Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2043987	10/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
First Choice Urgent Care	472 West Poplar Ave, Suite 201, Collierville, TN	

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 review of the laboratory's proficiency testing attestation statements and interview with the technical consultant, the testing personnel failed to sign the proficiency testing attestation statements for 2016 event three, 2017 event two, and 2017 event three. The findings include: 1. Review of the laboratory's proficiency testing attestation statements for 2016 event three and 2017 events two and three revealed no testing personnel signatures. 2. Interview with the technical consultant on October 8, 2018 at 10:00 am confirmed the testing personnel did not sign the proficiency testing attestation statements for 2016 event three, 2017 event two, and 2017 event three.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the calibration records for the Drew 3 complete blood count

	(CBC) instrument and interview with the technical consultant, the laboratory's quality assessment process was ineffective when it failed to detect problems with correct calibration target assignments in 2017. The findings include: 1. Review of the calibration records for the Drew 3 CBC instrument revealed calibration performed on July 5, 2017 with the following errors for calibration target assignment: LOT EX0717 Package insert target Target Assigned WBC 9.3 9.4 RBC 4.49 4.51 HGB 13.9 13.4 MCV 87.8 89.5 PLT 254 242 No corrective action was documented for the incorrect targets and no review of the calibration by the technical consultant. 2. Interview with the technical consultant on October 8, 2018 at 3:30 pm confirmed that review of calibrations is not part of the quality assessment process. The quality assessment process was ineffective when it failed to detect and correct problems with incorrect calibration target assignments in 2017.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the validation study performed for the Medonic M-Series complete blood count (CBC) instrument, and interview with the technical consultant, the laboratory failed to verify the manufacturer's normal range for the Medonic M-Series CBC instrument in 2017. The findings include: 1. Observation of the laboratory on October 8, 2018 at 8:45 am revealed the Medonic M-Series CBC instrument (serial # 29446) in use for patient testing. 2. Review of the validation study performed for the Medonic M-Series CBC instrument on October 5, 2017 revealed no patient normal range study was performed. 3. Interview with the technical consultant on October 8, 2018 at 1:00 pm confirmed patient normal range study was not performed as part of the validation for the Medonic M-Series CBC instrument in 2017. The laboratory uses the manufacturer's normal ranges.
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 review of the validation studies performed for the Medonic M-series complete blood count (CBC) instrument and interview with the technical consultant,

	the laboratory director failed to ensure the validation study for Medonic M-series CBC instrument was adequate in 2017. 1. Review of the validation study performed for the Medonic M-series CBC instrument (serial # 29446) on October 5, 2017 revealed no normal range study was performed and no there was no signature of the laboratory director indicating review of the study. 2. Interview with the technical consultant on October 8, 2018 at 1:00 pm confirmed the laboratory director failed to ensure validation studies were adequate for the Medonic M-Series CBC instrument in 2017.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the validation study performed for the Medonic M-Series complete blood count (CBC) instrument and interview with the technical consultant, the technical consultant failed to verify validation studies met manufacturer's specifications for the Medonic M-Series CBC instrument in 2017. The findings include: 1. Review of the validation study performed on October 5, 2017 for the Medonic M-Series complete blood count (CBC) instrument (serial #29446) revealed no signature of the technical consultant. 2. Interview with the technical consultant on October 8, 2018 at 1:00 pm confirmed the technical consultant failed to ensure the validation studies performed for the Medonic M-Series CBC instrument met manufacturer's specifications in 2017.