

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2277070	(X3) Date Survey Completed 12/18/2025
Name of Provider or Supplier Optima Dermatology	Street Address, City, State 5817 Happy Hollow Road, Milford, 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 Practice Manager (PM), and the Histology Technician (HT), the laboratory failed to establish and follow written policies and procedures to assess the competency of one staff member performing in the role of the Clinical Consultant, (CC), Technical Consultant (TC), Technical Supervisor (TS), and General Supervisor (GS). This affected one of three staff members reviewed for competency. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 11/21/2025 and provided on the date of the inspection, found one staff member qualified and performing in the role of CC, TS, TC, and GS. Two additional staff members were listed for other roles. 2. Review of the laboratory's competency records from 07/18/2024 through 12/18/2025, did not find any competency assessment documentation for the staff performing as the CC, TS, TC, and GS. 3. Review of the policy and procedure manual titled "CLIA Manual" signed and dated by the Laboratory Director on 07/21/2025, found no mention of competency assessments for the CC, TS, TC, and GS. 4. An interview on 12/09/2025 at 10:00 AM with PM and HT, confirmed the laboratory failed to establish and follow a policy and procedure for conducting CC, TS, TC, and GS competency assessments from 07/18/2024 through 12/18/2025. 5. Review of laboratory documentation revealed 795 patients tested in the subspecialty of Histopathology from 07/18/2024 through 12/18/2025.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p>

(e)(15) 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 on record review and an interview with the Practice Manager (PM), the Laboratory Director (LD) failed to specify in writing the duties and responsibilities for personnel performing in the role of the Clinical Consultant (CC), Technical Supervisor (TS), Technical Consultant (TC), and General Supervisor (GS). This affected one of three staff members reviewed for duties and responsibilities. Findings include: 1. Review of the laboratory's form CMS-209 signed and dated by the LD on 11/21/2025, found one staff member performing in the role of CC, TS, TC, and GS. 2. Review of the policy and procedure manual titled, "CLIA Manual" approved via signature and date by the LD on 07/21/2025 revealed no evidence of the written duties and responsibilities for the CC, TS, TC, and GS, as delegated by the LD. 3. An interview on 12/18/2025 at 9:30 AM with the PM confirmed the LD failed to specify in writing the duties and responsibilities of the CC, TS, TC, and GS. 4. Review of laboratory documentation revealed 795 patients tested in the subspecialty of Histopathology from 07/18/2024 through 12/18/2025.