

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0885058	(X3) Date Survey Completed 03/11/2020
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 2685 Jolly Road, Okemos, MI	
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:</p> <p>. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to follow policies to assess competency of 3 (Testing Personnel #3, #4, and #6) of 6 testing personnel listed on the CMS-209 form. Findings include: 1. A review of testing personnel competency assessments revealed a lack of documentation for the following testing personnel performing high-complexity histopathology testing listed on the CMS-209 form: a. Testing Personnel #3 b. Testing Personnel #4 c. Testing Personnel #6 2. A review of the laboratory's established "Quality Assessment Procedures" policy revealed a section stating, "The competency of Test Personnel and all staff members will be evaluated and documented every year by the Laboratory Director or an appropriate, designated staff member and every six months for the first year of training to ensure that all laboratory staff maintains their competency in testing and laboratory management function. Proper training will be provided to correct and deficiencies found." 3. An interview on 3/11/2020 at 10:15 am with TP2 confirmed the competency assessments for the testing personnel listed above were not available.</p>