

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2066470	(X3) Date Survey Completed 04/27/2018
Name of Provider or Supplier Desert Star Institute For Family Planning	Street Address, City, State 5501 N 19th Ave Ste 420, Phoenix, AZ	
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 lack of Proficiency Testing (PT) records for review and interview with the laboratory director, the laboratory failed to maintain a copy of all PT records for a minimum of 2 years. Findings include: 1. The laboratory performs moderate complexity patient testing under the specialty of Immunohematology, with an approximate annual test volume of 1,000. It is the practice of the laboratory to participate in three PT events per year for the regulated analyte, Rh testing. 2. No documentation was presented for review for the 1st event of 2016 to indicate the laboratory maintained copies of all the PT records, including a copy of the PT program report form used by the laboratory to record results and the attestation statement signed by the analyst and laboratory director. 3. The laboratory director confirmed that the records indicated above could not be located during the survey. ** This is a repeat deficiency from the last survey conducted on 04/20/2016.</p>