

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D1004029	<b>(X3) Date Survey Completed</b>  11/19/2018
<b>Name of Provider or Supplier</b>  Summit Surgery Center At St Mary's Galena	<b>Street Address, City, State</b>  18653 Wedge Pkwy Ste 170, Reno, NV	
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>	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on November 19, 2018. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director, the laboratory failed to establish and follow written quality assessment policies and procedures to ensure that expired laboratory reagents were not available for use and to ensure that maintenance was performed on the microscope as scheduled. Findings include: The laboratory did not establish and follow written policies and procedures for quality assessment to check for expiration dates and signs of deterioration of laboratory reagents and to check that preventative maintenance on the microscope was performed according to schedule. a. Expired tissue marking dyes were observed on the laboratory counter available for use. The orange tissue marking dye expired in April 2018 and the blue tissue marking dye expired in August 2018. The laboratory director discarded the expired dyes upon discovery and indicated during the on-site survey on 11/19/18 at approximately 2:30 PM that there were no patient cases read on-site since January 2018 and the expired dyes were not used. b. The maintenance label on the microscope indicated that maintenance was performed in May 2017 and due in</p>

May 2018. There were no records that maintenance had been performed in May 2018 on the microscope. The laboratory director indicated that the microscope had not been used since January 2018 and confirmed that maintenance on the microscope should have been performed in May 2018. The laboratory performs approximately four pathology tests annually.