbapenemase gene) using phenotypic, molecular or whole-genome sequencing methods of identification*", many STLT have already made one or more of the following reportable (or required for submission) in their jurisdiction: CRE, CRPA, and/or CRAB. This approach has been taken knowing that many clinical laboratories are unable to perform all the tests necessary to determine if an organism is carbapenemase-producing or contains a carbapenemase gene. STLT are encouraged to consider making CRE, CRPA, and CRAB (or subsets of these organisms with AST results that are more likely to represent CPO) reportable (and/or required for submission) in their jurisdiction, in order to facilitate identification those organisms which are CPO and notifiable to CDC. Jurisdictions may also choose to make CRE, CRPA, and CRAB reportable in order to conduct surveillance and response to these organisms, regardless of whether or not they are carbapenemase-producing or contain a carbapenemase gene.

5.2 Examples from STLT that have made one or more of the following reportable: CRE, CRPA, and CRAB (See **Appendix C** for links to STLT reporting and submission guidance as well as example language form several jurisdictions)

6. Electronic laboratory reporting (ELR) to STLT and public health communication with laboratories

- State health agencies should clearly communicate with laboratories regarding reporting requirements for CPOs. This communication should include:
 - Their jurisdiction's surveillance definition for CPO. Note that this may differ from clinical definitions. The current CSTE position statement definition can be found here: <u>Council of State and Territorial</u> <u>Epidemiologists Position Statement 22-ID-04</u>
 - (https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/ps2022/22-ID-04_CPO.pdf)
 - When to report CPO
 - How to report: see HL7 guidance below
 - Whom to contact at the public health jurisdiction for questions regarding testing methods and reporting
- Examples of written guidance for labs from several state health agencies (See Appendix C)

State health agencies should also be aware of laboratory practices that may impact the quality of ELR messages for CPOs. These may include:

- Differences among laboratories in how CPO ELR messages are triggered. If the lab is able to automate CPO ELR messaging, this will require less work for the lab and reduce opportunities for missed reports. However, some labs will need to trigger ELR manually, depending on a jurisdiction's definition of CPO and its complexity.
- Laboratory compliance with current CLSI guidelines for MIC values. The use of outdated MIC breakpoints can affect the interpretation of test results, especially for qualitative results.
- Suppression of certain resistance test results according to CLSI guidelines and/or clinical formularies. This may result in missing test results for some antimicrobials of interest to public health or inability to identify cases and report them to public health.

6.1 Best practices for surveillance of antimicrobial resistance via ELR

- Links to HL7 Implementation Guides
 - HL7 2.5.1 is the ideal message structure for sending antimicrobial resistance messages, as it allows for the capturing of parent-child relationships in a more complete fashion than using HL7 2.3.1.
 Culture and susceptibility reporting is outlined in Appendix A of the R1 ELR IG.
 - HL7 Version 2.5.1 Implementation Guide Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Standards Product Brief - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) | HL7 International (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98)
 - The section(s) of parent/child, culture and susceptibilities should be noted.
 - Errata for V 2.551 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 HL7 Standards Product Brief - V251 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata | HL7 International (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=245)
 - HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1-US Realm* HL7 Standards Product Brief - HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm | HL7 International (<u>http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279</u>)

- Link to 2017 CRE ELR Best Practices document: https://www.cste2.org/Publications/CRE_ELR_Best_Practices_FINALv1.0_20170515.pdf
- Contact CDC Electronic Data Exchange at edx@cdc.gov for questions on how to build and implement NNDSS HL7 case notification messages, including AST results.

6.2 Issues with LOINC and SNOMED codes

- Generic LOINC codes may be used, making it difficult for systems to classify results correctly. Culture tests where LOINC codes are used are "generic" and require SNOMED codes to properly associate the results with the correct condition. Positive culture results cannot be received by systems if generic LOINC codes are used without SNOMED codes.
 - *Recommendation:* Encourage laboratory use of standard specific LOINC and SNOMED codes that can assist in properly identifying CRO, and work with laboratory and epidemiology staff to ensure that the selected codes are correct.
 - LOINC Code look up: (https://search.loinc.org/ (https://loinc.org/wplogin.php?redirect_to=https%3A%2F%2Floinc.org%2Fsearch%2F&reauth=1)
 - SNOMED Code look up: <u>http://www.snomedbrowser.com/;</u> https://www.nlm.nih.gov/research/umls/Snomed/snomed_browsers.html (https://www.nlm.nih.gov/research/umls/Snomed/snomed_browsers.html)
 - HAI MMG codes: <u>https://ndc.services.cdc.gov/mmgpage/healthcare-associated-infections-multidrug-resistant-organisms-hai-mdro-message-mapping-guide/</u>
- LOINC codes that do not specify the method used (e.g., disk diffusion, broth dilution/MIC, ETest, etc.)
 - Recommendation: Encourage labs to use method specific LOINC codes.

6.3 Issues with laboratory's information management system (LIMS)

- *Missing carbapenemase results.* Lack of carbapenemase testing results (MHT/CarbaNP, molecular panels, PCR). Facilities may be performing carbapenemase testing but not sending results to public health agencies (PHAs). This results in PHAs not knowing the resistance mechanism for CRE cases and needing to contact facilities to find out the testing mechanism. Some labs may report these results in comments. Reports may say "carbapenemase production" without including what tests were used to come to that conclusion, or the lab may not have run the appropriate tests.
 - *Recommendation:* PHAs should understand which labs in your jurisdiction are performing these tests.
- Ambiguous notes/comments which may or may not indicate that carbapenemase testing was performed. Some labs perform carbapenemase testing while others make assumptions about carbapenemase production based on overall phenotype. ELR message comments may not always make it clear whether a test was performed or not.
 - Examples: "Demonstrates production of a carbapenemase," "Likely carbapenemase producer"
 - Recommendation: PHAs should request that labs include confirmatory carbapenemase test results as "child" linkages to the "parent" organism ID. If this isn't possible, PHAs should be aware of what carbapenemase test (if any) a lab uses, and what phenotypes trigger its use.

6.4 ELR resources including sample ELR guidance (CA DPH) and examples of commonly observed deficiencies in received HL7 ELR messages (See Appendix D)

6.5 Relevant LOINC and SNOMED codes (See Appendix E)

6.6 Considerations for reporting NGS results

Laboratories performing NGS might not be able to routinely submit these results via ELR. Because of this limitation, STLT public health agencies should consider the following when making CPO reportable when detected by NGS:

- Is the laboratory performing NGS using a method validated under CLIA for diagnostic use? If tests are not validated, NGS results are not being used to guide clinical treatment decisions, and laboratories might not have a routine method for reporting these.
- What data elements are reportable? WGS can identify allelic variants (e.g., *bla*_{NDM-5}), and assign a sequence type (e.g., *E. coli* ST-131); this granularity is not available using most molecular or phenotypic tests, but this more detailed information can contribute to better understanding of regional epidemiology within a jurisdiction.
- Are NGS results reportable if the organism-carbapenemase combination was previously reported? For example, if a laboratory reported a KPC-positive *Klebsiella pneumoniae* case previously identified by MALDI-TOF and a PCR-based test, is an NGS result for a *Klebsiella pneumoniae* ST-258 harboring a *bla*_{KPC-2} also reportable? Some jurisdictions might opt to receive WGS reports only when a novel or rare carbapenemase is detected (e.g., *bla*_{IMI-2}), or request all WGS results to simplify reporting.
- What is the expected method of reporting? If ELR is not an option, are there other options available? For example, some labs that cannot report via ELR may report via secure email or fax directly to their local health department.

Because NGS can be relatively uncommon, STLT public health agencies should consider consulting with clinical and public health laboratories performing sequencing in their jurisdiction to determine the most efficient and practical way to facilitate reporting of these results.

6.7 Additional data elements for public health investigation (example STLT case reporting forms)

In addition to the minimum data elements necessary for case reporting to CDC, STLT agencies might want to collect more detailed information relevant to an investigation or response. This might include previous and subsequent healthcare exposure and potential high-risk healthcare contacts to inform screening recommendations; and risk factors such as presence of indwelling devices, being mechanically ventilated, co-colonization or -infection with *C. auris*, and international or out-of-state healthcare exposure. See **Appendix F** for specific examples of STLT case reporting forms.

7. How to submit case notifications to CDC

Confirmed CPO cases are routinely notifiable to CDC per the position statement.

7.1 Data elements to include for submission per the MMG (Condition-specific MMG processes are currently under review; additional information will be forthcoming – see www.cdc.gov/nndss/case-surveillance-modernization/ (www.cdc.gov/nndss/case-surveillance-).

 CPO case notifications can only be accepted through the National Notifiable Diseases Surveillance System (NNDSS). Jurisdictions may send CPO cases using HL7 messaging through either the Generic V2.0 MMG (GenV2) or the CPO-specific HAI MDRO MMG (ndc.services.cdc.gov/mmgpage/generic-v2-0-message-mapping-guide/). The CPO tab in the HAI MDRO MMG includes all requested data elements from CDC. Although CDC encourages sending all requested data elements to improve national surveillance, jurisdictions are not required to send all elements. The NNDSS Technical Resource Center (www.cdc.gov/nndss/trc/index.html) can assist jurisdictions in onboarding the HAI MDRO MMG. CPO case examples can be viewed in the CPO Test Case Scenario Worksheets tab of the MMG. When onboarding, jurisdictions will work with the NNDSS and CDC CPO teams to answer all outstanding questions related to implementation. When sending CPO case notifications, there are two separate event codes: (50270) for clinical cases and (50271) for screening cases. For those sending only the generic MMG, separate event codes will allow CDC to better understand the distribution between clinical and screening cases. Case classifications are assigned by STLT public health agencies prior to CDC notification. (See Section 2 for case definitions).

- Specifics on each data element are available in the MMGs. However, here are some general tips to keep in mind:
- The reporting jurisdiction for all NNDSS conditions is based on subject residency jurisdiction. In following that national guidance for all NNDSS conditions, reporting for CPO is based on the subject's (i.e., patient's or resident's) usual state of residence at the time of the condition. However, as CPO is a healthcare-associated infection (HAI) and transmission typically occurs within healthcare settings, the jurisdiction of the healthcare facility is often the most relevant jurisdiction for public health responses and investigations. Communication across states is therefore needed when patients are transferred to another state or when a patient is identified as having a CPO in a healthcare facility of a state other than their residency state. A minimum set of data elements for inter-jurisdictional reporting can be helpful, and might include name, date of birth, specimen source, date of collection, facility name and type of facility where specimen was collected More detailed epidemiologic information, such as patient risk factors, prior healthcare exposure, and the context for how the case-patient was identified, can be additionally helpful though not essential.

As many patients with CPO are residents of long-term care facilities, jurisdictions may find it helpful to become familiar with the Revised Guidelines for Determining Residency for Disease Notification Purposes (PDF) (ndc.services.cdc.gov/wp-content/uploads/2021/02/11-SI-04.pdf) which explains that the jurisdiction of usual residency may be a healthcare setting for people living long-term in an institutionalized setting, such as a nursing home.

8. Additional resources

8.1 Resources for surveillance and response

- **CORHA Proposed** Investigation/Reporting Thresholds and Outbreak Definition for Carbapenem-Resistant Enterobacteriaceae (CRE) (corha.org)
- M100Ed32 | Performance Standards for Antimicrobial Susceptibility Testing, 32nd Edition (clsi.org) (http://em100.edaptivedocs.net/Login.aspx? ga=2.224561170.948929043.1663873824-2118344032.1660842784)

8.2 CDC resources

- CDC MDRO Containment and Prevention Guidelines (www.cdc.gov/hai/containment/index.html)
- CDC Antimicrobial Resistance Laboratory Network (www.cdc.gov/drugresistance/laboratories.html)
- Antimicrobial Resistance and Patient Safety Portal (CDC) <u>Antibiotic Resistance | A.R. & Patient Safety Portal</u> (cdc.gov)

9. Appendices

Appendix A: Examples of Phenotypic Testing Methods and Molecular Tests for Carbapenemase Genes

Phenotypic tests	Molecular tests
Carba NP	BD Max Check-Points CPO
Carbapenem inactivation method (CIM)	FilmArray (BioFire)
EDTA-modified CIM (eCIM)	Nucleic acid amplification test (NAAT) (e.g., PCR)
Immunochromatography test (ICT) ^[1] including	Streck ARM-D
the NG-Test Carba 5	Verigene Gram-Negative Blood
Metallo-β-lactamase test (e.g., E-test)	Culture Nucleic Acid Test (BC-GN)
Modified carbapenem inactivation method (mCIM)	Whole-genome sequencing (WGS)
Modified Hodge test (MHT) ^[2]	Xpert Carba-R

^[1]ICT is a phenotypic test that can identify a specific enzyme (carbapenemase).

^[2] The Modified Hodge Test is no longer included in CSLI guidelines and should only be used in conjunction with other phenotypic or molecular tests for carbapenemases. See CLSI M100 guidelines at <u>https://clsi.org/all-free-resources/</u>

Appendix B:

Example Scenarios Demonstrating Implementation

(e.g., screening vs. clinical, duplicate cases, etc.)

- A person classified as a clinical case should not be counted as a screening case thereafter for the same organism/carbapenemase combination (e.g., patient with known NDM+ E. coli infection who later has NDM+ E. coli colonization should not be counted as a separate case).
- A person classified as a screening case can be later counted as a clinical case with the same organism/carbapenemase combination (e.g., patient with an NDM+ E. coli peri-rectal screening swab who later develops NDM+ E. coli blood stream infection would be counted twice, once in each category). This is the only way that the same organism/carbapenemase combination can be counted twice for the same person.
- A case with a known carbapenemase but unknown organism should only be counted once for that carbapenemase (e.g., an NDM+ screening case is later screened at a different facility and tests NDM+ positive and no organism is identified again).
- A case with a specific carbapenemase/organism combination who later tests positive for the same organism which is known to be a carbapenemase-producer (i.e., mCIM+) but for some reason, mechanism testing is not completed, would result in two cases counted for the same person (e.g., NDM+ E. coli and later, mCIM+ E. coli identified in same individual, but mechanism testing never completed.
- A case with multiple gene targets identified in the same organism (e.g., NDM+/OXA-48+ K. pneumoniae) would be counted once for this specific organism/carbapenemase combination. If the same individual had a subsequent culture that was positive for NDM+ E. coli (but negative for OXA-48), then this would count as a SECOND case.
- A ventilated LTACH resident has a sputum culture that is positive for VIM+ CRPA in 2022. This resident previously in 2021, had a positive rectal swab that was positive for VIM collected at a different facility, but no organism was ever isolated from that swab. This individual would be counted twice- once as a screening VIM+/no organism case in 2021 and again as a clinical VIM+/CRPA case in 2022.
- A resident of a skilled nursing facility is admitted to the hospital and has a sputum culture that is positive for OXA-23+ CRAB. After return to the skilled nursing facility, the resident is accidentally included in a subsequent PPS of the ventilator unit and a rectal swab is OXA-23 positive. CRAB is eventually cultured from the swab. This case would be counted only once, as a clinical OXA23+ CRAB case.
- WGS identified an OXA-113 in a CRAB isolated from a patient's urine culture. This would NOT count as a case, as OXA-113 (which is considered an OXA-51-like gene) is known to be intrinsic to CRAB isolates and known to not be plasmid-mediated. (As a result, the identification of this gene in a CRAB isolate does not trigger an ARLN alert).
- A local health department conducts a PPS for CPO colonization at a skilled nursing facility. The team collects a rectal swab from Patient A that results positive for KPC. Subsequent culture of the swab grows no organism. Patient A would be reported as a KPC+/no organism identified, screening case.
- Patient A lives is a skilled nursing facility, and the state health department recommends a point prevalence survey to screen for CPO on 12/1/2022. Patient A's rectal swab tests positive for NDM, but no organism was ultimately cultured from the swab. On 1/1/2023, Patient A is sent to the hospital due to symptoms of an infection. At the hospital, a urine specimen is collected and tests positive for NDM+ E. coli. Patient A would be counted twice: once as an NDM+ screening case on 7/1/2022 and once as a clinical NDM+ E. coli case on 9/1/2022.
- Patient A has a prior history of NDM+ K. pneumoniae infection from a urine specimen on 1/1/2020. On 7/1/2022, he is hospitalized for an infection, where a blood specimen tests positive for NDM+ K. pneumoniae. Even though the specimen sources are different and collected three years apart, Patient A would only be counted once as an NDM+ K. pneumoniae clinical case on 1/1/2019.

Appendix C:

Examples of State Health Department Guidance for Isolate Reporting and Submission

(As of May 2023)

Links to the *current* MDRO reporting and isolate submission guidance from a variety of jurisdictions are provided below. Additionally, the specific language from a selection of these jurisdictions is also provided for reference and additional detail. (Of note, a number of jurisdictions report that their current reporting and isolate submission guidance is under review or in the process of being updated.)

- California
 - o Laboratory Reportable Diseases (PDF)
- Colorado
 - o Laboratory Guidance for Reportable AR Organisms.pdf Google Drive
- Connecticut
 - <u>Connecticut: CRE_CRAB_LabReporting.pdf (ct.gov)</u>
- Massachusetts
 - o Infectious Disease Reporting and Regulations for Health Care Providers and Laboratories | Mass.gov
- Minnesota
 - o Reportable Infectious Diseases: Reportable Diseases A-Z Minnesota Dept. of Health (state.mn.us)
- Tennessee
 - o <u>2022-Detailed-Laboratory-Guidance.pdf (tn.gov)</u>
- Virginia:
 - o <u>Virginia Reportable Disease List</u> and <u>Conditions Reportable by Directors of Laboratories</u>

Connecticut

<u>When to report CRE results</u>: Please send lab report (electronic or OL15c) to DPH and submit bacterial isolate to SPHL when an isolate is **first identified with any MIC or zone criteria that indicates possible CRE**, even if this has not yet been confirmed by additional testing.

Laboratory criteria for CRE reporting:

1. Enterobacteriaceae species*, if the specimen is collected from urine, a respiratory source, blood, or other normally sterile site

AND

 Isolate is resistant⁺ to any carbapenem (Doripenem, Imipenem, Meropenem, or Ertapenem) Note: Report based on MIC and Zone Diameter, not on interpretation alone. Please refer to Table. Note: All Proteus, Morganella, and Providencia are resistant to imipenem, so resistance to imipenem only for these genera does not require reporting.

OR

The organism displays production of carbapenemase (e.g. KPC, NDM, VIM, IMP, and OXA-48) by PCR regardless of susceptibility results.

*Enterobacteriaceae genera (common ones bolded): Citrobacter, Enterobacter, Hafnia, Klebsiella, Morganella, Proteus, Providencia, Salmonella, Serratia, Shigella, Yersinia, Alterococcus, Arsenophonus, Brenneria, Buchnera, Budvicia, Buttiauxella, Calymmatobacterium, Candidatus Phlomoacter, Cedecea, Edwardsiella, Erwinia, Ewingella, Kluyvera, Leclercia, Leminorella, Moellerella, Obesumbacterium, Pantoea, Pectobacterium, Photorhabdus, Plesiomonas, Pragia, Rahnella, Raoultella, Saccharobacter, Sodalis, Tatumella, Tralbulsiella, Wigglesworthia, Xenorhabdus, Yokenella

[†]**Table.** MIC and Zone Diameter Interpretive Criteria for *E. Coli, Klebseilla* species, and *Enterobacter* species by antimicrobial, based on <u>2018 CLSI breakpoints (M100-S28)</u>

MIC Criteria (µg/mL)			Zone Diameter Criteria (nearest whole mm)				
Doripenem	Imipenem	Meropenem	Ertapenem	Doripenem	Imipenem	Meropenem	Ertapenem
≥4	≥4	≥4	≥2	≤19	≤19	≤19	≤18

Note: If breakpoints above are not in use at your facility, please contact DPH for individualized guidance.

Lab Testing Data Elements to report for CRE:

- Patient and Provider information
- CRE culture results
 - Genus and species of organism (e.g. *Klebsiella pneumoniae*)
 - Specimen source (e.g. urine, sputum, BAL, pleural fluid, blood, abscess, CSF, etc.)
 - Body site (e.g. peripheral blood, groin, left great toe, etc.)
 - Date of collection
- Susceptibility results
 - For each drug: MIC value (when available), zone diameter (when available), and interpretation
 - Methodology (e.g. Vitek, Phoenix, Microscan, Sensititre, Kirby-Bauer, E-test)
- PCR results for carbapenemase (when available)
 - Positive carbapenemase findings
 - o Negative results of carbapenemases tested

<u>When to report CRAB results</u>: Please send lab report (electronic or OL15c) to DPH and submit bacterial isolate to SPHL when an isolate is **first identified with any MIC or zone criteria that indicates possible CRAB**, even if this has not yet been confirmed by additional testing.

Laboratory criteria for CRAB reporting:

1. *Acinetobacter species**, if the specimen is collected from urine, a respiratory source, a wound, blood, or other normally sterile site

AND

 Isolate is resistant[†] to any carbapenem except Ertapenem (Doripenem, Imipenem, and Meropenem) Note: Report based on MIC and Zone Diameter, not on interpretation alone. Please refer to Table. Note: All Acinetobacter are resistant to Ertapenem, so Acinetobacter resistant to ertapenem only does not require reporting

OR

The organism displays production of carbapenemase (e.g. KPC, NDM, VIM, IMP, and OXA-48) by PCR regardless of susceptibility results.

*Include A. baumannii, A. baumannii complex, A. calcoaceticus-baumannii complex, and all subspecies (e.g. Acinetobacter pittii, Acinetobacter nosocomialis, Acinetobacter calcoaceticus)

***Table.** MIC and Zone Diameter Interpretive Criteria for *Acinetobacter baumannii* by antimicrobial, based on CDC <u>Multi-site Gram Negative Surveillance Initiative</u>

MIC Criteria (µg/mL)			Zone Diameter Criteria (nearest whole mm)		
Doripenem	Imipenem	Meropenem	n Doripenem Imipenem Meropenem		
>1	≥8	≥8		≤18	≤14

Note: Breakpoints for doripenem established by FDA. Note that these may not align with CLSI breakpoints. If breakpoints above are not in use at your facility, please contact DPH for individualized guidance.

Lab Testing Data Elements to report for CRAB:

- Patient and Provider information
- CRAB culture results
 - o Genus and species of organism (e.g. Acinetobacter baumannii)
 - o Specimen sources (e.g. urine, sputum, wound, BAL, pleural fluid, blood, abscess, CSF, etc.)
 - o Body site (e.g. peripheral blood, groin, left great toe, etc.)
 - Date of collection
- Susceptibility results
 - For each drug: MIC value (when available), zone diameter (when available), interpretation
 - Methodology (e.g. Phoenix, Microscan, Vitek, Kirby-Bauer, E-test)
- PCR results for carbapenemase (when available)
 - o Positive carbapenemese findings
 - Negative results of carbapenemases tested

Massachusetts

The **Massachusetts** Department of Public Health *requires* the following to be **reported**:

All Laboratories shall report results indicating antimicrobial resistance in the following organisms directly to the Department through secure electronic laboratory reporting mechanisms, or other method, as defined by the Department. Information shall include the name of a laboratory contact, the specified test results, date of specimen collection, source of specimen, and the case's full name, date of birth, sex, race and ethnicity, full address, telephone number, and name of the ordering health care provider, when available.

Carbapenemase-producing and/or carbapenem-resistant Enterobacteriaceae

Neisseria gonorrhoeae resistant to ceftriaxone

Vancomycin-resistant Staphylococcus aureus (VRSA)

Vancomycin-intermediate Staphylococcus aureus (VISA)

Invasive methicillin-resistant Staphylococcus aureus (MRSA)

Invasive penicillin-resistant Streptococcus pneumoniae

If antimicrobial resistance of an unexplained or novel nature is identified in any infectious organism, the laboratory must contact the Department within five business days.

The Massachusetts State Public Health Laboratory requests submission of:

- Carbapenem-resistant Enterobacterales (CRE) isolated from any source, with resistance to one or more of the following carbapenems: imipenem, meropenem, doripenem (at MIC ≥4 mcg/ml), or ertapenem (at MIC ≥2 mcg/ml); EXCEPTION: ertapenem resistance alone is not a criterion for isolate submission.
 - Requested organisms include but are not limited to isolates of Citrobacter, *E. coli*, Enterobacter, Klebsiella, Morganella, Proteus, Providencia, and Serratia species.
 - Note: Due to intrinsic resistance found in *Morganella morganii*, Proteus and Providencia species, isolates of these organisms that exhibit monoresistance to imipenem are no longer required for submission.
- Any organism demonstrating carbapenemase production, by phenotypic testing using the mCIM- Modified Carbapenem Inactivation Method; or Carba-NP; or detection of any of the following gene targets: KPC; NDM; OXA; VIM; and IMP by mechanism-specific PCR test.
 - All Carbapenem-resistant Acinetobacter baumannii (CRAB) isolates.
 - All Carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) isolates that are also non-susceptible to cefepime and/or ceftazidime.

Please submit one isolate per patient per year. If a repeat isolate is identified with a significantly different resistance profile less than a year after the first, please submit or contact the lab for guidance.

New Jersey

The New Jersey State Department of Health <u>currently</u> requests reporting of:

- Carbapenem-Resistant *Enterobacteriaceae* (CRE) positive for a non-blaKPC carbapenemase resistance gene (e.g., blaNDM, blaIMP, blaVIM, blaOXA48)
- Carbapenem-Resistant Acinetobacter spp. resistant to one or more of the following: imipenem (≥8 μg/mL), meropenem (≥8 μg/mL), or doripenem (≥8 μg/mL) and/or positive for a carbapenemase resistance gene (e.g., blaKPC, blaNDM, blaIMP, blaVIM, blaOXA48)
- Carbapenem-Resistant *Pseudomonas aeruginosa* (CRPA) positive for a carbapenemase resistance gene (e.g., blaKPC, blaNDM, blaIMP, blaVIM, blaOXA48)
- Pan-non susceptible organisms

The New Jersey State Public Health and Environmental Laboratory <u>currently</u> requests submission of:

- Carbapenem-Resistant Enterobacterales (CRE):
 - Organisms: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, and Enterobacter spp.
 - Resistance to one or more of the following: imipenem (≥4 µg/mL), meropenem (≥4 µg/mL), doripenem (≥4 µg/mL), or ertapenem (≥2 µg/mL)
 - Carbapenem-Resistant Pseudomonas aeruginosa (CRPA):
 - Resistance to one or more of the following: imipenem (≥8 µg/mL), meropenem (≥8 µg/mL), or doripenem (≥8 µg/mL)
 - Source: Non-mucoid isolates
 - Carbapenem-Resistant Acinetobacter spp.:
 - Resistance to one or more of the following: imipenem (≥8 µg/mL), meropenem (≥8 µg/mL), or doripenem (≥8 µg/mL)

The **New Jersey** State Department of Health is currently in the process of updating reporting/submission requirements and <u>will be requiring</u> the following:

- 1. **Isolate submission**: "Microbiologic culture isolates of the following organisms, and specimens obtained from humans associated with the identification of, or potentially containing, these organisms":
 - Carbapenem-Resistant Enterobacteriaceae (CRE): Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Klebsiella aerogenes, Citrobacter spp. and Enterobacter spp. resistant to one or more of the following carbapenems using current FDA and/or CLSI interpretive criteria: doripenem, imipenem, meropenem or ertapenem, and/or positive for a non-blaKPC carbapenemase resistance gene (e.g., blaNDM, blaIMP, blaVIM, blaOXA48) if testing is available and performed (Center for Drug Evaluation and Research. "Antibacterial Susceptibility Test Interpretive Criteria." U.S. Food and Drug Administration, FDA, https://www.fda.gov/drugs/development-resources/antibacterial-susceptibility-test-interpretive-criteria);
 - Carbapenem-Resistant *Pseudomonas aeruginosa* (CRPA) non-mucoid isolates resistant to one or more of the following carbapenems according to interpretive criteria provided by U.S Food and Drug Administration and/or CLSI, "Antibacterial Susceptibility Test Interpretive Criteria" available at https://www.fda.gov/drugs/development-resources/antibacterial-susceptibility-test-interpretivecriteria/: doripenem, imipenem, or meropenem;

- Carbapenemase-producing organisms (CPO), including but not limited to *Enterobacterales*, *Acinetobacter baumannii* and *Pseudomonas aeruginosa*;
- Pan-non susceptible organisms
- Case Reporting: "Confirmed cases of the following are reportable by the close of the next business day following the date of either confirmation of a communicable disease, infection, or condition diagnosis, or receipt of a laboratory result or other indicator of communicable disease, infection or condition (with respect to administrators who are not diagnosticians):
 - Carbapenemase-producing organisms (CPO), including but not limited to *Enterobacterales*, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*

Virginia

Introduction

The State Board of Health updated the Virginia Regulations for Disease Reporting and Control (12 VAC 5-90-80) effective November 14, 2018. **Carbapenemase-producing organisms (CPOs) were added to the reportable** disease list and conditions reportable by directors of laboratories. Thus, the responsibility for reporting the presence of these organisms rests with physicians, directors of medical care facilities, and directors of laboratories. Because of the special laboratory testing needed to identify and confirm these organisms, however, it is expected that laboratories will be the primary responsible party for reporting these organisms. A further complexity exists because of the differing levels of capacity for identifying and/or confirming the presence of these organisms in laboratories. The guidance below is intended to clarify requirements for **reporting** and for **submitting isolates** for further public health testing.

Definition

Carbapenemase Producing Organisms (CPO) are defined as organisms where the isolate is:

• Positive for carbapenemase production by a phenotypic method (e.g., mCIM, Carba NP)

-OR-

• Positive for a known carbapenemase resistance mechanism by a recognized test (e.g., PCR, X-pert CarbaR)

Reporting

Virginia Reportable Disease List	Virginia Isolate Submission List
 Report all carbapenemase-producing organisms (CPO), infection or colonization, to your <u>local</u> <u>health department</u> (LHD) Submit a laboratory report and/or <u>Epi-1 form</u>; see Table 1. Include available antimicrobial susceptibility testing (AST) results. 	 Submit carbapenem-resistant Enterobacteriaceae (CRE) and carbapenem-resistant <i>Pseudomonas</i> <i>aeruginosa</i> (CRPA) isolates to the Division of Consolidated Laboratory Services (DCLS) for further public health testing unless the laboratory is capable of conducting a comparable level of testing for carbapenemase-production as DCLS; see Table 1. This additional testing is not available for other CROs at this time. Use the DCLS Clinical Microbiology/Virology Request Form. Include available AST results with specimen submissions.

Table 1. Recommendations for Isolate Submission to DCLS and Reporting to LHD Based on Hospital/ ReferenceLaboratory Testing and Electronic Laboratory Reporting (ELR) Capacity

Laboratory Testin	g and ELR Capacity	Isolate Submissio	on and Reporting
CRE and CRPA testing capability	ELR capacity	Send CRE and CRPA isolate to DCLS?	Reporting Method to LHD for CPO ^A
Unable to perform phenotypic/molecular testing comparable to that conducted by DCLS	Yes	Yes	Not applicable for CP-CRE and CP-CRPA; DCLS reports results to LHD. All other confirmed CPOs should be reported via ELR.
	No	Yes	Not applicable for CP-CRE and CP-CRPA; DCLS reports results to LHD. All other confirmed CPOs should be reported via Epi- 1 form and/or lab report.
Able to perform comparable	Yes	No*	ELR of carbapenemase- production result.
phenotypic/molecular testing comparable to that conducted by DCLS ⁺	No	No*	Epi-1 form and/or lab report for carbapenemase- production result.

^ Hospitals using an out-of-state reference laboratory must include these findings in the ELR messages if their laboratory information system is able to do so. If not, submit to public health by fax or mail.

+ <u>Please contact the HAI/AR Program</u> to inquire if your laboratory can be exempt from sending CRE and CRPA isolates for further testing at DCLS.

* Per agreement with Virginia Department of Health, except when requested for further public health testing.

Appendix D: Electronic Laboratory Reporting (ELR) Resources

Electronic Laboratory Reporting Guidance (CA DPH)

Reporting		
Component	Description	Example
Genus and Species	Use the most specific SNOMED codes for genus and species identification. Each accession number should be associated with at least one organism.	Use SNOMED code 446870005 (Carbapenem resistant Klebsiella pneumoniae) rather than 712662001 (Carbapenem resistant Enterobacteriaceae organism).
	Specimens with no organism identified but positive for a carbapenemase should be indicated using the appropriate LOINC code.	LOINC code 100901-8 (Enterobacteriaceae. carbapenemase resistance phenotype in Anal by Organism specific culture) indicates a rectal swab that is carbapenemase positive but with no organism isolated.
Specimen Source	Use LOINC codes to include information about specific specimen source.	Use LOINC code 630-4 (bacteria identified in urine by culture) rather than 11475-1 (Microorganism identified in Specimen by Culture).
Carbapenem ase Results	Use parent-child relationships to tie organism and carbapenemase identification observations to the organism observation.	<i>Klebsiella pneumoniae</i> would be the parent observation, and the child observation would be the associated KPC results.
	Laboratories performing a carbapenemase test that identifies specific carbapenemase types or genes should report the specific carbapenemase type(s) or gene(s) identified and the corresponding SNOMED code to indicate if result is positive or detected.	If an isolate is positive for <i>bla</i> _{NDM} gene, use LOINC code 73982-1 (Carbapenem resistance blaNDM gene Presence by Molecular method) rather than the more generic 86930-5 (Carbapenemase Presence in Isolate), and SNOMED code 260373001 (Detected) to confirm the result.
	All local codes and fields indicating the presence of a carbapenemase should be clear.	Do not use the term "carbapenemase-resistant [insert organism]." If the organism is positive for a carbapenemase enzyme or gene, please indicate this using the appropriate LOINC code. The term "KPCKP" should indicate a KPC-positive <i>Klebsiella pneumoniae</i> isolate and would preferably be written out and correspond to a specific LOINC code indicating the carbapenemase result.
Test Type	For organism identification, AST, or carbapenemase detection, labs should use a LOINC code that specifies the test method used (to the extent possible)	Use LOINC code 75756-7 (Bacteria identified in isolate by MS.MALDI-TOF) rather than the more generic 42803- 7 (Bacteria identified in Isolate)
Comments	Do not send comments using multiple result OBX segments; place comments in NTE segments rather than OBX segments.	Rather than use OBX 7 "identification and susceptibility," OBX 8 "Testing to follow", place comments in a single NTE segment. If there are multiple OBXs, use the OBX 4 (observation sub-id) to group related OBXs.

If important results are indicated in the comments, please ensure that these results are also indicated in an OBX segment using the appropriate LOINC or SNOMED code.	NTE segments should not be used to communicate important information, such as organism, specimen source, or carbapenemase results, <i>unless</i> the result is already indicated in an OBX segment.

Examples of commonly observed deficiencies in received HL7 ELR messages:

- No utilization of parent/child linking of susceptibility labs to the organism(s), or parent/child relationships are used incorrectly. Without proper parent/child linkages, determining which susceptibility results go with each identified organism may be difficult without the verification of paper laboratory results.
 - *Recommendation*: Make sure facilities are submitting the correct linking values and jurisdictions have the capability to utilize the parent/child result to link the susceptibility test to the organism.
- *Missing specimen information specimen source site (SPM8), specimen type, etc.* Specimen information is needed to determine the timeframe for defining a case as new or recurrent.
 - *Recommendation:* Specimen information should be sent.
- Results are sent in NTE segments
 - *Recommendation:* All results should be sent in an OBX segment; quantitative results should be sent in a numeric or structured numeric segment. Qualitative results should be sent in an OBX segment, perhaps using a CE or CWE data type, using national standard vocabulary such as LOINC and/or SNOMED. NTE segments should not be used to communicate important information.
- Comments are sent in multiple result (OBX) segments. This can result in potentially important information not being communicated to downstream systems. If the information does come through, use of multiple OBX segments can make reading results difficult.
 - Example: OBX|7 "identification and susceptibility," OBX|8 "Testing to follow"
 - *Recommendation*: Placing comments in NTE segments rather than OBX segments. When there are multiple OBXs, use the OBX|4 (observation sub-id) to group related OBXs

Appendix E:

Relevant LOINC and SNOMED Codes

The text and tables below are excerpts from the California Department of Public Health (CDPH) ELR

Guidance for laboratories reporting carbapenemase-producing organisms.

A. Electronic Laboratory Reporting (ELR) Best Practices

- Use the most specific and up-to-date SNOMED^[1] and LOINC^[2] codes for all ELR messages.
 - o For LOINC codes, send the Long Common Name to accompany the LOINC code in messaging.
 - o All reports should, to the extent possible, indicate the following:
 - Genus and species
 - Type of specimen tested
 - Test method for the type of test performed for this case, such as the test brand or software, or type of PCR
 - Carbapenemase gene identified in the CPO
 - o See Tables 4-6 for a list of preferred codes and terms
- Please contact <u>HAIProgram@cdph.ca.gov</u> with specific questions about data elements, or <u>CaIREDIEELR@cdph.ca.gov</u> for more information on formatting ELR messages.

[1] SNOMED lookup: <u>http://browser.ihtsdotools.org/</u>

^[2] LOINC term lookup: <u>https://search.loinc.org/</u>

Table 4. Example LOINC and SNOMED Codes for Organism Identification

LOINC Code	LOINC Name (Long Common Name)	SNOMED Code	SNOMED Name	
Coue		Coue		
44841-5	Bacteria # 2 identified in Specimen by Culture*	91288006	Acinetobacter baumannii	
17970-5	Bacteria # 2 identified in Urine by Culture	113381003	Acinetobacter radioresistens	
44038-8	Bacteria [Presence} in Specimen*	734350003	Carbapenemase-producing bacteria (organism)**	
17928-3	Bacteria identified in Blood by Aerobe culture	55744003	Citrobacter amalonaticus	
600-7	Bacteria identified in Blood by Culture	114262000	Citrobacter braakii	
610-6	Bacteria identified in Body fluid by Aerobe culture*	6265002	Citrobacter freundii	
90274-2	Bacteria identified in Catheter tip by Aerobe culture*	114264004	Citrobacter koseri	
42803-7	Bacteria identified in Isolate*	33115003	Enterobacter asburiae	
43409-2	Bacteria identified in Isolate by Culture*	14385002	Enterobacter cloacae	
75756-7	Bacteria identified in Isolate by MS.MALDI-TOF*	414102007	Enterobacter cloacae complex	
634-6	Bacteria identified in Specimen by Aerobe culture*	114454006	Enterobacter hormaechei	
635-3	Bacteria identified in Specimen by Anaerobe culture*	114456008	Enterobacter kobei	
6463-4	Bacteria identified in Specimen by Culture*	432763001	Enterobacter ludwigii	
32355-0	Bacteria identified in Specimen by Respiratory culture	29511003	Enterobacter nimipressuralis	
622-1	Bacteria identified in Sputum by Aerobe culture	112283007	Escherichia coli	
6460-0	Bacteria identified in Sputum by Culture	76694001	Hafnia alvei	
623-9	Bacteria identified in Sputum by Cystic fibrosis resp culture	62592009	Klebsiella aerogenes	
43408-4	Bacteria identified in Tissue by Culture	40886007	Klebsiella oxytoca	
630-4	Bacteria identified in Urine by Culture	65186004	Klebsiella ozaenae	
6462-6	Bacteria identified in Wound by Culture	56415008	Klebsiella pneumonia	
73834-4	Bacteria.carbapenem resistant identified in Anal by Organism specific culture	431976004	Klebsiella variicola	
94151-8	Bacteria.carbapenem resistant identified in Specimen by Organism specific culture*	243301005	Morganella morganii	
76346-6	Microorganism identified in Isolate by MS.MALDI-TOF*	716346000	Pluralibacter gergoviae	

11475-1	Microorganism identified in Specimen by Culture*	73457008	Proteus mirabilis
664-3	Microscopic observation in Specimen by Gram stain*	45834001	Proteus vulgaris
		14196002	Providencia rettgeri
		1445008	Providencia stuartii
		52499004	Pseudomonas aeruginosa
		450413007	Pseudomonas otitidis
		416832000	Raoultella ornithinolytica
		23787004	Serratia liquefaciens
		33522002	Serratia marcescens
		113697002	Stenotrophomonas maltophilia

*Please indicate specific specimen source

**Parent observation, please indicate genus and species

Table 5. Example LOINC and SNOMED Codes for Carbapenemase Detection

LOINC Code	LOINC (Long Common Name)	SNOMED Code	SNOMED Name
88245-6	Carbapenem resistance blaIMP gene by Probe in Positive blood culture		
95540-1	Carbapenem resistance blaIMP+blaVIM genes by Molecular method		
88246-4	Carbapenem resistance blaKPC gene by Probe in Positive blood culture		
88247-2	Carbapenem resistance blaNDM gene by Probe in Positive blood culture		
86712-7	Carbapenem resistance blaOXA gene by Molecular method		
88248-0	Carbapenem resistance blaOXA gene by Probe in Positive blood culture		Detected
86713-5	Carbapenem resistance blaOXA-134-like gene by Molecular method	260373001 260415000	
93390-3	Carbapenem resistance blaOXA-23-like+blaOXA-48-like genes in Isolate or Specimen by Molecular method		Not Detected
86714-3	Carbapenem resistance blaOXA-51-like gene by Molecular method		
88249-8	Carbapenem resistance blaVIM gene by Probe in Positive blood culture		
95809-0	Carbapenem resistance genes by Molecular method*		
77924-9	Enterobacteriaceae.carbapenem resistant in Anorectal or stool specimen by Organism specific culture*		

interim vers	ion - Updated 5.11.23	_	
85823-3	Carbapenem resistance blaGES gene by Molecular method		
85833-2	Carbapenem resistance blaGIM gene by Molecular method		
85824-1	Carbapenem resistance blaIMP gene by NAA with probe detection	-	
49617-4	Carbapenem resistance blaKPC gene by Molecular method	-	
73982-1	Carbapenem resistance blaNDM gene by Molecular method		
85827-4	Carbapenem resistance blaOXA-48-like gene by Molecular method	10828004	Positive
85825-8	Carbapenem resistance blaOXA-23-like gene by Molecular method	260385009	Negative
85826-6	Carbapenem resistance blaOXA-24-like gene by Molecular method		
85828-2	Carbapenem resistance blaOXA-58-like gene by Molecular method		
98065-6	Carbapenem resistance blaOXA-143 gene by Molecular method		
85829-0	Carbapenem resistance blaSPM gene by Molecular method		
85830-8	Carbapenem resistance blaVIM gene by NAA with probe detection	-	
86930-5	Carbapenemase [Presence] in Isolate*		
85498-4	Carbapenem resistance blaIMP gene by Molecular method	· · · · ·	Detected Not Detected Equivocal
85499-2	Carbapenem resistance blaKPC gene by NAA with probe detection	260373001 260415000	
85500-7	Carbapenem resistance blaNDM gene by NAA with probe detection	42425007 419984006	
85503-1	Carbapenem resistance blaOXA-48 gene by Molecular method		Inconclusive
85501-5	Carbapenem resistance blaVIM gene by Molecular method		
100900-0	Enterobacteriaceae.carbapenem resistance panel - Anal by Organism specific	culture*	
100901-8	Enterobacteriaceae.carbapenemase resistance phenotype in Anal by Organisr	n specific cultu	re*
63368-5	Carbapenem resistance genes [Identifier] by NAA with probe detection*		
85502-3	Carbapenemase resistance genes panel by Molecular genetics method*		
97324-8	Carbapenem resistant bacteria identification and resistance panel by Molecular genetics method*		
74676-8	Carbapenemase [Type] in Isolate by Carba NP*		

*If applicable, use SNOMED/LOINC codes to indicate organism and type of carbapenemase detected

Table 6. Example LOINC Codes for Antimicrobial Susceptibility Results

LOINC Code	LOINC Name (Long Common Name)	
95767-0	Cefiderocol [Susceptibility] by Disk diffusion (KB)	
99503-5	Cefiderocol [Susceptibility] by Minimum inhibitory concentration (MIC)	
73648-8	cefTAZidime+Avibactam [Susceptibility] by Disk diffusion (KB)	
87734-0	cefTAZidime+Avibactam [Susceptibility] by Gradient strip	
73625-6	cefTAZidime+Avibactam [Susceptibility] by Minimum inhibitory concentration (MIC)	
72893-1	Doripenem [Susceptibility] by Disk diffusion (KB)	
58711-3	Doripenem [Susceptibility] by Gradient strip	
56031-8	Doripenem [Susceptibility] by Minimum inhibitory concentration (MIC)	
93767-2	Eravacycline [Susceptibility] by Gradient strip	
85423-2	Eravacycline [Susceptibility] by Minimum inhibitory concentration (MIC)	
35799-6	Ertapenem [Susceptibility] by Disk diffusion (KB)	
35800-2	Ertapenem [Susceptibility] by Gradient strip	
35801-0	Ertapenem [Susceptibility] by Minimum inhibitory concentration (MIC)	
18932-4	Imipenem [Susceptibility]	
280-8	Imipenem [Susceptibility] by Disk diffusion (KB)	
7019-3	Imipenem [Susceptibility] by Gradient strip	
23613-3	Imipenem [Susceptibility] by Method for Slow-growing mycobacteria	
279-0	Imipenem [Susceptibility] by Minimum inhibitory concentration (MIC)	
278-2	Imipenem [Susceptibility] by Minimum lethal concentration (MLC)	
93232-7	Imipenem+Relebactam [Susceptibility] by Gradient strip	
85424-0	Imipenem+Relebactam [Susceptibility] by Minimum inhibitory concentration (MIC)	
18943-1	Meropenem [Susceptibility]	
6653-0	Meropenem [Susceptibility] by Disk diffusion (KB)	
7029-2	Meropenem [Susceptibility] by Gradient strip	
6652-2	Meropenem [Susceptibility] by Minimum inhibitory concentration (MIC)	
6651-4	Meropenem [Susceptibility] by Minimum lethal concentration (MLC)	

90980-4	Meropenem+Vaborbactam [Susceptibility] by Gradient strip	
85427-3	Meropenem+Vaborbactam [Susceptibility] by Minimum inhibitory concentration (MIC)	
73637-1	Plazomicin [Susceptibility] by Disk diffusion (KB)	
94719-2	Plazomicin [Susceptibility] by Gradient strip	
73614-0	Plazomicin [Susceptibility] by Minimum inhibitory concentration (MIC)	

Appendix F: Examples of STLT CPO Case Reporting Forms

New Jersey: <u>Microsoft Word - MDRO CRF_Jan 2022.docx (nj.gov)</u>

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