Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D1043971	11/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Color Country Pediatrics	55 East Canyon Commercial Ave, Cedar City, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to retain six of six American Proficiency Institute, (API) bacteriology signed and dated attestation statements for at least two years. Findings include: 1. Proficiency testing record review failed to include the signed and dated statements that the testing person and laboratory director attest to the fact the laboratory performed API proficiency testing from Group A Streptococcus (GAS) the same as patient tests for 2019 and 2020 tests performed. 2. In interview conducted on 11/20/2020 at approximately 2:00 P.M., the laboratory technical consultant and manager confirmed the laboratory did not have signed and dated attestation statements for Bacteriology API proficiency tests.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including

	instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on patient and quality control records review lack of documentation and interview with staff, the laboratory failed to retain the Solana instrument printouts for molecular Group A Streptococcus (Strep) detection from throat swabs for at least two years. The laboratory performed approximately 40 tests per year in 2018 and 2019. Findings include: 1. The laboratory patient test records for Solana Group A Strep failed to include the cartridge sticker label (printout) from the Solana test system for patient DOB 02152019 for a Group A Strep performed on 05/13/2019. 2. Interview conducted on 11/20/2020 at approximately 3:30 P.M. with the laboratory manager /technical consultant confirmed the laboratory discontinued retaining the printouts for patient DOB 02152019.
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 staff, the laboratory director failed to review the IQCP at least annually for Solana molecular Streptococcus testing in 2019. The laboratory has temporarily discontinued Solana Strep testing since March 2020. The laboratory performed approximately 40 tests per year before suspending the test. Findings include: 1. IQCP review lacked documentation the director had reviewed the plan, quality control performance, proficiency testing results, reagent storage and testing environmental situations (such as contaminaton), to ensure patient test were not affected by changes to the system and the decreased frequency of control performance in 2019. 2. In an interview conducted on 11/20/2020 at approximately 3:30 P.M. staff confirmed the lab suspended testing in 2020 but did not document the IQCP was evaluated at least annually in 2019 to identify problems that may require more frequent quality control performance.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on testing personnel educational records review, lack of documentation, and interview with staff, one of six new moderate complexity testing personnel failed to have educational documentation to qualify as a moderate complexity testing person. (See D6065.)_

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on testing personnel educational records review, lack of documentation, and interview with staff, one of six new moderate complexity testing personnel failed to have educational documentation to qualify as a moderate complexity testing person. (New Test Person A). Findings include: 1. Personnel educational records review failed to include a high school diploma or transcript, a GED, an Associates, Bachelor's, Masters' or Doctorate Degree (or transcript) for 1 of 6 new testing personnel. 2. In an interview with the laboratory manager on 11/20/2020 at approximately 2:30 P.M. staff confirmed test person A did not have a copy of their highest diploma in the laboratory testing personnel credential records.