

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2088500	(X3) Date Survey Completed 03/08/2018
Name of Provider or Supplier Dialysis Clinic Inc Donor Services DBA New Mexico	Street Address, City, State 1609 University Blvd Ne, Albuquerque, NM	
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
D0000	The following deficiencies were cited during a certification survey completed on March 8, 2018 for the federal requirements of 42 CFR Part 493 for Laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on the review of 2016-2017 proficiency test records, personnel records, CMS Personnel Report Form 209, laboratory policy and interview with the technical consultant, the laboratory failed to ensure that the proficiency samples were tested by the same personnel that performed patient testing. The laboratory reported 34 patients (donors) were tested in a 12 month period for blood gases using the iSTAT chemistry analyzer. Findings are: 1. Review of the 2016-2017 submission forms and attestation statements revealed only one signature, that of the technical consultant for 3 of 3 test events in 2017 and 2 of 3 test events in 2016. 2. During interview on 3/08/2018 at 2:45 pm, the technical consultant stated that she tested the proficiency samples. She also stated that there was one time, while training a new testing person, that the samples were tested by someone else. 3. Review of CMS Personnel Report Form 209 completed by the laboratory indicated a total of 9 testing personnel and the technical consultant. 4. During interview on 3/08/2018 at 3:00 pm, the technical consultant was asked for the hire dates of the testing personnel. 7 of 9 testing personnel had been employed by the laboratory prior to January 2017 but there was no record of their participation in proficiency testing in 2016 or 2017. 5. Review of the laboratory's policy "iSTAT Testing Work Instruction" revealed the laboratory did not follow the</p>

written policy regarding proficiency testing. In section 6.2.7.4.2.3 the policy stated "Proficiency testing specimens will be handled in the same way as donor specimens." The laboratory director was not available for interview.

D2009

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on the review of 2016-2017 proficiency testing records, personnel records, CMS Personnel Report Form 209, laboratory policy, and interview with the technical consultant, the laboratory director or designee failed to attest, in writing, that the proficiency samples were tested by the same personnel that performed patient testing. The laboratory reported 34 patients (donors) were tested in a 12 month period for blood gases using the iSTAT chemistry analyzer. Findings are: 1. Review of the 2016-2017 submission forms and attestation statements revealed only one signature, that of the technical consultant, for 3 of 3 test events in 2017 and 2 of 3 test events in 2016. The only signed attestation statement was for the 1st event of 2017. All other attestation statements were blank. 2. During interview on 3/08/2018 at 2:45 pm, the technical consultant stated that she performed the testing, completed the submission forms, and discarded the forms after the results were submitted to the proficiency agency. 3. Review of CMS Personnel Report Form 209 completed by the laboratory indicated a total of 9 testing personnel and the technical consultant. 4. During interview on 3/08/2018 at 3:00 pm, the technical consultant was asked for the hire dates of the testing personnel. 7 of 9 testing personnel had been employed by the laboratory prior to January 2017 but there was no record of their participation in proficiency testing in 2016 or 2017. 5. Review of the laboratory's policy "iSTAT Testing Work Instruction" revealed the laboratory did not follow the written policy regarding proficiency testing. In section 6.2.7.4.2.3 the policy stated "Proficiency testing specimens will be handled in the same way as donor specimens." The laboratory director was not available for interview.