

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0978515	<b>(X3) Date Survey Completed</b>  12/16/2019
<b>Name of Provider or Supplier</b>  Raynham-Taunton Pediatrics	<b>Street Address, City, State</b>  876 Broadway, Raynham, MA	
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>D0000</b>	A CLIA paper desk review of proficiency testing was conducted for the the Raynham-Taunton Pediatrics laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of unsuccessful proficiency testing performance for the Bacteriology subspecialty, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
<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 proficiency testing review for calendar year 2019 (three testing events), of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing results, the</p>

	<p>laboratory failed to successfully participate (achieve a score of 80 percent or more) in a proficiency testing program for the Bacteriology subspecialty as evidenced by the following: The laboratory achieved a score for the Bacteriology subspecialty of sixty (60) percent for the second and third testing events of 2019 resulting in unsuccessful performance for the analyte. Refer to D2020 and D2028. .</p>
<p><b>D2020</b></p>	<p><b>BACTERIOLOGY</b> 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 proficiency testing review for calendar year 2019 (three testing events) the laboratory failed to attain an overall score of at least 80 percent for each Bacteriology subspecialty testing event. The laboratory achieved an overall testing event score of sixty (60) percent for the second and third testing events of 2019 resulting in unsatisfactory performance for each testing event. .</p>
<p><b>D2026</b></p>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review for calendar year 2019 (three testing events), the laboratory failed to ensure that remedial action was taken and documented in response to proficiency testing failures as evidenced by the following: The laboratory received an overall unacceptable testing score for the Bacteriology subspecialty of sixty (60) percent for the second testing event of 2019. The laboratory subsequently received an overall unacceptable testing score for the the Bacteriology subspecialty of sixty (60) percent for the third testing event of 2019. Based on the second unacceptable testing event scores there was no assurance that appropriate training had been undertaken and technical assistance employed to correct the problems associated with proficiency testing failures in the subspecialty area of Bacteriology. .</p>
<p><b>D2028</b></p>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(e)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review for calendar year 2019 (three testing events), the</p>

laboratory failed to achieve satisfactory performance for the subspecialty of Bacteriology. The laboratory achieved an overall testing event score of sixty (60) percent for the second and third testing events of 2019 resulting in unsuccessful performance for the subspecialty of Bacteriology Refer to D2016.