Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0522750	04/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Wee Care Pediatrics	2084 No 1700 W Suite A, Layton, UT	

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
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 manufacturer's instructions review, direct observation, lack of documentation, and interview with staff, the laboratory failed to ensure they followed the manufacturer's instructions to process Solana Group A Streptococcus tests at 95 Degrees C for one year of testing performed (April 2018 to April 2019). The laboratory performed approximately 2 to 4 tests per day. Findings include: 1. The Solana manufacturer's instructions reviewed included a process step for a 95 degree specimen and reagent incubation. 2. Direct observation included the 95 degree temperature heat block with a thermometer in place. 3. The laboratory failed to document the temperature met the temperature range (95 degrees +/- 2 degrees) each day Solana Group A Streptococcus tests were performed. 4. In an interview conducted on 04/02/2019 at approximately 5:15 P.M., the laboratory manager confirmed the laboratory did not record the 95 degree heat block temperature was within the acceptable temperature range each day of testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Individualized Quality Control Plan (IQCP) review, lack of documentation and interview with the laboratory manager, the laboratory director failed to review the Solana Group A Streptococcus quality control plan annually to determine the reduced frequency of quality control performance continued to be sufficient to prevent testing errors for 1 of 1 year of Group A Streptococcus testing (April 2018 to April 2019) reviewed. The laboratory performed approximately 2 -4patient tests per day. Findings include: 1. The IQCP reviewed was approved by the director on 07/01/2017. 2. The IQCP lacked documentation the director reviewed the plan since testing was implemented in 2018. 3. In an interview conducted on 04/02/2019 at approximately 5: 45 P.M., the laboratory manager stated the director had not documented continued approval of the IQCP after evaluating Group A Streptococcus testing performance over the first year of testing (April 2018 to April 2019).