Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2082079	06/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chilton Urgent Care	1210 7th Street South, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2017 - 2018 API (American Proficiency Institute) Proficiency Testing records and an interview with Testing Personnel #1, the laboratory failed to document reviews of two of four of the returned survey evaluations results, and failed to document corrective action for two of four surveys with results less than 100 % (percent). The findings include: 1. A review of the API Proficiency Testing records revealed no documentation of review (as indicated by the signature of the Laboratory Director or Technical Consultant) of the returned evaluations for Hematology surveys, 2017-Event #3 or 2018-Event #1. 2. A review of the survey results revealed no documentation of investigation or corrective action for two surveys with results less than 100% as follows: A) 2017-Event #2 Hematology with a score of 0% for the survey due to "Failure to participate", however staff failed to run the survey, and perform a self-evaluation of the results; B) 2017-Event #3 Hematology with a failing score of 60% for Lymphocytes, resulting in an overall score of 87% for the WBC (White Blood Cell) Differential. 3. In an interview on 6/21 /2018 at 1:00 PM, Testing Personnel #1 was asked if the Laboratory Director or Technical Consultant had reviewed the returned proficiency testing results for the above surveys, and if the laboratory had performed and documented corrective action for the analytes with scores less than 100%. Testing Personnel #1 answered no, thus confirming the above noted findings. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Hematology calibration records, reviews of the quality control (QC) and the patient data logs, and an interview with Testing Personnel (TP) #1, the laboratory failed to follow the manufacturer's instructions to verify the calibration by running QC before patient testing resumed. This was noted on one of one 2018 calibrations performed on the Horiba Medonic M Series Hematology analyzer. The findings include: 1. A review of calibration records for the Medonic Hematology analyzer revealed the instrument was calibrated on the OT (Open Tube) mode 3/7/2018 at 10:04 AM. 2. A review of the Medonic M Series User's Manual on page 62 revealed, under Section 7.2 Calibration, "...18 It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. ...". 3. A review of the cumulative Hematology quality control data and Levi-Jennings charts revealed QC was only run in the early morning, and then at 4:55 - 5:10 PM in the afternoon. The records showed no evidence QC was performed after the 10:04 AM calibration before patient testing resumed. A review of the patient data log from the instrument revealed eight patient CBC's (Complete Blood Counts) were performed between 10:05 AM and 4:54 PM. 4. During an interview on 6/19/2018 at 2:55 PM, TP #1 was asked if she had performed QC after the OT calibration on 3/7/2018 before she resumed patient testing. TP #1 explained the clinic was very busy that day, and the physician had said he really needed his patients' CBC's, so TP #1 finished the OT calibration, and immediately ran the patient samples. TP #1 further stated she was not able to perform the microtainer (MC) mode calibration till later in the afternoon, and then afterwards she ran QC for the MC and OT modes. Thus the above noted findings were confirmed. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the 2017 API (American Proficiency Institute) Hematology Proficiency Testing (PT) records, and an interview with Testing Personnel #1, the Laboratory Director failed to ensure proficiency testing results were submitted within the timeframes established by the PT program. The was noted on one of three 2017 surveys reviewed. The findings include: 1. A review of the 2017 API PT records

	revealed the second event Hematology survey received a score of 0%, due to "Failure to participate". The shipping date for this survey was 7/10/2017. 2. During an interview on 6/19/2018 at 12:50 PM, when asked why the laboratory had received a score of 0% for the 2017-Event #2 survey, Testing Personnel #1 stated a previous testing personnel was in charge of the lab at that time, however she was terminated on 7/10/2017. Testing Personnel #1 further stated staff continued to perform patient CBC's, however no one ran the survey when it arrived. Thus the above findings were confirmed. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on reviews of proficiency testing, Hematology calibration records, and personnel files for the testing staff, the laboratory failed to ensure a Technical Consultant was available to provide review of the technical performance of the testing personnel and the laboratory processes. The findings include: 1. A review of laboratory records revealed the Technical Consultant failed to: A.) Ensure all proficiency testing (PT) results were reviewed and signed, and further failed to ensure there was documentation of investigation and corrective actions for any PT results with scores less than 100%. (Refer to D5221.) B.) Ensure testing personnel followed the manufacturer's instructions to verify the calibration on the Medonic M Series by running QC before resuming patient CBC (Complete Blood Count) testing. (Refer to D5437.) C.) Ensure all semi-annual and annual competency evaluations were performed for testing personnel who performed moderate-complexity patient CBC testing. (Refer to D6053 and D6054.) 2. During an interview on 6/19/2018 at 12:50 PM, when asked when the previous Technical Consultant had discontinued her services to the laboratory, Testing Personnel #1 stated she believed it was in October 2017. 3. During a phone interview on 6/21/2018 at 9:30 PM, the current Technical Consultant was asked when he began serving as the Technical Consultant for this laboratory. The Technical Consultant stated he had started "about two weeks ago" (approximately 6/7/2018). Thus the above noted findings were confirmed. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records files, and an interview with Testing Personnel (TP) #1, the surveyor determined the Technical Consultant failed to ensure a semi-annual competency evaluations was performed and documented on one of four new testing personnel. The findings include: 1. A review of the personnel file (for employees who perform CBC testing) revealed TP #3 had training documentation dated 10/30/2017, however there was no documentation of a semi-annual evaluation. [The other three testing personnel were hired in early 2018 or were still in training.] 2.

	In an interview on 6/19/2018 at 12:45 PM, TP #1 was asked if the Technical Consultant (TC) had performed a semi-annual competency assessment for TP #3 after her training. TP #1 stated she did not think so because the previous TC had left in October 2017, and the new TC had not visited their lab yet. Thus the above noted findings were confirmed. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the personnel records files, and interviews with Testing Personnel (TP) #1 and #2, the surveyor determined the Technical Consultant failed to ensure annual competency evaluations were performed and documented on two of six testing personnel. The findings include: 1. A review of the personnel file (for employees who perform CBC testing) revealed no competency assessment documentation for TP #1 and #2, who had been performing patient testing since the previous survey. The other four testing personnel were hired within the last eight months. 2. A review of the personnel files revealed the following: A) TP #1: Training documentation dated 1/10/2017 with an evaluation (semi-annual) by the Technical Consultant performed on 1/31/2017; there was no documentation of an annual competency assessment in 2017 or 2018 B) TP #2: Training documentation dated 12 /12/2016 with an evaluation (semi-annual) by the Technical Consultant performed on 1 /31/2017; there was no documentation of an annual competency assessment in 2017 or 2018 3. In an interview on 6/19/2018 at 12:45 PM, TP #1 and #2 were asked if they had annual competency assessments performed since their last evaluations in January 2017. TP #1 stated the Technical Consultant had not performed an evaluation for her since that time. 4. As the interview continued, TP #2 stated she believed she had had an evaluation and provided the documentation. A review of the record dated 7/19 /2017 revealed it was a general evaluation for the nurses, not an evaluation of laboratory skills. [However, "Lab Controls" was listed as a "task" for nurses.] Thus the above noted findings were confirmed. 5. This is a repeat deficiency. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor