

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D0646583 | (X3) Date Survey Completed 02/11/2025 |
| Name of Provider or Supplier Chicago Department Of Public Health | Street Address, City, State 4909 W Division - Suite 411, Chicago, IL | |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
|---------------------------|---|
| D2016 | <p>SUCCESSFUL PARTICIPATION 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 CONDITION is not met as evidenced by: Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and College of American Pathologists (CAP) Proficiency Testing (PT) records confirmed the initial unsuccessful PT performance for the subspecialty of bacteriology (See D2028) for two consecutive PT events in 2024 (events two and three).</p> |
| D2028 | <p>BACTERIOLOGY CFR(s): 493.823(e)</p> |

(e) 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.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and College of American Pathologists (CAP) Proficiency Testing (PT) records the laboratory failed to achieve satisfactory performance for the subspecialty of bacteriology for two consecutive PT events in 2024 (events two and three) resulting in the initial unsuccessful PT performance for the subspecialty of bacteriology. Findings include: 1. Review of the CASPER Report 0155D, generated on 02-03-2025, the laboratory received the following unsatisfactory scores for the subspecialty of bacteriology. BACTERIOLOGY EVENT 2, 2024 - 60% Unsatisfactory EVENT 3, 2024 - 60% Unsatisfactory 2. Review of CAP PT evaluation reports for the events D5-B 2024 Gram Stain and D5-C 2024 Gram Stain confirmed the initial unsuccessful performance for the subspecialty of bacteriology.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and College of American Pathologists (CAP) Proficiency Testing (PT) records the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the subspecialty of bacteriology resulting in the laboratory's initial unsuccessful PT performance for the subspecialty of bacteriology for two consecutive PT events (event two and three) in 2024 (see D6014).

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and College of American Pathologists (CAP) Proficiency Testing (PT) records the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the subspecialty of bacteriology (see D2028) resulting in the laboratory's initial unsuccessful PT performance for the subspecialty of bacteriology for two consecutive PT events (event two and three) in 2024.