

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2112485	(X3) Date Survey Completed 10/08/2025
Name of Provider or Supplier Yale Dermatology-Branford	Street Address, City, State 322 East Main St Ste 2g, Branford, CT	
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 record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities for the clinical consultant (CC) and Technical Consultant (TC) in the subspecialty of histopathology and mycology. Findings include: 1. Record review on 10/8/2025 of the laboratory's 'CLIA Testing Personnel' binder revealed lack of documentation of competency assessment for the regulatory positions of CC and TC. 2. Record review on 10/8/2025 of the laboratory's 'Quality Management System' manual revealed lack of an established competency assessment policy and procedure to assess competency for the regulatory positions of CC as well as TC and defining frequency of such assessments. 3. Staff interview on 10/8/2025 at 10:38 AM with the laboratory director confirmed the above findings. 4. The laboratory performs 400 moderate complexity tests in the subspecialty of mycology and 1200 high complexity tests in the subspecialty of histopathology annually.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to follow their established policies and procedures and document the annual competency assessment for the testing personnel (TP) in the subspecialty of mycology. Findings include: 1. Record review on 10/8/2025 of the laboratory's 'CMS 209' form revealed 9 of 11 TP performing moderate testing in the laboratory. 2. Record review on 10/8/2025 of the laboratory's 'Quality Management System' manual revealed: 'Competency Evaluation of Personnel: A competency evaluation must be conducted for each test a person performs, with evaluation occurring six months after initial training and annually thereafter'. 3. Record review on 10/8/2025 of the laboratory's 'CLIA Testing Personnel' binder revealed lack of annual competency assessments for 6 of 9 moderate complexity TP for the year 2024 4. Staff interview on 10/8/2025 at 10:38 AM with the laboratory director confirmed the above findings. 5. The laboratory performs 400 moderate complexity tests annually in the subspecialty of mycology.