

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2130574	<b>(X3) Date Survey Completed</b>  08/13/2019
<b>Name of Provider or Supplier</b>  Clanton Pediatric Associates	<b>Street Address, City, State</b>  1011 Lay Dam Road, Clanton, AL	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the proficiency testing records, installation records for the Beckman Coulter Act Diff 2, order confirmations of proficiency testing, and an interview with the office manager, the surveyor determined the laboratory failed to ensure proficiency testing enrollment was done at the beginning of 2018. The Act Diff 2 was installed in July of 2017, and the laboratory participated in proficiency testing for the end of 2017; however failed to renew enrollment in 2018; although patient testing continued. The findings include: 1. A review of the CMS Casper Reports (#096) revealed no data for proficiency testing for year 2018. 2. A review of the AAB (American Associates of Bioanalysts) proficiency testing records for Event #1 of 2018 revealed the laboratory documented, on 3/8/18 the proficiency testing samples were not received, and the laboratory contacted the proficiency testing provider. According to the laboratory's note, the provider informed the laboratory the previous enrollment was sufficient for only the third event of 2017, when the laboratory began patient testing (the installation records for the Beckman Coulter Act Diff 2 were dated July of 2017). 3. Further review of the proficiency testing records revealed an order confirmation from AAB, dated 3/8/18, for the laboratory and would include Quarters 2 and 3 (Events #2 and #3). 4. During the exit interview on 8/13/19 at 12:30 PM, the</p>

surveyor inquired about the proficiency testing for 2018. The office manager stated she was not told about the late enrollment until July (2018). She stated the laboratory staff was under the impression the initial enrollment in 2017 for the third quarter testing was sufficient for one year.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

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 director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of the proficiency testing records, installation records for the Beckman Coulter Act Diff 2, order confirmations of proficiency testing, and an interview with the office manager, the surveyor determined the Laboratory Director failed to ensure proficiency testing enrollment was done at the beginning of 2018. The Act Diff 2 was installed in July of 2017, and the laboratory participated in proficiency testing for the end of 2017; however failed to renew enrollment in 2018; although patient testing continued. The findings include: 1. Refer to D2000 (Proficiency Testing Enrollment).

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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 director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on a review of the policies and procedures (manual) and an interview with the office manager, the surveyor determined the Laboratory Director failed to ensure the laboratory staff was provided a policy and procedure manual to include pertinent and current information, relating to all aspects of the pre-analytic, analytic and post-analytic system processes. The findings include: 1. A review of the policy and procedure manual revealed several procedures not related to the laboratory and current practices. The manual included a policy for DTM (Fungal Cultures) split sample accuracy verifications, which are not performed at the laboratory (the initial survey occurred in January of 2018 and fungal culture testing was not on the test menu at that time, either). The CBC (Complete Blood Count) procedure included a "reading sequence" of one through seven, and centrifugation of the sample. The laboratory utilizes the Beckman Coulter ACT Diff 2 for CBC testing, and the instrument was installed in July of 2017. The manual included a Quality Assurance Plan, which listed several elements, but did not detail any specifics. For example, the listing of personnel failed to include the requirements of qualified personnel or when

and how personnel would be trained and the competency assessed. The Quality Control listing under the QA Plan did not specify type and frequency or acceptability of quality control testing. The policy and procedure manual should include all policies and procedures for pre-analytic, analytic and post-analytic system processes, including who is responsible for what tasks. (The previous surveyor indicated in January 2018, the laboratory staff was in the process of compiling a policy and procedure manual). 2. During the exit interview on 8/13/2019, the surveyor discussed the above noted findings with the office manager.