

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0644240	(X3) Date Survey Completed 10/02/2023
Name of Provider or Supplier Shasta County Public Health Lab	Street Address, City, State 2650 Breslauer Way, Redding, CA	
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 desk review of CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and CMS CASPER Report 0153D entitled, "Unsuccessful (2 of 3) Report"), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of Bacteriology constituting unsuccessful PT performance. (See D2020)</p>

<p>D2020</p>	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events, Bacteriology, resulting in an "initial" (first) unsuccessful performance. The findings include: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for Bacteriology, as follows: 2022 Q3 2023 Q1 Bacteriology 63% 0% Q1 = First Testing Event Q3 = Third Testing Event b. Failure to achieve satisfactory performances for the same analyte or test in two out of three consecutive PT resulted in an unsuccessful performance for the analyte, Bacteriology.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory Director was not met. The laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6089)</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: For the analyte Bacteriology, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in unsuccessful PT performance (D2016 and D2020)</p>