

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0890077	<b>(X3) Date Survey Completed</b> 03/31/2023
<b>Name of Provider or Supplier</b> Austin Public Health	<b>Street Address, City, State</b> 15 Waller St, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on a proficiency testing desk review survey performed on April 10, 2023, the laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCIES</b> : D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This <b>CONDITION</b> is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile report, American Proficiency Institute (API) proficiency testing records, and College of American Pathologists</p>

	<p>(CAP) proficiency testing records, the laboratory failed to achieve successful performance in two of three consecutive testing events for Bacteriology between the second event of 2022 and the first event of 2023, resulting in unsuccessful participation. Refer to D2028.</p>
<b>D2028</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 Individual Laboratory Profile report, American Proficiency Institute (API) proficiency testing records, and College of American Pathologists (CAP) proficiency testing records, the laboratory failed to successfully participate in two of three consecutive testing events for Bacteriology between the second event of 2022 and the first event of 2023, resulting in unsuccessful participation. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 Individual Laboratory Profile report, the laboratory received a score of 60 percent for the second event of 2022 for Bacteriology and a score of 60 percent for the first event of 2023 for Bacteriology. 2. Based on review of the College of American Pathologists (CAP) proficiency testing records from 2022, the laboratory received a score of 60 percent for the second event of 2022 for Bacteriology. 3. Based on review of the American Proficiency Institute (API) proficiency testing records from 2023, the laboratory received a score of 60 percent for the first event of 2023 for Bacteriology.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 Individual Laboratory Profile report, American Proficiency Institute (API) proficiency testing records, and College of American Pathologists (CAP) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS-approved proficiency testing program for two of three events for Bacteriology between the second event of 2022 and the first event of 2023. Refer to D6016.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 Individual Laboratory Profile report, American Proficiency Institute (API) proficiency testing records, and College of American Pathologists (CAP) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS-approved proficiency testing program for two of three events for Bacteriology between the second event of 2022 and the first event of 2023. Refer to D2028.