

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0978515	(X3) Date Survey Completed 09/07/2021
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	A CLIA recertification survey was conducted for the laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC) on 9/7/21, the laboratory failed to participate in American Proficiency Institute (API) Proficiency Testing (PT) as evidenced by the following: The surveyor reviewed PT records for calendar years 2019, 2020, and 2021 on 9/7/21. The review revealed a 0% score for the Hematology specialty in first event in 2020 and the second event in 2021. The TC interviewed on 9/7/21 at 11:30 AM confirmed that the laboratory failed to participate in PT for the first event in 2020 and second event in 2021. .</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. Based on lack of record review and interview with the TC on 9/7/21, the laboratory failed to document maintenance of analyzers defined by the manufacturer and with at least the frequency specified by the manufacturer as evidenced by the following: The surveyor asked to review maintenance records required by the manufacturer for the Medonic Hematology analyzer for 2019, 2020, and 2021. The TC stated that the laboratory implemented the maintenance log for the analyzer about a week prior and that the laboratory was performing the necessary daily, monthly, and 6 month maintenance but was not recording it on the maintenance log sheet. The TC interviewed on 9/7/21 at 10:30 AM confirmed that manufacturer required maintenance on the Medonic Hematology analyzer was not documented in 2019, 2020, and 2021.