

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1094919	(X3) Date Survey Completed 12/02/2024
Name of Provider or Supplier Orange Coast Dermatology Inc	Street Address, City, State 22032 El Paseo Ste 150, Rancho Santa Margarita, 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
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 review of policies and procedures manuals, lack of laboratory records and interview with the Administrator Manager (AM) on December 2, 2024, the laboratory failed to establish and follow written policies and procedures to assess testing personnel competency in 2022, 2023 and 2024. The findings include: 1. It was the practice of the laboratory to perform Mycology using Potassium Hydroxide (KOH) testing. The Physician Assistants (PA) were responsible for preparing Wet Mount and report the results. 2. The laboratory's Administrator Manager affirmed on December 2, 2024, at approximately 12:00 pm, that the laboratory did not have written policies and procedures for assessment of employee competency and maintained no documentation for competency assessment. 3. The laboratory's testing declaration form, signed by the laboratory director on October 25, 2024, stated that the laboratory performed approximately 25 Mycology tests annually.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:
Based on review of policies and procedures manuals, laboratory records and interview with the Administrator Manager (AM) on December 2, 2024, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor and assess, and when indicated, correct problems identified in the analytic systems in 2022, 2023 and 2024. The findings include: 1. According to the laboratory's written policies and procedures for quality control assessment, the laboratory director was responsible to review all Quality Control (QC) charts and logs on at least a monthly basis. 2. On December 2, 2024, at approximately 12:30 pm, the laboratory administrator manager affirmed that the laboratory maintained no documentation to indicate that QC charts and logs had been reviewed monthly by the laboratory director for 3 of 3 years. 3. The laboratory's testing declaration form, signed by the laboratory director on October 25, 2024, stated that the laboratory performed approximately 205 histopathology and mycology tests annually.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies and procedures manuals, competency evaluation, quality assurance records, review of 6 randomly selected patient test results and interview with Administrator Manager on December 2, 2024, it was determined that the Laboratory director of high complexity testing failed to ensure that testing systems developed and used for histopathology and mycology procedures provide quality laboratory services for all aspects of test performance. See D5209, D5791.