

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0216863	<b>(X3) Date Survey Completed</b>  08/26/2020
<b>Name of Provider or Supplier</b>  Cd Laboratories, Inc	<b>Street Address, City, State</b>  810 Gleneagles Ct Ste 100, Baltimore, MD	
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> 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 review of the federal proficiency testing data report and review of the comparative evaluation summery from American Associates of Bioanalyst (AAB) proficiency testing (PT) program, the laboratory failed to successfully participate in the AAB PT program for bacteriology testing, in which the laboratory is certified under CLIA. (Refer to D2028)</p>
<b>D2028</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(e)</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.

This STANDARD is not met as evidenced by:

Based on review of the federal proficiency testing data report and review of the comparative evaluation summary from American Associates of Bioanalyst (AAB) proficiency testing (PT) program, the laboratory failed to successfully participate in the AAB PT program for bacteriology testing, in which the laboratory is certified under CLIA. The following analyte was noted as failed in the 1st and 2nd event 2020. Findings: 1. American Association of Bioanalysts 2020 2nd event Bacteriology 0% 2. American Association of Bioanalysts 2020 1st event Bacteriology 0%

**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 review of the federal proficiency testing data report and review of the comparative evaluation summary from American Associates of Bioanalyst (AAB) proficiency testing (PT) program, the laboratory director failed to ensure that the laboratory successfully participate in the AAB PT program for bacteriology testing, in which the laboratory is certified under CLIA. (Refer to D2028)

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the federal proficiency testing data report and review of the comparative evaluation summary from American Association of Bioanalyst (AAB) proficiency testing (PT) program, the laboratory director failed to ensure that an approved corrective action plan was followed when the laboratory failed to successfully attain a score of 80% in the AAB PT program for bacteriology testing, in which the laboratory is certified under CLIA. The following analyte was noted as failed in the 1st and 2nd event 2020. Findings: 1. The laboratory failed to satisfactorily participate in the AAB PT program for bacteriology 2. American Association of Bioanalysts 2020 2nd event Bacteriology 0% 3. American Association of Bioanalysts 2020 1st event Bacteriology 0%