

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2111882	(X3) Date Survey Completed 10/02/2024
Name of Provider or Supplier Oakview Dermatology	Street Address, City, State 2405 N Columbus St, Ste 100, Lancaster, 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 Mohs Department Manager (MDM), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS), and Testing Personnel (TP) based on the responsibilities of the position and at a frequency determined by the laboratory. This deficient practice had the potential to affect 585 out of 585 patients tested under the subspecialty of Histopathology from 02/14/2023 through 10/02/2024. Findings Include: 1. Review of the laboratory's form CMS-209 Personnel Report (CLIA) found one individual listed as the CC, TS, GS and TP, and a second individual listed as the CC and TP. 2. Review of the policy and procedure manual titled, "Oakview Dermatology Mohs Laboratory" approved via signature and date by the LD on 01/02/2023 found no mention of instructions for the CC, TS, GS, and TP competency assessment. 3. The Inspector requested an approved competency assessment policy and procedure, and 2023 and 2024 assessment documentation for the CC, TS, GS, and TP based on the responsibilities of the position from the MDM. The MDM confirmed the laboratory did not have an approved competency assessment policy and procedure, did not perform a competency assessment for the CC, TS, GS, and TP and was unable to provide the requested information. The interview occurred on 10/02/2024 at 11:50 a. m.</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 on record review and an interview with the Practice Manager (MDM), the Laboratory Director (LD) failed to specify in writing the duties and responsibilities of the Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS), and Testing Personnel (TP) listed on the form CMS-209. This deficient practice had the potential to affect 585 out of 585 patients tested under the subspecialties of Histopathology from 02/14/2023 through 10/02/2024. Findings include: 1. Review of the laboratory's form CMS-209 Personnel Report (CLIA) found one individual listed as the CC, TS, GS and TP, and a second individual listed as the CC and TP. 2. Review of the policy and procedure manual titled, "Oakview Dermatology Mohs Laboratory" approved via signature and date by the LD on 01/02/2023 failed to find evidence of the written duties and responsibilities for the CC, TS, GS, and TP as delegated by the LD. 3. The Inspector requested the duties and responsibilities of the CC, TS, GS, and TP from the MDM. The MDM confirmed the LD failed to specify in writing the duties and responsibilities of the CC, TS, GS, and TP and was unable to provide the requested information. The interview occurred on 10/02/2024 at 11:45 a.m.