

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0978515	(X3) Date Survey Completed 09/29/2020
Name of Provider or Supplier Raynham-Taunton Pediatrics	Street Address, City, State 876 Broadway, Raynham, MA	
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
D0000	Based on evidence of unsuccessful proficiency testing performance for the White Blood Cell Differential analyte, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
D2004	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review for calendar years 2019 and 2020 the laboratory failed to participate in one proficiency testing program before designating another program and notifying CMS of the change in designation as evidenced by the following: a) A review of 2019 and 2020 American Proficiency Institute (API) proficiency testing for hematology revealed that the laboratory was enrolled for calendar years 2019 and 2020. A review of CMS report a 0155D -Individual Laboratory Profile (proficiency testing) revealed that the laboratory was also enrolled in Wisconsin Laboratory State of Hygiene (WSLH) for hematology for calendar year 2020. b) There was no notification received by the State Agency or CMS regarding the change in designation of the proficiency testing service.</p>
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</p>

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.

This CONDITION is not met as evidenced by:
Based on proficiency testing review for calendar years 2019 and 2020 (three testing events), the laboratory failed to successfully participate (achieve a score of 80 percent or more) in the American Proficiency Institute (API) proficiency testing program for the White Blood Cell Differential analyte. Refer to D2123 and D2130.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on record review of calendar years 2019 and 2020 American Proficiency Institute (API) proficiency testing results, the laboratory failed to attain a testing event score of at least 80 percent for all hematology analytes as evidenced by the following testing event scores: a) White Blood Cell Differential Analyte: 1. 2019 MLE testing event 2 - score of 40 %. 2. 2019 MLE testing event 3 - score of 0 % -(failure to participate). b) The scores were confirmed by email correspondence with the technical consultant on 9/16/20.