Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0865203	01/17/2018
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on patient test records review, direct observation, lack of documentation, and interview with staff, the laboratory failed to verify the accuracy of Status DS urine drug screens at least twice a year. The laboratory tested approximately 1 urine drug screen per month. Findings include: 1. The laboratory failed to verify moderately complex urine drug screens at least twice a year for tests performed from July 8, 2016 to January 17, 2018 of urine drug screens reviewed. 2. In an interview with staff on 01 /17/2018 at approximately 11:55 A.M. staff confirmed they had not enrolled in proficiency testing or developed a method to verify urine drug screen tests at least twice annually in 2016 and 2017.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation, lack of an individualized quality control plan, and interview with staff, the laboratory failed to perform two

	levels of quality control each day of urine drug screen testing for 2 of 2 days of testing reviewed. The laboratory performed approximately 2 tests per month. Findings include: 1. Patient test records reviewed included documentation urine drug screens were performed for patients 136323-5 on 07/18/2016 and for 6439110-1 on 12/12 /2017. 2. Quality control records failed to include documentation the laboratory performed 2 levels of quality control on 07/18/2016 or on 12/12/2017. 3. In an interview conducted on 0117/2018 at approximately 1:15 P.M., staff confirmed the laboratory had not developed an IQCP for drug screening tests and that the laboratory did not perform 2 levels of quality control each day of drug screening testing.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on patient test records review, quality control records review, and interview with staff, the laboratory failed to perform control materials following a complete replacement of testing materials for 1 of 1 new lot number change of serum beta human chorionic gonadotrophin (hCG). The laboratory performed approximately 1 serum pregnancy per week. Findings include: 1. Patient test records review included documentation the laboratory performed a serum pregnancy test on 03/31/2016 for patient 152137-1 using lot number 5100076. Quality control was not performed for this lot number until 04/20/2016. 2. In an interview with staff on 01/17/2018 at approximately 1:15 P.M. staff confirmed the laboratory failed to document two levels of quality control for serum hCG for lot number 5100076.
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 lack of a written quality assessment plan and interview with staff the laboratory failed to define the method to be used to monitor that they verified the accuracy of Solana Streptococci tests at least twice a year. The laboratory tested approximately 4 Solana confirmatory throat screens per week since September 2017. Findings include: 1. The laboratory did not have a written quality assessment plan for Solana Streptococcus testing. 2. The laboratory failed to include a method for verifying test accuracy for the presence or absence of Strep Group A by the Solana method. 3. In an interview with staff on 01/17/2018 at approximately 11:30 A.M. staff confirmed the laboratory had not enrolled in proficiency testing, or have a written quality assessment plan that included Solana test accuracy at least twice a year.

D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Individualized Quality Control Plan (IQCP) review, patient test records review, quality control records review, and interview with staff, the laboratory failed to follow the laboratory instructions to perform quality control with each new lot number and once per month for 1 of 5 monthly quality control performance for Affirm VP tests reviewed (January 2018) and failed to perform monthly quality control for serum pregnancy tests (hCG) for one of two months of hCG tests reviewed . The laboratory performed approximately 2 Affirm VP tests per week and one serum pregnancy test per month. Findings include: 1. IQCP review documented the laboratory established the Affirm VP, (detects the presence of Gardnerella, Candida, and Trichomonas from Vaginal swabs) and hCG, quality control plan to include 2 levels of quality control be performed with each new lot number or shipment of Affirm VP cartridges and monthly. 2. Patient test record review included documentation the laboratory performed serum pregnancy testing on 11/01/2017 for patient 6659 and on 01/11/2018 for patient Date of Birth (DOB) 08/12/1959 for Affirm VP lot number 7150924. Patient test records review for hCG tests included documentation patient (DOB) 06/28/1995 was tested for qualitative serum hCG on 07 /11/2017. The laboratory failed to record they performed a positive and negative quality control in July 2017. 3. Quality control records review failed to include documentation for Affirm VP quality control since 07/20/2017 for the new lot number. The exact number of patients tested from July 2017 to January 2018 was not determined. 4. In an interview conducted on 01/17/2018 at approximately 1:00 P.M. staff confirmed they had not performed monthly QC since July 2017 for Affirm VP tests and did not performed monthly quality control for hCG tests in July 2017.