

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2277070	(X3) Date Survey Completed 07/18/2024
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Histology Technician (HT), the laboratory failed to follow their "Microscopic Examination for Fungus-KOH" policy and procedure. This deficient practice had the potential to affect 50 out of 50 patients tested in the subspecialty of Mycology from 12/18/2023 through 07/18/2024. Findings Include: 1. Review of the policy and procedure titled "Microscopic Examination for Fungus-KOH" signed and dated by the Laboratory Director on 06/24/2024 found the following statements: "Daily QC needs to be performed on each day of testing - to be conducted as follows: specimen to be collected by any testing personnel and results will need to be read by two testing personnel to make sure they are in agreement to continue testing for that day" 2. Review of test logs titled "Microscopic Examination for Fungus-KOH" from 12/18/2023 through 07/15/2024 did not find any daily QC read by two testing personnel. 3. The inspector requested the daily QC for the microscopic examination for fungus using KOH. The HT confirmed the laboratory did not conduct QC each day of patient testing for the microscopic examination for fungus using KOH as stated in the policy and procedure and was unable to provide the requested information. The interview occurred on 07/18/2024 at 11:15 a.m. QC; Quality Control KOH; Potassium Hydroxide</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p>

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual and an interview with the Histology Technician (HT), the Laboratory Director (LD) failed to ensure approved policies and procedures were available to all personnel responsible for any aspect of the testing processes. This deficient practice had the potential to affect 450 out of 450 patients tested under the subspecialties of Histopathology and Mycology from 12/18/2023 through 07/18/2024. Findings Include: 1. Review of the policy and procedure manual titled, "CLIA Manual", found an approved cover page signed and dated by the LD on 06/24/2024. Further review of each section of the policy and procedure manual found individual cover pages signed and dated by the LD on 06/24/2024. 2. Review of patient test logs revealed the following initial testing dates: Test Patient Initials Date Mohs IV 04/16/2024 KOH DC 12/18/2023 3. The HT confirmed patient testing had started prior to the LD policy and procedure approval. The interview occurred on 07/18/2024 at 10:30 a.m. KOH; Potassium Hydroxide

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

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 Histology Technician (HT), the Laboratory Director (LD) failed to specify in writing the duties and responsibilities of the Clinical Consultant (CC), Technical Supervisor (TS), Technical Consultant (TC), and General Supervisor (GS) listed on the form CMS-209. This deficient practice had the potential to affect 450 out of 450 patients tested under the subspecialties of Histopathology and Mycology from 12/18/2023 through 07/18/2024. Findings include: 1. Review of the laboratory's form CMS-209 Personnel Report (CLIA) found one individual listed as the 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 06/24/2024 failed to find evidence of the written duties and responsibilities for the CC, TS, TC, and GS as delegated by the LD. 3. An interview with the HT confirmed the LD failed to specify in writing the duties and responsibilities of the CC, TS, TC, and GS. The interview occurred 07/18/2024 at 10:20 a.m.