

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2129227	(X3) Date Survey Completed 03/12/2019
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 123 W Michigan St, Ottawa, IL	
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 the laboratory's policies, procedures, the lack of personnel documents, the Laboratory Personnel Report (CMS 209), and an interview with the testing personnel (TP); the laboratory failed to establish written competency procedures that meet personnel requirements and failed to follow written policies to assess employees performing Histopathology processing, affecting 1 out of 1 TP. Findings: 1. The CMS 209, personnel records, policies and procedures manual were reviewed. 2. The laboratory's competency procedure failed to include test performance and problem solving to evaluate it's TP performing tissue grossing and slide production. 3. The laboratory failed to follow competency policies to assess TP semiannually and annually. a). No competency documentation was presented for TP2A from 10/17/2017 (the initial survey) through to 03/2019. 4. On a Recertification survey conducted on 03 /12/19 at 11:50 AM, the TP confirmed the above findings.</p>