

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0471917	<b>(X3) Date Survey Completed</b> 11/13/2019
<b>Name of Provider or Supplier</b> Schafer Medical Center	<b>Street Address, City, State</b> 800 Isabel Sw, Ardmore, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 11/13/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director/technical consultant, testing person #1, and testing person #2 at the conclusion of the survey.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with testing person #2, the laboratory failed to have a written clinical consultant and technical consultant competency policy based the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed the manual titled "Policy Manual" and could not locate a written policy to evaluate the clinical consultant and technical consultant based on job responsibilities; (2) The surveyor asked testing person #2 if a written policy to evaluate the clinical consultant and technical consultant based on job responsibilities (to include the frequency of the competency assessments) was available and if competency assessments had been performed during 2018 and to date in 2019. Testing person #2 showed the surveyor documentation that competencies had been performed for the clinical consultant and technical consultant on 08/05/19. In addition, testing person #2 stated to the surveyor a policy to evaluate the clinical consultant and technical consultant, based on job responsibilities, had not been written.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with testing person #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) At the beginning of the survey, testing person #2 stated to the surveyor CMP (Comprehensive Metabolic Panel)\*, Lipid Profile\*, and Direct Bilirubin testing were performed on the Envoy 500 analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs for the analyzer, which required the following quarterly maintenance: (a) Replace ISE Tubing Set (b) Replace K Electrode (c) Replace Cl Electrode (d) Replace CO2 Electrode (3) The surveyor then reviewed maintenance records for 2018 and 2019. There was no documentation the quarterly maintenance had been performed as follows: (a) Replace ISE Tubing - Not performed between 08/10/18 and 03/05/19 (b) Replace K Electrode - Not performed between 08/29/18 and 03/05/19 (c) Replace Cl Electrode - Not performed between 08/09/18 and 03/05/19 (d) Replace CO2 Electrode - Not performed between 08/14/18 and 03/05/19 (4) The surveyor reviewed the records with testing person #2, who stated the quarterly maintenance had not been performed, as indicated above. \*CMP - Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein \*Lipid Profile - Total Cholesterol, HDL Cholesterol, Triglyceride Liver Profile - albumin, total protein, total bilirubin, alkaline phosphatase, ALT, AST, GGT