

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2172071	(X3) Date Survey Completed 07/11/2024
Name of Provider or Supplier Artius Dermatology Associates, Pc	Street Address, City, State 1921 N Gateway Blvd Ste 101, Fresno, CA	
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
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory's policies & procedures, patient test records, testing personnel qualifications & training records, and interview with the laboratory manager, it was determined that the laboratory director is herein cited for failure to ensure that prior to testing patient specimens, all personnel have the appropriate education and experience. See D6170.</p>
D6170	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on the interview with the laboratory manager (LM) and review of testing personnel qualification records on July 11, 2024 at approximately 11:00 a.m., the laboratory personnel performing gross examination (macro) failed to meet qualification requirements. Findings included: 1. It was the practice of the laboratory for gross examinations to be performed by non-certified/licensed personnel without supervision of a licensed medical doctor or qualified personnel. According to the LM,</p>

gross examinations (macro) were performed by their non-certified/licensed personnel since 2022. 2. Based on the review of the laboratory's submitted "Laboratory Personnel Report (CLIA)," Form CMS-209, signed by the laboratory director on July 1, 2024, and testing personnel qualifications information provided by the LM, apart from the laboratory director declared as the only testing personnel listed on the Form CMS-209, the two histology technicians did not possess the qualifications for testing personnel, high complexity testing. 3. During an interview at approximately 11:00 a. m. on July 11, 2024, the LM confirmed statement #1. 4. According to the laboratory's annual volume declaration, the laboratory performed 19,500 tests for histopathology. Therefore, the quality and accuracy of the patients' test results rendered by the laboratory cannot be assured.