

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2179899	(X3) Date Survey Completed 07/14/2022
Name of Provider or Supplier St Luke's Mohsmicrographicsurgery	Street Address, City, State 1600 St Luke'S Blvd, Suite 102, Easton, PA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 review of laboratory procedure manuals and interview with the Histotechnologist (HT), the laboratory failed to establish a competency assessment procedure to assess 1 of 2 Clinical Consultants (CC) for their supervisory responsibilities from 7/23/2020 to the day of survey. Findings Include: 1. On the day of survey, 07/14/2022 at 09:05 am, the laboratory could not provide a competency assessment procedure to assess the competency for 1 of 2 CC (CMS 209 Personnel #2) from 7/23/2020 to 07/14/2022. 2. The HT could not provide competency assessment documentation for 1 of 2 CC from 07/23/2022 to 07/14/2022. 3. The HT confirmed the findings above on 07/14/2022 around 10:15 am.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment records and interview with</p>

the Histotechnologist (HT), the Technical Supervisor (TS) failed to evaluate the annual competency assessment for 1 of 3 Testing Personnel (TP) who performed MOHS Micrographic surgery slides examined from 12/19/2020 to the day of survey. Findings include: 1. On the day of survey 07/14/2022 at 09:05 am, the HT could not provide competency assessment record for 1 of 3 TP (CMS 209 personnel #2) who performed MOHS Micrographic surgery slide examinations from 07/23/2020 to the day of survey. 2. The laboratory performed 2,824 MOHS Micrographic surgery slide examinations in 2021. 3. The HT confirmed the findings above on 07/14/2022 around 10:15am.