

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1005032	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier Tyler Nephrology Assoc , Pa	Street Address, City, State 1133 Medical Drive, Tyler, TX	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Review of American Association of Bioanalysts (AAB) laboratory proficiency testing (PT) documentation for 2016, 2017 and 2018, confirmed by staff interview, revealed that in the first event of 2017, the laboratory failed to provide attestation by testing personnel that samples were tested in the same manner as patient samples. Findings: 1. AAB PT documentation was reviewed. Attestation forms for the first event of 2017 showed no analyst signatures on forms for hematology (complete blood count), immunology (C3 and C4), and endocrinology (thyroid stimulating hormone). 2. In an interview at the site on 03-20-2018, testing person 1, the laboratory supervisor, stated she had not been aware the attestation forms were not signed by the analyst. .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory personnel competency verification documentation for 2017 and 2018, confirmed by staff interview, the laboratory failed to evaluate the</p>

competency of one of two testing personnel semiannually during the first year of employment. Findings: 1. Laboratory testing personnel competency verification documentation was reviewed. Documents for testing person 2 (CMS form 209) included orientation and initial training sheets dated 05-17-2017 and a competency evaluation sheet dated 03-02-2018. 2. In an interview at the site on 03-20-2018, testing person 1, the laboratory supervisor, stated that the competency evaluation dated 03-02-2018 was the only such evaluation performed on testing person 2. .