

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>14D0646644       | <b>(X3) Date Survey Completed</b><br><br>10/05/2023 |
| <b>Name of Provider or Supplier</b><br><br>Simple Laboratories   | <b>Street Address, City, State</b><br><br>7444 W Wilson Ave, Harwood Heights, IL |   |
| 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>D2016</b>              | <p><b>SUCCESSFUL PARTICIPATION</b><br/>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:<br/>Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and email correspondence with the American Association of Bioanalysts (AAB) PT program representative confirmed the laboratory's initial unsuccessful PT performance for the subspecialty of bacteriology (See D2028) for two consecutive PT events in 2023 (events one and two).</p> |
| <b>D2028</b>              | <b>BACTERIOLOGY</b>   |

CFR(s): 493.823(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, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and email correspondence with the American Association of Bioanalysts (AAB) PT program representative the laboratory failed to achieve satisfactory performance for the subspecialty of bacteriology for two consecutive PT events in 2023 (events one and two) resulting in the initial unsuccessful PT performance for the subspecialty of bacteriology. Findings include: 1. Review of the CASPER Report 0155D, generated on 10-06-2023, and AAB PT records, the laboratory received the following unsatisfactory scores for the subspecialty of bacteriology. BACTERIOLOGY EVENT 1, 2023 75% Unsatisfactory EVENT 2, 2023 71% Unsatisfactory 2. An email with the AAB PT representative on 09-27-2023 at 3:58 PM, confirmed the initial unsuccessful performance for the subspecialty of bacteriology.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 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, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and email correspondence with an AAB PT program representative the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the subspecialty of bacteriology (see D6016) resulting in the laboratory's initial unsuccessful PT performance for the subspecialty of bacteriology for two consecutive PT events (event one and two) in 2023.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that 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, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and email correspondence with an AAB PT program representative 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 one and two) in 2023.