

Change Request

Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats (OMB No. 0920-1310, Exp. Date 12/31/2027)

Summary

The proposed changes to the Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats package are 1) adding a new data collection instrument for data that is to be collected in REDCap for participating jurisdictions (Attachment 3h), 2) wording changes to two existing data collection forms to comply with current Executive Orders (Attachment 3f and 3g) , and 3) wording changes that enhance the clarity of the questions/instructions as well as the removal of questions that are no longer relevant (Attachment 3a, 2d, 2f, 2m, 2o, and 2s), and 4) the removal of two instruments that are no longer being collected (Attachment 2n and 2r).

Attachments

1. Attachment 3a_AR Lab Network Annual Report of Testing Methods for Carbapenemase-producing Organisms
2. Attachment 3f_AR Lab Network Alert and Monthly Data Report Form for Neisseria gonorrhoeae
3. Attachment 3g_AR Lab Network DAART data elements for Neisseria gonorrhoeae
4. Attachment 3h_Implementation of new HL7 messages—IT Initial Set up for Dermatophyte Reporting
5. Attachment 2d_I.4- HAIAR WHOLE GENOME SEQUENCING (WGS) OF GRAM-NEGATIVE AR THREATS IN JURISDICTION- Annual Evaluation and Performance Measurement Report
6. Attachment 2f_I.6- CARBAPENEMASE-PRODUCING ORGANISM (CPO) SCREENING IN JURISDICTION- Annual Evaluation and Performance Measurement Report
7. Attachment 2m_I.13- ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF INVASIVE HAEMOPHILUS INFLUENZAE (H. INFLUENZAE) IN JURISDICTION- Annual Evaluation and Performance Measurement Report
8. Attachment 2n_I.14- MYCOPLASMA GENTALIUM (MG)- Annual Evaluation and Performance Measurement Report
9. Attachment 2o_I.15- MOLECULAR Mtb TESTING- Annual Evaluation and Performance Measurement Report
10. Attachment 2r_I.18- HEALTHCARE WASTEWATER-BASED SURVEILLANCE - Annual Evaluation and Performance Measurement Report
11. Attachment 2s_I.19- COMMUNICATION AND COORDINATION OF ACTIONABLE EPI LAB DATA IN JURISDICTION- Annual Evaluation and Performance Measurement Report

Effect of Proposed Changes on Currently Approved Instruments

Attachment 3a AR Lab Network Annual Report of Testing Methods for Carbapenemase-producing Organisms		
Type of Change	Itemized Changes / Justification	Impact to Burden

Removal	<p>Questions:</p> <ol style="list-style-type: none"> 1. Record ID (label as State_monthyear, ex: AK_032021) 2. Does your lab utilize CDC's MicrobeNet? 3. If no, please describe the decision tree for AST in your lab 4. Alternatively, if no, you may upload any decision trees or workflow for AST in your lab 5. MBL screen method (select all that apply) 6. If other MBL method, please specify 7. If using an immunochromatography test, which brand are you using? 8. Report which state samples are sent to for WGS analysis. <p>Justification: No longer needed for collection from jurisdictions.</p>	Decrease in burden
Addition	<p>Questions:</p> <ol style="list-style-type: none"> 1. If yes, please describe which WGS (wet-lab) protocols are validated and verified under CLIA standards (e.g., DNA extraction, library preparation, MiSeq sequencing)? 2. Are your bioinformatic protocols validated and verified under CLIA standards? 3. If yes, please describe which bioinformatic tools and/or pipelines are validated and verified under CLIA standards? 4. If other, please specify 5. Is HAI/AR WGS conducted via a sequencing core facility that also supports WGS for other programs/pathogens? 6. If other, please specify. 7. Number of MiniSeq instruments available for use 8. Number of MiSeq DX instruments available for use 9. If other, please specify. 10. Are your bioinformatics supported through a contracted vendor/partner? 11. If other, please specify. <p>Justification: Added to completely capture different protocols and tools being used by laboratories for while genome sequencing.</p>	Increase in burden
Attachment 3f AR Lab Network Alert and Monthly Data Report Form for <i>Neisseria gonorrhoeae</i>		
Revision	<p>1. Patient's Sex</p> <p>Justification: Replaced gender with sex to comply with Executive Order</p>	No change to burden
Attachment 3g AR Lab Network DAART data elements for <i>Neisseria gonorrhoeae</i>		
Revision	<p>2. Patient's Sex</p> <p>Justification: Replaced gender with sex to comply with Executive Order</p>	No change to burden
Attachment 3h Implementation of new HL7 messages—IT Initial Set up for Dermatophyte Reporting		
Addition	<p>Questions:</p> <ol style="list-style-type: none"> 3. Record ID 	Increase in burden by 8 hours for updates to HL7

	<p>4. ARLN isolate or REDCap ID</p> <p>5. ARLN specimen id</p> <p>6. ARLN PHL State</p> <p>7. Public health laboratory name</p> <p>8. REDCap reporting date</p> <p>9. CDC use only - REDCap reporting date</p> <p>10. CDC use only - Days since created (Calculation)</p> <p>11. CDC use only - REDCap last updated date</p> <p>12. Clinical sample or Isolate</p> <p>13. Specimen type</p> <p>14. Specimen collection date</p> <p>15. Specimen received date</p> <p>16. Healthcare facility of origin state or territory</p> <p>17. Healthcare facility of origin zip code</p> <p>18. Healthcare facility of origin name</p> <p>19. Healthcare facility of origin id</p> <p>20. Submitter specimen id</p> <p>21. Submitter facility state or territory</p> <p>22. Submitter facility zip code</p> <p>23. Submitter facility name</p> <p>24. Submitter facility id</p> <p>25. Patient ID</p> <p>26. Patient date of birth</p> <p>27. Patient's age</p> <p>28. Patient age unit</p> <p>29. Patient's sex</p> <p>30. Patient's race</p> <p>31. Race Other</p> <p>32. Patient ethnicity</p> <p>33. Patient's county code of residence</p> <p>34. Patient's county of residence</p> <p>35. Patient's state or territory of residence</p> <p>36. Patient's country of residence</p> <p>37. Did your lab perform antimicrobial-resistant dermatophyte testing?</p> <p>38. Species identified by your lab</p> <p>39. Date the species identification was performed by your lab</p> <p>40. Date the species identified by your lab was reported to the submitter</p> <p>41. Amphotericin b MIC</p> <p>42. Other amphotericin b MIC</p> <p>43. Date of amphotericin b MIC</p> <p>44. Date amphotericin b MIC results reported</p> <p>45. Anidulafungin MIC</p> <p>46. Other anidulafungin MIC</p> <p>47. Date of anidulafungin MIC</p> <p>48. Date of anidulafungin MIC results reported</p> <p>49. Caspofungin MIC</p> <p>50. Other caspofungin MIC</p> <p>51. Date of caspofungin AFST</p>	reporting including additional testing, or LIMS re-validation.
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	<p>52. Date caspofungin MIC results reported</p> <p>53. Ibrexafungerp MIC</p> <p>54. Other ibrexafungerp MIC</p> <p>55. Date of ibrexafungerp MIC</p> <p>56. Date ibrexafungerp MIC reported</p> <p>57. Fluconazole MIC</p> <p>58. Other fluconazole MIC</p> <p>59. Date of fluconazole MIC</p> <p>60. Date flucoazole MIC reported</p> <p>61. Isavuconazole MIC</p> <p>62. Other isavuconazole MIC</p> <p>63. Date of isavuconazole MIC</p> <p>64. Date isavuconazole MIC results reported</p> <p>65. Itraconazole MIC</p> <p>66. Other itraconazole MIC</p> <p>67. Date of itraconazole MIC</p> <p>68. Date itraconazole MIC results reported</p> <p>69. Micafungin MIC</p> <p>70. Other micafungin MIC</p> <p>71. Date micafungin MIC</p> <p>72. Date micafungin MIC results reported</p> <p>73. Posaconazole MIC</p> <p>74. Other posaconazole MIC</p> <p>75. Date of posaconazole MIC</p> <p>76. Date posaconazole results reported</p> <p>77. Voriconazole MIC</p> <p>78. Other voriconazole MIC</p> <p>79. Date of voriconazole MIC</p> <p>80. Date voriconazole MIC results reported</p> <p>81. Ciclopirox MIC</p> <p>82. Other ciclopirox MIC</p> <p>83. Date of ciclopirox MIC</p> <p>84. Date ciclopirox MIC results reported</p> <p>85. Razuconazole MIC</p> <p>86. Other razuconazole MIC</p> <p>87. Date of razuconazole MIC</p> <p>88. Date razuconazole MIC results reported</p> <p>89. Rezafungin MIC</p> <p>90. Other rezafungin MIC</p> <p>91. Date of rezafungin MIC</p> <p>92. Date rezafungin MIC results reported</p> <p>93. Ketoconazole MIC</p> <p>94. Other ketoconazole MIC</p> <p>95. Date of ketoconazole MIC</p> <p>96. Date ketoconazole MIC results reported</p> <p>97. Luliconazole MIC</p> <p>98. Other luliconazole MIC</p> <p>99. Date of luliconazole MIC</p>
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	<p>100. Date luliconazole MIC results reported</p> <p>101. Oteseconazole MIC</p> <p>102. Other oteseconazole MIC</p> <p>103. Date of oteseconazole MIC</p> <p>104. Date oteseconazole MIC results reported</p> <p>105. Manogepix MIC</p> <p>106. Other manogepix MIC</p> <p>107. Date of manogepix MIC</p> <p>108. Date manogepix MIC results reported</p> <p>109. Griseofulvin MIC</p> <p>110. Other griseofulvin MIC</p> <p>111. Date of griseofulvin MIC</p> <p>112. Date griseofulvin MIC reported</p> <p>113. Terbinafine MIC</p> <p>114. Other terbinafine MIC</p> <p>115. Date of terbinafine MIC</p> <p>116. Date terbinafine MIC reported</p> <p>117. Flucytosine MIC</p> <p>118. Other flucytosine MIC</p> <p>119. Date of flucytosine MIC</p> <p>120. Date flucytosine MIC reported</p> <p>121. Isolate forwarded?</p> <p>122. Date isolate forwarded</p> <p>123. PHL where the isolate was forwarded</p> <p>124. PHL name where the isolate was forwarded</p> <p>125. Did your lab perform WGS on this isolate?</p> <p>126. Date isolate was whole genome sequenced</p> <p>127. WGS ID</p> <p>128. SRR number</p> <p>129. WGS comments</p> <p>130. Any comments from your lab?</p> <p>131. Do you want MDB to delete this record from your dataset?</p> <p>132. Is this a record update for a DAART record that cannot be resubmitted via HL7?</p>	
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Justification: This is a new data collection instrument that is intended to be collected in REDCap and HL7 messaging. This burden remains unchanged as this is already represented in the original time burden for Implementation of new HL7 messages – Initial set up.

Attachment 2d_I.4- HAIAR WHOLE GENOME SEQUENCING (WGS) OF GRAM-NEGATIVE AR THREATS IN JURISDICTION- Annual Evaluation and Performance Measurement Report

Revision	1. Proportion of sequencing attempts for prioritized isolates received (i.e., CPOS, as defined in the latest General Guidance for Whole Genome Sequencing of Healthcare-Associated Infection/Antibiotic Resistant	No change to burden
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	<p>Pathogens in State and Local Public Health Laboratories) that passed quality control (QC) in accordance with CDC criteria:</p> <ol style="list-style-type: none"> a. Numerator: Number of prioritized isolates that passed QC following first sequencing attempt (see guidance for sequencing priorities and QC thresholds) b. Denominator: Total number of sequencing attempts for prioritized isolates including all failed sequencing) c. Calculated: Percent of prioritized isolates tested by WGS that passed QC within first sequencing attempt <ol style="list-style-type: none"> 2. Number and type of prioritized isolates (i.e., CPOs, as defined in the latest General Guidance for Whole Genome Sequencing of Healthcare-Associated Infection/Antibiotic Resistant Pathogens in State and Local Public Health Laboratories) tested by WGS associated with a known epidemiological investigation <ol style="list-style-type: none"> a. Number of prioritized organisms tested by WGS b. Type of prioritized organisms tested by WGS 3. Median number and range from date of sequencing completion to recording the HAI WGS ID and NCBI or SRR-accession number in LIMS:ID to REDCap alerts records or AIMS DAART platform via HL7 2.5.1 messages or DHQP CSV upload: <ol style="list-style-type: none"> a. Median (in days) b. Range (in days) 	
Addition	<p>Justification: Modified language of existing data elements</p> <ol style="list-style-type: none"> 1. Number of prioritized isolates stratified by priority category (i.e., CPOs, as defined in the latest General Guidance for Whole Genome Sequencing of Healthcare-Associated Infection/Antibiotic Resistant Pathogens in State and Local Public Health Laboratories) tested by WGS: <ol style="list-style-type: none"> a. Total number of CRAB carrying Class A, Class B, or blaOXA-48-like carbapenemase genes tested by WGS b. Total number of Carbapenemase-producing/carbapenemase-gene positive CRPA tested by WGS c. Total number of Carbapenemase-producing/carbapenemase-gene positive CRE tested by WGS <p>Justification: Added because this element requires 3 data sources and will give us an indicator to monitor distribution of funds across CPO organisms, to improve prospective guidance/training products, and to better assist PHL programs with technical assistance.</p>	No change to burden

Attachment 2f_I.6- CARBAPENEMASE-PRODUCING ORGANISM (CPO) SCREENING IN JURISDICTION- Annual Evaluation and Performance Measurement Report		
Addition	<ol style="list-style-type: none"> 1. Total number of swabs tested for CPOs: <ol style="list-style-type: none"> a. Cepheid b. CRAB colonization screening c. Culture-based screening (excluding CRAB) <p>Justification: New data element needed.</p>	No changes to burden
Attachment 2m_I.13- ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF INVASIVE HAEMOPHILUS INFLUENZAE (H. INFLUENZAE) IN JURISDICTION- Annual Evaluation and Performance Measurement Report		
Revision	<ol style="list-style-type: none"> 1. Proportion of isolates with AST results reported to CDC-Bacterial Meningitis Laboratory (CDC-BML) yearly: <ol style="list-style-type: none"> a. Numerator: Number of isolates with AST results reported to CDC yearly b. Denominator: Number of HI isolates received for testing at AR Lab Network c. Calculated: Percentage of isolates with AST results reported to CDC yearly 2. Number of isolates with AST results reported to CDC-Bacterial Meningitis Laboratory (CDC-BML) yearly (out of up to 500) 3. Proportion of isolates transported to CDC-BML yearly <ol style="list-style-type: none"> a. Numerator: Number of viable isolates transported to CDC or in CDC posession b. Denominator: Total number of HI isolates tested at AR Lab Network c. Calculated: Percent of isolates transported to CDC yearly <p>Justification: Modified language of existing data elements</p>	No changes to burden
Attachment 2n_I.14- MYCOPLASMA GENTALIUM (MG)- Annual Evaluation and Performance Measurement Report		
Removal	Justification: Instrument is no longer being collected	Reduction in burden of 1 hour
Attachment 2o_I.15- MOLECULAR Mtb TESTING- Annual Evaluation and Performance Measurement Report		
Addition	<ol style="list-style-type: none"> 1. Number and percentage of reports issued within 11 days of receipt or identification if performing CLIA-compliant testing <p>Justification: This addition is a passive data element and may not be included in REDCap/CAMP for data entry. However, we are including it as optional for recipients who choose to report.</p>	No changes to burden
Attachment 2r_I.18- HEALTHCARE WASTEWATER-BASED SURVEILLANCE - Annual Evaluation and Performance Measurement Report		

Removal	Justification: Instrument is no longer being collected	Reduction in burden of 1 hour
Attachment 2s_I.19- COMMUNICATION AND COORDINATION OF ACTIONABLE EPI LAB DATA IN JURISDICTION- Annual Evaluation and Performance Measurement Report		
Revision	<p>1. Median number and range from receipt of CRE, CRPA, CRAB and Candida isolates to communication of final testing results to submitting laboratory (report each pathogen separately):</p> <p>a. Median (in days) b. Range (in days)</p> <p>Justification: Clarifies that each pathogen should be reported separately as opposed to median and range in aggregate across the four pathogens.</p>	No changes to burden

Change in Annualized Burden Hours

Two performance measure instruments (Attachment 2n and 2r) and are no longer being collected and thus need to be deleted. This will reduce the overall burden of the package by 2 hours. Additionally, Attachment 3h will increase the burden package by 8 hours for updates to HL7 reporting, including additional testing, or LIMS re-validation. We have also reevaluated the burden of IT maintenance for HL7 message updates. Respondents will only need to complete this once per year as opposed to four times a year, as described in the original package. Due to this change, burden for IT maintenance has decreased by 32 burden hours. This will take the package from 57,872 burden hours to 57,846 hours.

Updated Burden Table

Attachment	Type of Respondents	Form name	Number of Respondents	Average Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
2a	Public Health Laboratories	I.1 – ROUTINE TESTING BY GENERA IN JURISDICTION-Annual	57	1	10/60	10

		Evaluation and Performance Measurement Report				
2b	Public Health Laboratories	I.2- EXPANDED DRUG SUSCEPTIBILITY TESTING (ExAST) IN JURISDICTION- Annual Evaluation and Performance Measurement Report	7	1	10/60	1
2c	Public Health Laboratories	I.3- CANDIDA SPECIES IDENTIFICATION IN JURISDICTION- Annual Evaluation and Performance Measurement Report	57	1	10/60	10
2d	Public Health Laboratories	I.4- HAIAR WHOLE GENOME SEQUENCING (WGS) OF GRAM-NEGATIVE AR THREATS IN JURISDICTION- Annual Evaluation and Performance Measurement Report	Up to 57	1	10/60	10
2e	Public Health Laboratories	I.5- C. AURIS COLONIZATION	Up to 57	1	10/60	10

		SCREENING IN JURISDICTION- Annual Evaluation and Performance Measurement Report					
2f	Public Health Laboratories	I.6- CARBAPENEMASE -PRODUCING ORGANISM (CPO) SCREENING IN JURISDICTION- Annual Evaluation and Performance Measurement Report	Up to 57	1	10/60	10	
2g	Public Health Laboratories	I.7- AZOLE RESISTANCE IN CLINICAL ASPERGILLUS FUMIGATUS ISOLATES- Annual Evaluation and Performance Measurement Report	2	1	20/60	1	
2h	Public Health Laboratories	I.8- N. GONORRHOEAE WHOLE GENOME SEQUENCING (WGS)- Annual Evaluation and Performance Measurement Report	4	1	10/60	1	
2i	Public Health	I.9-	4	1	20/60	1	

	Laboratories	GONOCOCCAL (GC) ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) IN JURISDICTION- Annual Evaluation and Performance Measurement Report				
2j	Public Health Laboratories	I.10- WHOLE GENOME SEQUENCING (WGS) OF S. PNEUMONIAE - Annual Evaluation and Performance Measurement Report	2	1	20/60	1
2k	Public Health Laboratories	I.11- CLOSTRIDIODES DIFFICILE (C. DIFFICILE) TESTING IN JURISDICTION- Annual Evaluation and Performance Measurement Report	2	1	20/60	1
2l	Public Health Laboratories	I.12- ANTIFUNGAL RESISTANT TINEA DERMATOPHYTES -Annual Evaluation and Performance	3	1	20/60	1

		Measurement Report				
2m	Public Health Laboratories	I.13- ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF INVASIVE HAEMOPHILUS INFLUENZAE (H. INFLUENZAE) IN JURISDICTION- Annual Evaluation and Performance Measurement Report	2	1	20/60	1
2o	Public Health Laboratories	I.15- MOLECULAR Mtb TESTING- Annual Evaluation and Performance Measurement Report	Up to 20	1	10/60	3
2p	Public Health Laboratories	I.16- C. AURIS WHOLE GENOME SEQUENCING (WGS) IN JURISDICTION- Annual Evaluation and Performance Measurement Report	Up to 57	1	10/60	10
2q	Public Health Laboratories	I.17- MONITORING CRE CRPA IN	Up to 2	1	20/60	1

		COMPANION ANIMALS TO FROM HUMANS- Annual Evaluation and Performance Measurement Report				
2s	Public Health Laboratories	I.19- COMMUNICATION AND COORDINATION OF ACTIONABLE EPI LAB DATA IN JURISDICTION- Annual Evaluation and Performance Measurement Report	57	1	10/60	10
2t	Public Health Laboratories	I.20- CHARACTERIZATION OF THE CLINICAL LABORATORY NETWORK IN JURISDICTION- Annual Evaluation and Performance Measurement Report	57	1	10/60	10
2u	Public Health Laboratories	I.21 NEISSERIA GONORRHOEAE ETEST FOR SHARP	17	1	20/60	6

3a	Public Health Laboratories	AR Lab Network Annual Report of Testing Methods for Carbapenemase-producing Organisms	57	1	2	114
3b	Public Health Laboratories	AR Lab Network Monthly Data Report Form for Carbapenemase-producing Organisms	57	1302	20/60	24,738
3c	Public Health Laboratories	AR Lab Network Alert Report Form for Carbapenemase-producing Organisms	57	214	3/60	610
3d	Public Health Laboratories	AR Lab Network Alert and Monthly Data Report Form for <i>Candida</i>	Up to 57	1671	20/60	31,749
3e	Public Health Laboratories	AR Lab Network Form for Phylogenetic Tree-level Mycotics Reporting	Up to 57	30	6/60	171
3f	Public Health Laboratories	AR Lab Network Alert and Monthly Data Report Form for <i>Neisseria gonorrhoeae</i>	17	93	6/60	158
3g	Public Health Laboratories	AR Lab Network DAART data	4	50	10/60	33

		elements for <i>Neisseria gonorrhoeae</i>				
NA	Public Health Laboratories	HL7 Messages updates-IT Maintenance	32	1	20/60	11
NA	Public Health Laboratories	Implementation of new HL7 messages—IT Initial Set up (may include 3b 3d, 3f, 3g, 3h)	11	4	3	132
N/A	Public Health Laboratories	Updates to HL7 reporting including additional testing, or LIMS re-validation.	8	1	1	8
NA	Public Health Laboratories	CSV files updates for Carbapenemase-producing organisms-IT Maintenance	24	1	1	24
	Total					57,846