Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0870785	05/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Family Practice	202 South 2nd Street, Hartsville, SC	

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
D0000	A Recertification Survey was initiated on 05/16/2023 and concluded on 05/16/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, document reviews, and interview, the laboratory failed to maintain the refrigerator temperature for storage of complete blood count (CBC) controls for in 1 of 1 refrigerator observed. Findings included: Review of the "Eightcheck - 3WP X-tra" package insert revised March 2021, indicated "Eightcheck-3WP X-tra is to be stored closed at 2-8 (degrees) C [Celsius]." During the laboratory tour on 05/16/2023 at 2:20 PM, the surveyor observed vials of CBC controls in the refrigerator. Testing Personnel (TP) #1 presented the surveyor with the temperature log and a temperature binder that was kept near the refrigerator. Review of the laboratory's temperature log dated 08/13/2021 to 05/16/2023, revealed there were only 56 times the temperature was recorded as being between 2-8 degrees Celsius. In an interview on 05/16/2023 at 4:10 PM, TP #1 stated the range listed on the temperature log was carried over from the previous manager. TP #1 stated the one temperature log reviewed by the surveyor was the only one the laboratory had.

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 document review and interview, the laboratory failed to verify the reportable range of complete blood counts (CBCs) on 1 of 1 new analyzer installed. Findings included: Review of an "Implementation Completion Form" dated 03/04/2021, revealed the Sysmex pocH-100i hematology analyzer was installed on 03/04/2021. The form indicated the reportable range (linearity) studies were checked off as completed/passed; however, the records were not available for review during the survey. During an interview on 05/16/2023 at 4:15 PM, Testing Personnel (TP) #1 and TP #2 both stated they did not know if the reportable range study was performed. Both stated the staff that were present when the analyzer was installed have retired. Review of patient reports for Patients #1, #2, #3, #4, and #5, revealed there was no reportable range on the final reports.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on policy review, document review and interview, the laboratory director /technical consultant failed to evaluate the competency for 2 of 2 testing personnel (TP), TP #1 and TP #2. Findings included: Review of a laboratory policy titled "[Laboratory name] Clinical Laboratory Quality Assurance Program," last reviewed 04/03/2020, revealed: "The LD [Laboratory Director] will validate annually the competency of the lab staff based on a written competency tool." Review of the training checklist for TP #1 and TP #2 revealed both received training on 09/01/2021. There were no other competency evaluations provided for review. During an interview on 05/16/2023 at 4:15 PM, TP #1 stated she did not know competency should be performed annually.