

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0191111	(X3) Date Survey Completed 10/18/2021
Name of Provider or Supplier Advanced Dermatology Associates Ltd	Street Address, City, State 1259 South Cedar Crest Blvd Suite 100, Allentown, 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:</p> <p>A. Based on review of the competency assessment policy, lack of documentation and interview with testing personnel (TP) #21 and #22, the laboratory failed to follow their competency policy to assess the competency of 03 of 04 technical supervisors in 2019 and 2020. Findings include: 1. The laboratory competency assessment policy states, "Staff who hold CLIA supervisor positions: (general supervisor, technical consultant, technical supervisor, or clinical consultant), will be assessed annually for their supervisory competency in addition to laboratory". 2. On the day of survey, 10/18/2021, the laboratory could not provide the following personnel competency assessment records for 2019 and 2020: - 03 of 04 TS. 3. TP #21, TP #22 and the laboratory director confirmed the findings above on 10/18/2021 around 2:30 pm. B. Based on review of the competency assessment policy and interview with testing personnel (TP) #21 and #22, the laboratory failed to have a complete competency assessment policy that states to evaluate each testing personnel for each test performed in 2019 and 2020. Findings include: 1. On the day of survey, 10/18/2021, the laboratory could not provide a competency assessment policy that states to assess each TP for each microscopic examination analyzed (potassium hydroxide, scabies and tzanck) in 2019 and 2020. 2. The laboratory could not provide individual competency assessment documentation for each microscopic examination performed by TP in 2019 and 2020. 3. TP #21, TP #22 and the laboratory director confirmed the findings above on 10/18/2021 around 2:30 pm.</p>

D6051**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) competency assessment records, peer review records and interview with TP #21 and TP #22, the technical consultant failed to assess the competency of all TP through internal blind testing samples or peer review in 2020. Findings Include: 1. The peer review for scabies, potassium hydroxide (KOH) and tzancks policy states, "peer review should be done once every 6 months for KOH and scabies slides per provider". 2. On the day of survey, 10/18/2021, a review of TP competency assessment records and peer review records revealed, all testing personnel were not assessed through internal blind testing samples or peer review for KOH and scabies microscopic examinations in 2020. 3. TP #21, TP# 22 and the laboratory director confirmed the finding above on 10/18/2021 around 2:30 pm.