

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0724764	<b>(X3) Date Survey Completed</b>  07/02/2019
<b>Name of Provider or Supplier</b>  Yale Mohs Surgery Lab	<b>Street Address, City, State</b>  40 Temple St, Ste 5a, New Haven, CT	
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>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to ensure new testing personnel (TP) received appropriate training to perform high complexity testing prior to reporting patient test results. Findings include: 1. TP record review on 7/2/19 revealed the laboratory did not have training documentation for 2 of 2 new TP. 2. Staff interview with the LD on 7/2/19 at 9:50 AM confirmed the above findings. 3. The laboratory performs 6,238 tests annually in the subspecialty of histopathology.</p>
<b>D6127</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> 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 semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the technical supervisor (TS) failed to evaluate new testing personnel (TP) twice during the first year of employment. Findings include: 1. Competency record review on 7/2/19, revealed, the laboratory did not have twice annual competency documentation for 2 of 2 new grossing TP during the first year of employment. 2. Staff Interview with the TS on 7/2/19 at 9:50 AM, confirmed the laboratory did not document twice annual competency evaluations for 2 of 2 new grossing TP during the first year of employment. 3. The laboratory performs 3,119 grossing tests per year in the specialty of histopathology.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

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.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the technical supervisor (TS) failed to document annual competency of testing personnel (TP) to assess the knowledge and skills necessary to perform high complexity laboratory testing. Findings include: 1. Competency record review on 7/2/19, revealed the laboratory did not have annual competency documentation after the first year of employment for of 2 of 2 grossing TP in 2017 or 2018. 2. Staff Interview with the TS on 7/2/19 at 9:50 AM, confirmed the laboratory failed to document annual competency evaluations for 2 of 2 TP in 2017 and 2018. 3. The laboratory performs 6,238 tests per year in the specialty of histopathology.