Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2130574	01/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clanton Pediatric Associates	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter AcT Diff validation records and an interview with the laboratory manager, the laboratory director failed to document his review and approval (as indicated by his signature and date) of verification procedures used to determine the accuracy, precision and other pertinent performance characteristics of the AcT Diff Hematology analyzer. The findings include: 1. A review of the Beckman Coulter AcT Diff validation records revealed the Beckman service representative had signed the validation records. 2. There was no evidence of the Laboratory Director's approval of the validation procedure for the new analyzer. 3. In an interview conducted on 1/9/2018 at 12:30 PM, the laboratory manager confirmed the above noted findings. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor