

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0978515	(X3) Date Survey Completed 10/07/2024
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) record review and interview with the Technical Consultant (TC) the laboratory failed to ensure proficiency testing (PT) was rotated amongst all testing personnel (TP) in the specialty of Microbiology. Finding include: 1. Record review on 10/4/2024 of the laboratory's 2023 and 2024 API Microbiology PT records revealed, one of two TP (TP2) did not run PT samples in 2023 or 2024. 2. Record review on 10/4/2024 of the laboratory's 2023 and 2024 competency records for TP2, revealed: a. The section referring to PT performance was checked off as completed. b. The competency records were signed by the TC. 3. Record review on 10/4/2024 of the laboratory's PT policy revealed, "It is important that each testing person actively participate in the PT program." 4. Staff interview on 10/4/2024 at 11:00 AM with the TC confirmed TP2 did not participate in PT in 2023 and 2024, yet it was marked as completed on TP2's 2023 and 2024 competency form. 5. The laboratory performs 3,000 tests annually in the specialty of Microbiology.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>

This STANDARD is not met as evidenced by:
Based on American Proficiency Institute (API) proficiency testing (PT) record review and interview with the Technical Consultant (TC), the laboratory failed to ensure attestation sheets were signed by testing personnel (TP) in the specialty of Microbiology. Findings include: 1. Record review on 10/4/2024 of the laboratory's 2023 API Microbiology PT records revealed, the laboratory did not have a copy of the attestation sheet signed by the analyst and for the 2023 supplemental Microbiology event. 2. Record review on 10/4/2024 of the laboratory's PT policy revealed, "The person performing the test signs the form in the indicated area." "The signed PT attestation sheets must be kept for 2 years." 3. Interview with the TC on 10/4/2024 at 11:00 AM confirmed the above findings. TC stated, "API did not provide one for this survey." 4. The laboratory performs 3,000 tests annually in the specialty of Microbiology.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on record review and confirmed through an interview with the technical consultant (TC), the TC failed to assess the competency of all testing personnel (TP) through testing previously analyzed specimens, internal blind testing samples or external proficiency testing (PT) samples in the specialty of Microbiology. Findings include: 1. Record review on 10/4/2024 of the laboratory's 2023 and 2024 American Proficiency Institute Microbiology PT attestation sheets revealed 1 of 2 TP (TP2) did not participate in testing external PT samples in the specialty of Microbiology. 2. Record review on 10/4/2024 of the laboratory's PT policy revealed, "It is important that each testing person actively participate in the PT testing program." 3. Record review on 10/4/2024 of the laboratory's 2023 and 2024 competency assessment records for TP2 revealed: a. The Section titled, 'Has performed proficiency samples' was checked off as being performed. b. The competency records were signed by the TC. c. The form did not contain any information concerning previously analyzed or internal blind samples. 4. Staff interview on 10/4/2024 at 11:00 AM with the TC confirmed TP2 did not perform PT or test a previously analyzed or blind sample in 2023 and 2024 in the specialty of Microbiology. 5. The laboratory performs 3,000 tests annually in the specialty of Microbiology.