

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1039033	(X3) Date Survey Completed 11/17/2021
Name of Provider or Supplier Associates In Dermatology Inc	Street Address, City, State 2205 Crocker Rd, Suite 109, Westlake, OH	
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 an interview with the CLIA Coordinator, the laboratory failed to follow a written policy and procedure to assess competency of the Clinical Consultant (CC) as specified in the personnel requirements in subpart M. All patients tested at this laboratory had the potential to be affected. Findings Include: 1. A virtual review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 11/22/2021, found five individuals that fulfilled the role of the CC, other than the Lab Director (LD) 2. A virtual review of the laboratory's "Personnel Training Policy and Procedure found the following statement: "...2. The Clinical Team Lead will monitor that the Lab Director has provided and documented the training of the Clinical Consultant (CC) and Testing Personnel (TP) on an annual basis while performing the bi-annual QA reviews...." 3. A virtual review of the laboratory's Competency Assessment documentation, failed to find evidence that the five delegated CCs were assessed for competency, based on the regulatory responsibility of that role, at a frequency determined by the laboratory. 4. A video phone call interview with the CLIA Coordinator, on 11/17/2021 at 1:42 PM, confirmed that the lab failed to follow the policy and procedure for assessing and documenting the competency of the CC based on the regulatory responsibility of that role, at a frequency determined by the laboratory. Thus the documentation could not be produced at the time of the inspection.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p>

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based upon a record review and an interview with the CLIA Coordinator, the Laboratory Director (LD) failed to specify the duties and responsibilities of the Clinical Consultants (CC) listed on the CMS-209. All patients tested at this laboratory had the potential to be affected. Findings include: 1. A virtual review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 11/22/2021, found five individuals that fulfilled the role of the CC, other than the Lab Director (LD). 2. A virtual review of policies and procedures failed to find evidence that the duties and responsibilities of the CC were specified in writing, with regulatory responsibilities delegated to those individuals by the LD. 3. A video phone call interview with the CLIA Coordinator on 11/17/2021 at 1:42 PM, confirmed that the LD failed to specify in writing, the regulatory responsibilities of the five CCs, delegated to those individuals by the LD. Thus, the documentation could not be produced at the time of the inspection.