Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0977694	04/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Chilton Medical Associates	108 Medical Center Drive, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the Accutest proficiency testing records and an interview with Testing Personnel (TP) #2 (Laboratory Supervisor), the surveyor determined the testing personnel and/or the Laboratory Director (LD) failed to sign the attestation statement for each testing event in 2018 - 2020. This affected 14 of 16 events, reviewed by the surveyor. The finding include: 1. The following attestation statements for Hematology and Microscopy proficiency testing were not signed by the Laboratory Director (LD) and/or the testing personnel: a) Hematology Event #2, 2018 (no signature by LD); Microscopy Event #2, 2018 (no signature by LD nor TP). b) Hematology Event #3, 2018 (no signature by LD nor TP) c) Hematology Event #1, 2019 (no signature by LD nor TP); Microscopy Event #1 2019 (not signed by TP) d) Hematology Event #2, 2019 (no LD signature); Microscopy Event #2 2019 (not signed by the TP) e) Hematology Event #3, 2019 (no signature by LD nor TP) f) Hematology Event #1, 2020 and Microscopy Event #1, 2020 (no signature by LD) g) Hematology Event #2, 2020 and Microscopy Event #2, 2020 (no signature by LD) h) Hematology Event #3, 2020 and Microscopy Event #3, 2020 (no signature by LD) 2. In an interview on April 13, 2021 at 10:58 AM, TP # 2 confirmed the above noted findings. At 1:30 PM, during the exit interview, proficiency testing requirements were discussed with TP #2 (Laboratory Supervisor) and the Office Manager.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	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)(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 a review of the Accutest proficiency testing records, a review of the Quality Assurance policy and procedure with checklists, and an interview with Testing Personnel #2 (also the Laboratory Supervisor), the surveyor determined the Laboratory Director (also the Technical Consultant) failed to review and evaluate the results of microscopic proficiency testing results, to ensure any problems were identified and corrective actions were implemented, if needed. This affected 4 of 8 microscopic testing events, reviewed by the surveyor. The findings include: 1. A review of the Accutest proficiency testing records for 2018 - 2020 revealed the laboratory was enrolled in proficiency testing for microscopic tests: Potassium Hydroxide (KOH); Vaginal Wet Preparations and Urine Sediment Examinations, all non-regulated analytes. 2. A review of the proficiency testing events for Microscopy revealed the following events, which were not graded by Accutest: a) Event #2, 2018, Urine Sediment Examination b) Event #2, 2019, Urine Sediment Examination c) Event #3, 2019, Urine Sediment Examination d) Event #1, 2020, Urine Sediment Examination 3. A review of the Quality Assurance checklists for 2020 revealed the item number indicating ungraded results were investigated and findings documented were check-marked as having been done. 4. At 11:25 AM on April 13, 2021, Testing Personnel #2 confirmed the above noted findings of un-graded proficiency testing results. At 1:30 PM, during the exit interview, proficiency testing requirements for evaluating results, not graded by the proficiency testing provider, were discussed with TP #2 (Laboratory Supervisor) and the Office Manager. The surveyor also discussed the importance of documenting accurate assessments of laboratory systems, during the quality assurance monitoring.