Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0865203	01/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cottontree Family Practice	2230 N University Pkwy #1a, Provo, 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
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation and interview with staff, the laboratory failed to ensure quality control materials were of the same matrix as patient samples for serum pregnancy tests. The laboratory performed approximately 2 serum pregnancy tests per month. Findings include: 1. Direct observation of quality control materials for pregnancy tests revealed the quality control material was a urine matrix for lot KW00076 expiring 2021-09-30. 2. In an interivew with staff on 01/09/2020 at approximately 11:30 A.M. staff was asked to produce the quality control material for serum pregnancy tests. The surveyor was given control material labeled for urine pregnancy test controls. Staff stated they did not realize the controls were not for serum pregnancy tests.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory director failed to ensure a quality assessment program was established and maintained for serum pregnancy tests from January 2018 to January 2020. The laboratory performs approximately 2 tests per week. Findings include: 1. The laboratory procedure manual failed to include an approved quality assessment program for the serum pregnancy tests performed. 2. In an interview conducted on 01/09/2020 the laboratory staff confirmed the lab no longer had an approved qualify assessment procedure for serum pregnancy tests. Based on lack of documentation and confirmation by staff, the laboratory failed to establish and maintain the quality assessment program for their serum pregnancy Individual Quality Control Plan (IQCP). The laboratory failed to monitor that reduced frequency serum pregnancy quality control could identify test problems for 1 of 2 years reviewed (2019). Findings include: 1. The laboratory director approved the IQCP on 03/01/2018. The laboratory lacked documentation the plan was reviewed to ensure quality control was performed at the stated frequency for each new lot number prior to testing patient samples and/or monthly and that testing problems could still be identified with the lowered testing frequency. 2. In an interview with staff on 01/09/2020 at approximately 11:30 A.M. staff confirmed the IQCP was not evaluated annually in 2019.