

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521865	(X3) Date Survey Completed 06/10/2024
Name of Provider or Supplier Dermatology Clinic Of Idaho	Street Address, City, State 7733 W Emerald St, Boise, ID	
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
D0000	Based on review of the Centers for Medicare and Medicaid Services (CMS) 116 application form and the CMS-209 personnel form submitted by the laboratory and an interview with the practice manager on 6/10/2024, the laboratory director or delegated designee failed to sign the forms attesting that the information was correct and the laboratory was operated in accordance with federal and state regulations. The findings include: 1. An email was sent on 5/29/2024 instructing the facility to complete the CMS-116 and CMS-209 and return within one week of the laboratory's inspection, 6 /10/2024. 2. A reminder email was sent on 6/6/2024 and on 6/7/2024 the laboratory sent the forms. A review of the forms identified that the laboratory director failed to sign both the CMS-116 and CMS-209. 3. An interview with the practice manager on 6 /10/2024 at 12:56 pm confirmed that the laboratory director failed to sign both forms and was not at the laboratory to sign them. She stated that she would get the forms to him and have him sign them. 4. An email reminder was sent on 6/17/2024 and as of 6 /21/2024 the laboratory failed to send the completed and signed CMS-116 and CMS-209 forms. 5. The laboratory reports performing 205 tests annually.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory documents, a lack of documentation and an interview with the practice manager on 6/10/2024, the laboratory failed to perform verification of accuracy for potassium hydroxide (KOH) and Mohs examinations at least twice annually in 2022, 2023 and 2024. The findings include: 1. A lack of documentation for bi-annual verification identified that the laboratory failed to document verification of accuracy for KOH slide examinations at least twice annually in 2022 and 2023. 2. A lack of documentation for bi-annual verification identified that the laboratory failed</p>

	<p>to document verification of accuracy for Mohs examinations at least twice annually in 2022, 2023 and 2024. 3. An interview with the practice manager on 6/10/2024 at 2:00 pm confirmed the above findings. 4. The laboratory reports performing 205 KOH and Mohs examinations annually. 5. This is a repeat deficiency for failure to verify the accuracy of fungal cultures twice annually from inspections performed on 9/19/2016 and 7/9/2018.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records, laboratory policies and procedures, a lack of documentation and interviews with the practice manager on 6/10/2024, the laboratory director failed to ensure that testing personnel had appropriate training and were competent to perform testing, policies and procedures were available for testing personnel to follow, that microscope maintenance was performed and that the laboratory had a quality assurance plan. See D6102, D6103, D6106, D6095 and D6094.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures and an interview with the practice manager on 6/10/2024, the laboratory director failed to establish a quality assurance (QA) policy to ensure accurate and reliable test results. The findings include: 1. A review of the laboratory policies and procedures identified that the laboratory director failed to establish and follow a QA policy to monitor and assess general laboratory systems, preanalytic, analytic and post analytic activities that identified and corrected failures in quality. 2. An interview with the practice manager on 6/10/2024 at 2:05 pm confirmed the above finding. 3. The laboratory reports performing 205 tests annually.</p>
<p>D6095</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures, a lack of documentation and</p>

an interview with the practice manager on 6/10/2024, the laboratory director failed to ensure a policy for microscope maintenance was established and followed since the last inspection on 6/9/2022. The findings include: 1. A review of laboratory policies identified that the laboratory director failed to ensure the establishment of a policy for microscope maintenance. 2. A lack of documents identified that the laboratory failed to perform and document microscope maintenance since the last inspection on 6/9/2022. 3. An interview with the practice manager on 6/10/2024 at 2:08 pm confirmed there was not a microscope maintenance policy or documentation of microscope maintenance. 4. The laboratory reports performing 205 slide examinations annually.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

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.

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records and an interview with the practice manager on 6/10/2024, the laboratory director failed to ensure employee competency was assessed since the last inspection on 6/9/2022. The findings include: 1. A review of the CMS 209 identified three (3) testing personnel (TP) performing potassium hydroxide (KOH) slide examination testing and one (1) TP performing Mohs procedures. 2. A review of training and competency assessment records identified that the laboratory director failed to have annual competency assessments for one (1) of three (3) TP in 2022 for KOH slide examinations. 3. A review of training and competency assessment records identified that the laboratory director failed to have annual competency assessments for three (3) of three (3) TP in 2023 for KOH slide examinations. 4. A review of training and competency assessment records identified that the laboratory director failed to have annual competency assessments for one (1) of one (1) TP in 2022 and 2023 for Mohs procedures. 5. An interview with the practice manager on 6/10/2024 at 1:00 pm confirmed the above findings. 6. The laboratory reports performing 205 slide examinations annually.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on a review of laboratory policies and procedures, training and competency assessment records and an interview with the practice manager on 6/10/2024, the laboratory director failed to ensure written policies and procedures to assess testing

personnel (TP) training and competency were established and followed in 2022 and 2023. The findings include: 1. A review of policies and procedures identified that the laboratory director failed to ensure a policy was established for the training and competency assessment of TP. 2. A review of training and competency assessment records identified that the laboratory director failed to have annual competency assessments for TP in 2022 and 2023. See D6102 3. An interview with the practice manager on 6/10/2022 at 2:05 pm confirmed the above findings. 4. The laboratory reports performing 205 tests annually.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

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 a review of policies and procedures and an interview with the practice manager on 6/10/2024, the laboratory director failed to ensure approved laboratory policies and procedures were available since the last inspection on 6/9/2022. The findings include: 1. A review of laboratory policies and procedures identified that the laboratory director failed to ensure the establishment and approval of laboratory policies and procedures for training and competency assessment, biannual verification for KOH and Mohs procedures and a Mohs procedure to be followed. 2. An interview with the practice manager on 6/10/2024 at 2:05 pm confirmed that the laboratory director had not established or approved the above laboratory policies and procedures. 3. The laboratory reports performing 205 Mohs and KOH slide examinations annually.