

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0865203	(X3) Date Survey Completed 09/26/2022
Name of Provider or Supplier Cottontree Family Practice	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) documentation and an interview with the Lab Manager, the laboratory failed to maintain attestation statements, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens for 2 of 4 PT Events reviewed. Findings include: 1. A review of PT documentation at approximately 2:30 PM on 9/26/22 revealed that attestation statements for American Proficiency Institute (API) 2022 Chemistry Core 1st Event and 2022 Chemistry Core 2nd Event, were not signed by the person performing the test or by the Lab Director. 2. An interview with the Lab Manager at approximately 2:35 PM on 9/26/22 confirmed that the attestation statements for API 2022 Chemistry Core 1st Event and 2022 Chemistry Core 2nd Event, were not signed by the person performing the test or by the Lab Director.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

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 inspection of control materials and an interview with the Lab Manager, the laboratory failed to label the OSOM hCG Serum Control Set with the identity, storage requirements, and expiration date. The laboratory performs 141 serum hCG tests annually. Findings include: 1. An inspection of control materials at approximately 2:00 PM on 9/26/22, revealed that the positive and negative vials of the OSOM hCG Serum control set were not labeled with the identity, storage requirements, and expiration date. 2. An interview with the Lab Manager at approximately 2:05 PM confirmed that the positive and negative vials of the OSOM hCG Serum control set were not labeled with the identity, storage requirements, and expiration date.