Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D1060326	05/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wee Care Pediatrics-Roy	5682 S 3500 W Suite A, Roy, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on records reviewed and interview with the laboratory manager, the laboratory failed to establish a written policy to assess personnel competency for testing Total Bilirubin using the Piccolo instrument and testing for Group A Streptococcus using the Solana instrument since the last survey on March 28, 2019. Findings include: 1. Review of laboratory policies and procedures revealed the laboratory failed to establish and perform competency assessments for nine of nine testing personnel. 2. Interview with the laboratory manager on May 4, 2022 at approximately 3:00 p.m. confirmed there was no competency assessment policy established or performed for testing personnel.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on records reviewed and interview with the laboratory manager, the laboratory failed to document proficiency testing evaluation for results received from 2021, Event 1, Alanine Aminotransferase analyte from the American Proficiency Institute. Findings include: 1. Review of 2021 Event 1, Chemistry proficiency testing records, revealed there was no documentation of any corrective action taken to resolve a test

	score of 80 percent for Alanine Aminotransferase analyte. 2. Interview with the laboratory manager on May 4, 2022 at approximately 3:30 p.m. confirmed no corrective action was taken for proficiency test scores that were less than 100 percent.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on records review and interview with the laboratory manager, the laboratory failed to establish written policies and procedures for specimen submission, handling and referral for Total Bilirubin testing using the Piccolo instrument and Group A Streptococcus testing using the Solana instrument since the last survey on March 28, 2019. Findings include: 1. Review of laboratory records revealed there was no policy and procedure for patient preparation, specimen collection, specimen handling and specimen storage and preservation for Total Bilirubin and Group A Streptococcus molecular testing since the last survey on March 28, 2019. 2. Interview with the laboratory manager on May 4, 2022 at approximately 2:45 p.m. confirmed there were no written policy and procedure for specimen submission, handling and referral.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager, the laboratory failed to establish a procedure to ensure corrective actions are taken for life-threatening test results for Total Bilirubin testing with the Piccolo instrument since the

	last survey on April 2, 2019. Findings include: 1. Review of Total Bilirubin test results printed from the Piccolo instrument and patient records, revealed there were no established panic value reference range provided for five of five Total Bilirubin test results. 2. Interview with the laboratory manager on May 4, 2022 at approximately 3: 45 p.m. confirmed there were no established panic value reference range provided for five of five Total Bilirubin test results.
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 records reviewed and interview with the laboratory manager, the laboratory failed to define temperature criteria for the refrigerator and freezer for proper storage of testing reagents and controls used for testing Total Bilirubin on the Piccolo instrument and for testing Group A Streptococcus on the Solana since the last survey on April 2, 2019. Findings include: 1. Review of temperature records for the freezer used for storage of Hepatic Panel test kits for Total Bilirubin testing and storage of the Solana Strep Complete Assay kit including quality control material used for testing for Group A Streptococcus revealed there was no defined normal temperature range for storage. 2. Interview with the laboratory manager on May 4, 2022 at approximately 2:30 p.m. confirmed there was no normal temperature reference range defined for the refrigerator and freezer used for the storage of testing reagents and quality control material used for Total Bilirubin and Group A Streptococcus testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, tour of the laboratory and interview with the laboratory manager, the laboratory failed to properly label test kits with opened and expiration dates for Hepatic Panel test kits used for Total Bilirubin testing and the Solana Strep Complete Assay test kits used for Group A Streptococcus testing since the last survey on April 2, 2019. Findings include: 1. Tour of the laboratory revealed one of one Hepatic Panel test kit used to test Total Bilirubin with the Piccolo instrument and one of one Solana Strep Complete Assay Kit used to test for Group A Streptococcus using the Solana instrument were not labeled with opened dates and expiration dates. 2. Interview with the laboratory manager on May 4, 2022 at approximately 2:30 p.m.

	confirmed the opened Hepatic Panel test kit and the Solana Strep Complete Assay kit were not labeled with opened dates and expiration dates.
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 records review and interview with the laboratory manager, the laboratory failed to establish and follow a written policy and procedure for quality assessment for Total Bilirubin and Group A Streptococcus testing performed in the laboratory since the last survey on March 28, 2019. Findings include: 1. Review of laboratory records revealed there was no procedure manual for ongoing monitoring of a quality assessment program for Total Bilirubin and Group A Streptococcus testing. 2. Review of temperature records for the heat block used with the Solana instrument for testing for Group A Streptococcus and temperature records for the freezer and refrigerator that stored the Solana Strep Complete Assay test kit and the Hepatic Panel test kit revealed the temperature records were not reviewed on a monthly basis by the laboratory director or designee since the last survey on March 28, 2019. 3. Interview with the laboratory manager on May 4, 2022 at approximately 2:50 p.m. confirmed there was no procedure manual for the quality assessment program and temperature records were not reviewed on a monthly basis by the laboratory director or designee since the last survey on March 28, 2019.