Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2097939	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Stopwatch Urgent Care	5415 Summerville Road, Suite B, Phenix City, 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
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 personnel records, a review of quality control and assessment records, and interviews with Testing Personnel (TP) #5 and the office manager (also a testing personnel, as needed, although not listed on the CMS form #209), the surveyor determined the Laboratory Director (LD) failed to ensure a quality assessment program was maintained to ensure all testing personnel of moderate complexity testing were trained and their competency assessed. The laboratory did not provide a Quality Assessment policy and procedure for review by the surveyor. The LD further failed to ensure testing personnel did not perform patient testing of Complete Blood Counts (CBCs), prior to ensuring quality control testing was acceptable. This affected eight of eight testing personnel, and greater than fifty patient specimens on at least six days of testing. The findings include: 1. A review of the personnel records revealed the following training and/or competency evaluations without signature of the LD or either Technical Consultant (TC), to signify review and approval: a) The Emerald training, dated 2/21/19, and the semiannual competency evaluation, dated 8/21/19 for TP #1. b) The Emerald training, dated 12/5/18, and the semiannual competency evaluation (dated 6/5/19), and remedial Hematology training, dated 9/25/19, for TP #2. c) For TP #3, the initial training, dated 6/25/19, and the remedial training, dated 9 /24/19 were not signed by the LD or either of the TCs. d) TP #4's initial training was documented as completed on 7/6/19, and remedial Hematology training on 9/24/19.

	None of these personnel records were signed by the LD or TC to signify appropriate and adequate training. e) The annual competency evaluation, dated 4/16/19, for TP #5 was not signed by the LD or either TC. f) For TP #6, the initial training (Emerald), dated 2/12/19, and the semiannual competency evaluation, dated 8/12/19. g) The annual competency evaluation, dated 7/6/19, for TP #7 was not signed by the LD or TC. h) The office manager's competency was documented as being assessed on 5/1 /18, although the record was not signed by the LD or TC. 2. In an interview on 10/29 /19 at 10:30 AM, the surveyor inquired of the office manager her extent of testing in the laboratory. The office manager confirmed she occasionally performs moderate complexity testing when needed. The office manager had previously been considered solely testing personnel, prior to becoming the office manager. The surveyor stated to the office manager and TP #5 the requirement to list all personnel of moderate complexity testing on the CMS personnel report (form #209). 3. In an interview on 10 /29/19, 10:17 AM - 10:30 AM, the surveyor discussed with TP #5 and the office manager, the lack of the LD's or TC's signature on the training and/or competency assessments, to indicate the personnel had received appropriate and adequate training and found to be competent in laboratory skills performed by each testing personnel. 4. Refer to D6028. 5. A review of the quality control and quality assessent records revealed 10/21/17, two of the three quality controls were outside of acceptable limits. The testing personnel performed patient CBC (Complete Blood Count) testing and reported the results of at least 12 patients. On 6/20/19, the testing personnel failed to ensure at least two of three levels of quality control were acceptable, prior to tesing patient specimens and reporting the results. The quality assurance records indicated the patients' reports were reviewed by the physician to determine how and if the patients were affected by the test runs without acceptable quality control. The quality assurance records also indicated the testing personnel had received remedial training, after this June incident. Again in August of 2019 [8/16 (18 patients), 8/17 (13 patients), 8/18 (13 patients), and 8/19 (26 patients)], the testing personnel ran patient specimens and reported the results, although the quality control was found unacceptable, and no corrective actions were taken by the testing personnel. 6. The surveyor discussed the findings related to unacceptable quality control and patient testing, with TP #5 and the office manager on October 29, 2019 at 1:10 PM. TP #5 confirmed the above noted findings. 7. Also refer to D6028. 8. On October 29, 2019 at 10:52 AM, during the surveyor's review of the policy and procedure manual, the surveyor inquired if the laboratory had a policy and procedure out-lining the quality assurance (QA) program. At 11:19 AM, the QA policy and procedure had not been received, so the surveyor inquired again. The office manager pointed out the manual containing the monthly QA checklists and chart reviews; but no written policy and procedure for quality assurance. The office manager stated she called the technical consultant (TC #1) to assist with locating the policy. At 12:35 PM, the office manager stated TC #1 told her the policy was on-site; and she was awaiting the staff to "pull" the policy for the surveyor's review. The staff failed to provide a written QA policy and procedure for review by the surveyor. A QA policy was not provided to the surveyor for review prior to the exit.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the

appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:
Based on a review of personnel and quality control records and an interview with Testing Personnel (TP) #5 and the office manager (also a testing personnel, as needed, although not listed on the CMS form #209), the surveyor determined the Laboratory Director (LD) failed to ensure all testing personnel of moderate complexity testing were trained and their competency assessed. This was evident by the lack of signature by the LD or delegee (Technical Consultant) on the training and/or competency records of at least eight personnel, and the repeated quality control issues. The findings include: 1. A review of the personnel records revealed the following training and/or competency evaluations without signature of the LD or either Technical Consultant (TC), to signify review and approval: a) The Emerald training, dated 2/21 /19, and the semiannual competency evaluation, dated 8/21/19 for TP #1. b) The Emerald training, dated 12/5/18, and the semiannual competency evaluation (dated 6/5 /19), and remedial Hematology training, dated 9/25/19, for TP #2. c) For TP #3, the initial training, dated 6/25/19, and the remedial training, dated 9/24/19 were not signed by the LD or either of the TCs. d) TP #4's initial training was documented as completed on 7/6/19, and remedial Hematology training on 9/24/19. None of these personnel records were signed by the LD or TC to signify appropriate and adequate training. e) The annual competency evaluation, dated 4/16/19, for TP #5 was not signed by the LD or either TC. f) For TP #6, the initial training (Emerald), dated 2/12 /19, and the semiannual competency evaluation, dated 8/12/19. g) The annual competency evaluation, dated 7/6/19, for TP #7 was not signed by the LD or TC. h) The office manager's competency was documented as being assessed on 5/1/18, although the record was not signed by the LD or TC. 2. In an interview on 10/29/19 at 10:30 AM, the surveyor inquired of the office manager her extent of testing in the laboratory. The office manager confirmed she occasionally performs moderate complexity testing when needed. The office manager had previously been considered solely testing personnel, prior to becoming the office manager. The surveyor stated to the office manager and TP #5 the requirement to list all personnel of moderate complexity testing on the CMS personnel report (form #209). 3. In an interview on 10 /29/19, 10:17 AM - 10:30 AM, the surveyor discussed with TP #5 and the office manager, the lack of the LD's or TC's signature on the training and/or competency assessments, to indicate the personnel had received appropriate and adequate training and found to be competency in laboratory skills performed by each testing personnel. 4. A review of the quality control and quality assessent records revealed 10/21/17, two of the three quality controls were outside of acceptable limits. The testing personnel performed patient CBC (Complete Blood Count) testing and reported the results of at least 12 patients. On 6/20/19, the testing personnel failed to ensure at least two of three levels of quality control were acceptable, prior to tesing patient specimens and reporting the results. The quality assurance records indicated the patients' reports were reviewed by the physician to determine how and if the patients were affected by the test runs without acceptable quality control. The quality assurance records also indicated the testing personnel had received remedial training, after this June incident. Again in August of 2019 [8/16 (18 patients), 8/17 (13 patients), 8/18 (13 patients), and 8/19 (26 patients)], the testing personnel ran patient specimens and reported the results, although the quality control was found unacceptable, and no corrective actions were taken by the testing personnel. 5. The surveyor discussed the above noted findings with TP #5 and the office manager on October 29, 2019 at 1:10 PM. TP #5

	confirmed the above noted findings.
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 records; personnel, proficiency testing, and quality control, a review of quality assurance checklists, a lack of written delegation of responsibility by the Laboratory Director, and an interview with Testing Personnel (TP) #5 and the practice manager, the surveyor determined the Laboratory Director failed to specify, in writing, the responsibilites and duties assigned to each qualified Technical Consultant. This affected all records mentioned above for the survey review period (September 7, 2017 - October 29, 2019). The findings include: 1. A review of the proficiency testing records (Event #3, 2017, Events #1 and #3 of 2018, and Events #1 and 2, 2019) revealed the reviews, evaluation and any needed corrective actions were documented by either of two technical consultants. 2. The technical consultants had also documented review of the quality control and quality assurance checklists, as well as, had initialed at least two competency assessments of the eight listed testing personnel. 3. The policy and procedure manual provided to the surveyor failed to include a letter of delegation. At 11:19 AM on October 29, 2019, the surveyor inquired of TP #5 of letter of delegation. TP #5 referred the inquiry to the practice manager (also a testing personnel, who had not been listed on the CLIA Personnel Report form). The practice manger left the room to check another binder, she identified as the "CLIA Binder." The practice manager reviewed the Quality Assurance (QA) Manual and noted the QA checklists and chart reviews, but no letter of delegation. Again at 12:35 PM, the surveyor inquired about the letter of delegation. The practice manager stated she had called Technical Consultant (TC) #1, who stated the laboratory has a letter of delegation (not yet provided for review) and staff should be able to locate the letter. A letter of delegation was not provided to the surveyor for review prior to the exit.