Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2082079	12/31/2020
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
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 proficiency testing records and an interview with Testing Personnel #1 (also the team leader for the laboratory), the Laboratory Director failed to sign the attestation statements provided by American Proficiency Institute (API). This was noted on three of eight 2018 - 2020 Hematology proficiency testing events, reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records revealed Hematology Event #2 2019, Event #3 2019, and Event #3 2020 attestation statements were not signed by the Laboratory Director/delegate. 2. During an interview on 12/31/2020 at 12:20 PM, Testing Personnel #1 confirmed attestations were not signed by the Laboratory Director/delegate.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during

	the PT event. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing records and an interview with Testing Personnel #1, the laboratory failed to maintain a copy of instrument printouts for the testing performed. This was noted on two of eight 2018 - 2020 Hematology proficiency testing events, reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records revealed the staff failed to retain instrument printouts of the testing performed for Hematology events #1 and #2 of 2020. 2. During an interview on 12/31/2020 at 12:20 PM, Testing Personnel #1 confirmed instrument printouts were not retained for the events listed in paragraph 1.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing records and an interview with Testing Personnel #1, the Laboratory Director failed to review and evaluate the results received from American Proficiency Institute (API). This was noted on three of eight 2018 - 2020 Hematology proficiency testing events, reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records revealed 2019 Event #1, Event #2, and Event #3 performance evaluations with results, obtained on the above mentioned testing events, were not reviewed and evaluated by the Laboratory Director. 2. During an interview on 12/31/2020 at 12:20 PM, Testing Personnel #1 confirmed the above events were not reviewed and evaluated by the Laboratory Director. At 12:30 PM, the surveyor discussed the notes for Event #3, 2019, added by a former employee, who referenced the samples were retested and found acceptable, but no probable cause of error documented. Testing Personnel #1 stated the staff's note would not be the laboratory director's review.
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 American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel #1, the laboratory failed to document corrective action for testing scores of less than one hundred percent. This was noted on one of eight 2018 - 2020 Hematology Proficiency Testing Events. This deficiency was also cited on the previous survey, conducted on 6/19/2018. The findings include: 1. A review of the proficiency testing records revealed the laboratory scored 98 % (percent) for the Complete Blood Count (CBC) overall and 93 % for the White Blood Cell Differential on Hematology Event #2 2020. The laboratory failed to document corrective action for the less than one hundred percent scores. 2. During an interview on 12/31/2020 at 12:20 PM, Testing Personnel #1 confirmed no corrective action was documented for the testing event. 3. This is a repeat deficiency.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Hematology maintenance records, a review of the Medonic User Manual, and an interview with Testing Personnel #1, the laboratory failed to document monthly maintenance. This was noted on 3 months of 16 months reviewed by the surveyor. The findings include: 1. A review of the Hematology maintenance records revealed the staff failed to document the monthly cleaning and clot prevention on the Medonic Maintenance form, for August, October and December of 2019. 2. A review of the Medonic User Manual revealed in section 8 page 65 under Monthly Cleaning: the cleaning and clot prevention procedure should be performed monthly. 3. During an interview on 12/31/2020 at 1:00 PM, Testing Personnel #1 confirmed she was not employed at the laboratory during the time the maintenance documentation was missed. However, the personnel confirmed the monthly maintenance was not documented on the Medonic Maintenance form.
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, a review of the Medonic User Manual, and an interview with Testing Personnel #1, the laboratory failed to follow the manufacturer's instructions to perform quality controls after calibration, and before running patient samples. This was noted on one of six 2018-2020 calibrations reviewed. The findings include: 1. A review of Hematology records revealed the Medonic was calibrated on 09/09/2020 at 01:32 PM, however three levels of quality control were not performed until 09/10/2020 at 8:32 AM. 2. A review of the Medonic User Manual revealed, Page 62 Step 18 "It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. See section 6.1 to perform QC." 3. During an interview on 12/31/2020 at 12:40 PM, Testing Personnel #1 confirmed the above noted findings, stating 1 patient CBC's (Complete Blood Counts) was performed on 09/09/2020 at 3:44 PM after the calibration was run and before the quality controls were performed on the following day. 4. This is a repeat deficiency.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of temperature logs and Medonic User Manual, the laboratory failed to document corrective action when temperatures were not within acceptable limits. This was noted in three of eleven months reviewed by the surveyor. The findings include: 1. A review of temperature logs revealed Room Temperature range 68 - 82.5 degrees F (20 - 28 degrees C) was outside of range the following days: 01/14/2019 (65 degrees F), 01/16/2019 (64 degrees F), 01/24/2019 (57 degrees F), 01/26/2019 (62 degrees F), 02/08/2019 (67 degrees F), 02/16/2019 (48 degrees F), 04/18/2019 (67 degrees F), and 04/26/2019 (67 degrees F). Corrective actions were not documented for the days when the temperature exceeded acceptable range. 2. A review of Medonic User Manual Page 83 states "64 -90 degrees F (18 - 32 degrees C) Room Temperature".
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of laboratory records (Personnel, Proficiency Testing, Hematology Maintenance, Calibration and Quality Control), a review of policies and procedures and the Medonic User Manual, an interviews with the team-leader of the laboratory (Testing Personnel #1), the surveyor determined the laboratory director failed to perform his responsibilities as outlined. The findings include: Refer to D6021: 1. All attestation statements for proficiency testing were signed by the Laboratory Director or a qualified designee (Refer to D2009); 2. All proficiency testing records for each event performed during the survey review period was retained. The laboratory failed to retain the instrument printouts for each event (Refer to D2015). 3. All graded results of proficiency testing, returned to the laboratory from the proficiency testing provider, were reviewed and evaluated to ensure if any corrective actions were needed, were implemented and documented (Refer to D5211). 4. Corrective actions were documented for any proficiency testing results of less than one hundred percent accuracy (Refer to D5221). 5. The laboratory personnel documented monthly maintenance for the Medonic (Refer to D5429). 6. The laboratory personnel followed the manufacturer's instructions to perform quality controls after calibration, and before running patient samples (Refer to D5437). 7. Testing Personnel (TP) #4 and a former

	testing personnel, presented with at least a high-school diploma, prior to being trained and performing Complete Blood Count (CBC) testing on patient samples (Refer to D6029). 8. He specified, in writing, the duties/responsibilities of each person involved in all phases of the testing processes (Refer to D6032). 9. The Technical Consultant performed competency assessments semiannually and annually for testing personnel, who perform moderate-complexity testing (Refer to D6053 and D6054).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of laboratory records (Personnel, Proficiency Testing, Hematology Maintenance, Calibration and Quality Control), a review of policies and procedures and the Medonic User Manual, an interviews with the team-leader of the laboratory (Testing Personnel #1), the surveyor determined the laboratory director failed to establish and maintain a quality assurance program to ensure: 1. All attestation statements for proficiency testing were signed by the Laboratory Director or a qualified designee (Refer to D2009); 2. All proficiency testing records for each event performed during the survey review period was retained. The laboratory failed to retain the instrument printouts for each event (Refer to D2015). 3. All graded results of proficiency testing, returned to the laboratory from the proficiency testing provider, were reviewed and evaluated to ensure if any corrective actions were needed, were implemented and documented (Refer to D5211). 4. Corrective actions were documented for any proficiency testing results of less than one hundred percent accuracy (Refer to D5221). 5. The laboratory personnel documented monthly maintenance for the Medonic (Refer to D5429). 6. The laboratory personnel followed the manufacturer's instructions to perform quality controls after calibration, and before running patient samples (Refer to D5437). 7. Testing Personnel (TP) #4 and a former testing personnel, presented with at least a high-school diploma, prior to being trained and performing Complete Blood Count (CBC) testing on patient samples (Refer to D6029). 8. He specified, in writing, the duties/responsibilities of each person involved in all phases of the testing processes (Refer to D6032). 9. The Technical Consultant performed competency assessments semiannually and annually for testing personnel, who perform moderate-complexity testing (Refer to D6053 and D6054).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can

	perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the personnel and proficiency testing records and an interview with Testing Personnel #1 (the team leader of the laboratory), the surveyor determined the Laboratory Director (LD) failed to ensure Testing Personnel (TP) #4 and a former testing personnel, presented with at least a high-school diploma, prior to being trained and performing Complete Blood Count (CBC) testing on patient samples. This affected one of six active moderate-complexity testing personnel and one former testing personnel (terminated during the survey review period). The findings include: 1. A review of personnel records revealed no educational record on file for TP #4, who began her training on 11/20/2020. The personnel is currently in-training to perform moderate-complexity testing, although the laboratory has not verified the educational credentials. 2. A review of the proficiency testing records revealed a type written name of a former employee on the attestation statement for Hematology Event #1, 2020. TP #1 had signed the attestation statement as the testing personnel. A review of the former employee's personnel file revealed no educational record or training document. 3. In an interview on December 31, 2020 at 12:20 PM, TP #1 stated the former employee was assigned to perform the proficiency testing, however terminated her employment prior to performing the proficiency testing. Hence, TP #1 completed the proficiency testing. The surveyor reviewed the personnel files with TP #1, who confirmed there was no education or training record (CBC testing) for the former employee. The surveyor inquired if the employee had been testing patient samples with no verification of education or documentation of training. TP #1 confirmed the former employ had tested patient CBC specimens, and she started her employment around January 2020 and terminated employment around April of 2020. TP #1 further confirmed there was no education on file for TP #4, who began training for CBC testing on 11/20/2020.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, which included the laboratory director's job description, and an interview with Testing Personnel #1, the Laboratory Director failed to specify, in writing, the duties/responsibilities of each person involved in all phases of the testing processes. The findings include: 1. A review of the laboratory's policy and procedure manual, last signed by the laboratory director on 10/01/2020, revealed a type-written job description for the LD, but for no other positions. Included in the LD's job description was the following: "A Laboratory

	Director may delegate some of the above listed responsibilities to a qualified Technical Consultant. Refer to CLIA 493.1407..." 2. During an interview on 12/31 /2020 at 12:20 PM, the surveyor asked Testing Personnel #1 (TP #1) if the laboratory had job descriptions for the personnel. TP #1 stated she believed she maintained job descriptions in her office files for testing personnel (not provided during the survey), but confirmed the laboratory had no job descriptions for the Technical or Clinical Consultants. The surveyor discussed the requirements for a letter of delegation for the Technical Consultant, which TP #1 confirmed the laboratory did not have a letter of delegation.
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 a review 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 had 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 by running quality control (QC) before resuming patient CBC (Complete Blood Count) testing. (Refer to D5437). C.) Ensure all personnel, who performs moderate-complexity, were assessed for competency, semi-annually and annually (Refer to D6053 and D0654). 2. This is a repeat deficiency.
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, a review of policies and procedures, and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate and document the competency of individuals at least semiannually during the first year of performing CBC's (Complete Blood Counts). This affected one of six personnel, who performs moderate complexity testing. The findings include: 1. A review of the personnel records revealed Testing Personnel (TP) #2 initially trained on the Medonic for CBC testing on 12/10/2019. A fellow laboratory staff member documented an annual assessment, performed in November of 2020 for TP #2, however, the semiannual competency of the testing personnel was not done. 2. A review of the policy, titled "TRAINING OF LABORATORY TESTING PERSONNEL" revealed the following: "...Competency assessment must be performed by the Technical Consultant." 3. During an interview on 12/31/2020 at 10: 00 AM, TP #1 (the team-leader of the laboratory) confirmed no semiannual

	competency assessment was done on TP #2. During a follow-up interview at 12:20 PM, TP #1 and #2 confirmed the above noted findings. 4. This is a repeat deficiency.
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, a review of the policies and procedures, and an interview with Testing Personnel (TP) #1, the Technical Consultant failed to evaluate and document the performance of individuals at least annually after the first year of performing CBC's (Complete Blood Counts). This affected one of six testing personnel, who perform moderate complexity testing. The findings include: 1. A review of the personnel evaluation records revealed no annual competency assessment for TP #1 in 2019. TP #1 was a previously qualified testing personnel, with several years employment with the laboratory (prior to 2018). 2. A review of the policy, titled "TRAINING OF LABORATORY TESTING PERSONNEL" revealed the following: "...Competency assessment must be performed by the Technical Consultant." 3. During an interview on 12/31/2020 at 10:00 AM, TP #1 did not provide a reason why her competency assessment for 2019 was not done. In a follow-up interview at 12:20 PM, TP #1 stated she may have assessments retained somewhere else, since she was recently reassigned at this laboratory location. No documentation of the annual performance review for 2019 was provided. 4. This is a repeat deficiency.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the personnel and proficiency testing records and an interview with Testing Personnel #1 (the team leader of the laboratory), the laboratory failed to ensure Testing Personnel (TP) #4 and a former testing personnel, presented with at least a high-school diploma, prior to being trained and performing Complete Blood Count (CBC) testing on patient samples. This affected one of six active moderate-complexity testing personnel and one former testing personnel (terminated during the survey review period). The findings include: 1. A review of personnel records revealed no educational record on file for TP #4, who began her training on 11/20

	/2020. The personnel is currently in-training to perform moderate-complexity testing, although the laboratory has not verified the educational credentials. 2. A review of the proficiency testing records revealed a type written name of a former employee on the attestation statement for Hematology Event #1, 2020. TP #1 had signed the attestation statement as the testing personnel. A review of the former employee's personnel file revealed no educational record or training document. 3. In an interview on December 31, 2020 at 12:20 PM, TP #1 stated the former employee was assigned to perform the proficiency testing, however terminated her employment prior to performing the proficiency testing. Hence, TP #1 completed the proficiency testing. The surveyor reviewed the personnel files with TP #1, who confirmed there was no education or training record (CBC testing) for the former employee. The surveyor inquired if the employee had been testing patient samples with no verification of education or documentation of training. TP #1 confirmed the former employ had tested patient CBC specimens, and she started her employment around January 2020 and terminated employment around April of 2020. TP #1 further confirmed there was no education on file for TP #4, who began training for CBC testing on 11/20/2020.