

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 21D0909947	<b>(X3) Date Survey Completed</b> 07/15/2019
<b>Name of Provider or Supplier</b> Verghese - Ling Md Pa	<b>Street Address, City, State</b> 26840 Point Lookout Road, Leonardtown, MD	
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>D3001</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory did not maintain spore check documentation for the sterilizer used for MOHS surgical instruments. Findings: 1. The laboratory performed spore checks to ensure function of the sterilizer, it was observed that the laboratory did not maintain the results of the checks; and 2. These findings were confirmed during interview with the laboratory director on the day of survey.</p>
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory did not ensure proper labeling of microscope slides labeled quality control. The slides are prepared for frozen sections during MOHS surgery, but the laboratory did not follow it's written procedures by not adding the patient identification and stage of removal to the label. Findings: 1. The written procedure states that MOHS surgery slides contain identifying information such as the case number and stage of surgery, but it was observed that the slide selected by the lab as the quality control slide (to check the daily adequacy of the</p>

tissue preparation and stain) was labeled "quality control" and did not include patient case number and stage of surgery; and 2. These findings were confirmed during interview with the lab director on the day of survey.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory did not have documentation showing that "MOHS Surgeon 2", participated in a proficiency check to verify reliability and accuracy of microscopic examinations performed for MOHS surgery. Findings: 1. The laboratory did not have records showing that a selection of MOHS cases were reviewed by a second qualified reviewer for tissue and stain quality and final outcome based on microscopic examination for "MOHS Surgeon #2"; and 2. These findings were confirmed during interview with the laboratory director on the day of survey.