

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0470314	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Oklahoma Surgical Group Pllc	Street Address, City, State 1211 North Shartel, Suite 200, Oklahoma City, OK	
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 findings were reviewed with testing person #2, the office manager, and the practice manager, at the conclusion of the survey.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, and interview with testing person #2, the office manager, and the practice administrator, the laboratory failed to follow the manufacturer's instructions for performing waived testing. Findings include: OPERATOR MANUAL (1) At the beginning of the survey, the practice administrator stated to the surveyor the laboratory performed macroscopic urinalysis (i.e., pH, Glucose, Blood, Protein, Ketones, etc.) using the Multistix 10SG urine dipsticks which were read on two Clinitek Status+ analyzers (designated as #1 and #2); (2) The surveyor asked testing person #2, the office manager, and the practice administrator for the manufacturer's instructions (operator's manual) for the Clinitek Status+ dipstick readers. Testing person #2, the office manager, and the practice administrator could not locate the manufacturer's instructions by the end of the survey; (3) The surveyor explained the only requirement for performing waived testing was to follow the manufacturer's instructions for quality control testing, maintenance, etc., which were included in the manufacturer's instructions. In addition, the surveyor explained the manufacturer's instructions for all testing were to be retained for at least 2 years after the testing was discontinued; (4) Testing person #2, the office manager, and the practice administrator, stated to the surveyor, the laboratory had not retained the manufacturer's instructions to ensure testing was performed as required. CONTROL TESTING (1) Testing person #2, the office manager, and the practice administrator,</p>

stated to the surveyor the laboratory analyzed two levels of urine QC (Quality Control) materials (Bio Rad Liquichek Urine Controls, Level 1 and Level 2) each morning of patient testing; (2) The surveyor reviewed the manufacturer's instructions (package insert) for the reagent dipsticks. It stated under "Quality Control": "Test positive and negative quality controls with new lots, new shipments or reagents, and when you open a new bottle."; (3) The surveyor then reviewed QC records from 11/01/16 through 05/31/18. The following was identified: (a) The lot number and expiration date of reagent dipsticks had not been documented when a new lot number, new shipment, or new bottle had been put into use; (b) The lot number and expiration date of new lot numbers of QC materials had not been documented. It could not be determined when new QC lot numbers had been put into use. (4) The surveyor asked testing person #2, the office manager, and the practice administrator, if the the laboratory had another record that showed the information not found in the QC records. Testing person #2, the office manager, and the practice administrator explained the laboratory had not documented when new lot numbers, new shipments, or a new bottle of reagent dipsticks had been put into use, and had not documented the date and expiration date when new QC lot numbers had been put into use. Therefore, the surveyor could not determine if the laboratory had performed QC testing as required by the manufacturer. NOTE: D1001 was cited on the previous recertification survey performed 10/26/16.