

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0090304	(X3) Date Survey Completed 12/22/2022
Name of Provider or Supplier Waterville Family Practice	Street Address, City, State 31 Front Street, Waterville, ME	
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 review of the proficiency testing (PT) data report (Casper Report 155D) and PT graded results from the American Proficiency Institute (API), the laboratory failed to successfully participate for the regulated analyte Chemistry. Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of the Proficiency Testing (PT) data report (CASPER Report 155), and graded results from the proficiency testing organization American Proficiency institute (API), the laboratory failed to successfully participate in the Chloride analyte, and has sustained an unsuccessful participation in PT for Chemistry. Findings include:

1. Record review on 12/5/22 of the CASPER 155, and graded results from API revealed: a. API 2022 Event 2 for Chloride, the score was 20% and was unsatisfactory. b. API 2022 Event 3 for Chloride, the Score was 60% and was unsatisfactory.
2. Interview with the laboratory manager (LM) on 12/22/22 at 12:00pm confirmed the above findings.
3. The laboratory performs 35,000 tests annually under the specialty of Chemistry.