Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2055268	04/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Immediate Care Foley	1265 South Mckenzie Street, Foley, 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
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 reviews of the validation records for the non-waived "Chem 8+" cartridge (used for the determination of Sodium [Na], Potassium [K], Chloride [Cl], Carbon Dioxide [CO2], Blood Urea Nitrogen [BUN], Creatinine and ionized Calcium [iCa]) on the I-Stat analyzer, and an interview with Testing Personnel #1, the laboratory failed to ensure the manufacturer's performance specifications for precision were verified, and the Laboratory Director's review and approval of the validation was documented as indicated by signature and date after the test was deemed moderate-complexity by the FDA (Food and Drug Administration) in 2020. This affected one of one new non-waived tests implemented since the previous survey. The findings include: 1. A review of the poorly organized "I-Stat" binder revealed validation studies for the Chem 8+ cartridge were mixed in with other records. The surveyor noted the Chem 8+ procedure at the front of the binder with a note from the previous technical consultant, "validation completed 6/2020" [June 2020]. The Laboratory Director had initialed the page with the dates, "2/20/20" and "2022". 2 The surveyor located the data for Quality Control Level 1 runs from 5/15 thru 5/24/2020 (ten days). However, there was no documentation the data was analyzed and evaluated to confirm the precision of the analytes, as stated in the manufacturer's performance specifications. In a different section of the binder, the surveyor located a Calibration

	Verification performed on 6/11/2020 (which may have been used to establish Reportable Range and Accuracy). There was no indication the Laboratory Director had reviewed any of the above documentation after the validation testing was performed. 3. During an interview on 4/26/2022 at 5:30 PM, Testing Personnel #1 confirmed she had no other records for the Chem 8+ validation. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration verification (C/V) records for the non-waived "Chem 8+" cartridge (used for the determination of Sodium [Na], Potassium [K], Chloride [Cl], Carbon Dioxide [CO2], Blood Urea Nitrogen [BUN], Creatinine and ionized Calcium [iCa]) on the I-Stat analyzer, and an interview with Testing Personnel #1, the laboratory failed to perform one of two 2021 C/V's. The findings include: 1. A review of the records for the non-waived I-Stat Chem 8+ cartridge revealed the laboratory performed a three-level C/V on 6/19/2021. However, there was no indication the C/V due the second half of 2021 was performed. 2. During an interview on 4/26/2022 at 5: 30 PM, Testing Personnel #1 searched the December 2021 records, and confirmed she had no documentation for the second 2021 C/V. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the records for the non-waived "Chem 8+" cartridge (used for the determination of Sodium [Na], Potassium [K], Chloride [Cl], Carbon Dioxide [CO2], Blood Urea Nitrogen [BUN], Creatinine and ionized Calcium [iCa]) on the I-Stat analyzer, and an interview with Testing Personnel #1, the laboratory failed to ensure a valid IQCP (Individualized Quality Control Plan) which included the Laboratory Director's review and approval (as indicated by signature and date) was in effect after the test was deemed moderate-complexity by the FDA (Food and Drug Administration) in 2020. This affected one of one new non-waived tests implemented since the previous survey. The findings include: 1. A review of QC records for the non-waived I-Stat Chem 8+ cartridge revealed the laboratory had implemented an IQCP to reduce the frequency of QC testing to every 30 days and with each new lot number/shipment. The approval page for the I-Stat IQCP and page three of the IQCP procedure with spaces for the Laboratory Director's signature and date were both blank. The surveyor noted the Laboratory Director's initials (with no date) toward the bottom of page two of three of the I-Stat IQCP procedure, however it was unclear whether this indicated approval. 2. During an interview on 4/26/2022 at 5:00 PM, the surveyor and Testing Personnel #1 reviewed the above documents; Testing Personnel #1 then stated the laboratory did have the Laboratory Director's approval of the IQCP. However, the IQCP approval page Testing Personnel #1 provided was for the Triage Meter at another facility in Mobile; the laboratory was unable to provide documentation of the Laboratory Director's approval of the I-Stat Chem 8+ IQCP. SURVEYOR ID# 32558 Licensure and Certification Surveyor