

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1073404	(X3) Date Survey Completed 02/11/2021
Name of Provider or Supplier Dr Bills Kids	Street Address, City, State 426 Highway, 26 East, Cochran, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on February 11, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing (PT) documents from American Proficiency Institute (API) for 2019 and 2020, the Laboratory failed to document the review and evaluation of the laboratory's proficiency testing results. Findings: 1. Review of the PT documents from API, the laboratory failed to document the review and evaluation for testing of Immunology, Hematology, and Chemistry for the three events for 2020. In 2019 the laboratory failed to provide documentation of review and evaluation of Immunology for the three events, Hematology for events one and three, and for Chemistry events two and three. 2. Interview with Staff #2, #3, and the LD on February 11, 2021, at approximately 4:30 pm, in the laboratory, confirmed the lack of document review and evaluation of the proficiency testing results.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the Proficiency Testing (PT) documents from American Proficiency Institute (API) for 2019 and 2020, the Laboratory Director (LD) failed to document the review and evaluation of the laboratory's proficiency testing results.

Findings: 1. Review of the PT documents from API, the LD failed to document the review and evaluation for testing of Immunology, Hematology, and Chemistry for the three events for 2020. In 2019 the laboratory failed to provide documentation of review and evaluation of Immunology for the three events, Hematology for events one and three, and for Chemistry events two and three. 2. Interview with Staff #2, #3, and the LD on February 11, 2021, at approximately 4:30 pm, in the laboratory, confirmed the lack of document review and evaluation of the proficiency testing results.