

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2171439	(X3) Date Survey Completed 09/22/2022
Name of Provider or Supplier Ada West Dermatology	Street Address, City, State 4574 N Ten Mile Rd Ste 120, Meridian, 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
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a lack of documents and an interview with the laboratory lead on 9/22/2022, the laboratory failed to ensure that testing personnel performing potassium hydroxide (KOH) examinations had initial training and competency assessments (see D5209); failed to perform bi-annual verification of KOH examinations (see D5217). Both D5209 and D5217 are repeat deficient practices from the previous inspection on 3/4/2021 and there is no documentation of initial training, competency assessments or bi-annual verification for KOH examinations since the facility began testing in October 2019.</p>
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 a review of laboratory procedures, the Centers for Medicare and Medicaid</p>

Services (CMS) 209 personnel form, an interview with the laboratory lead on 9/22 /2022 and a lack of documentation, the laboratory failed to follow written procedures to assess testing personnel's training and competency for potassium hydroxide (KOH) examinations in 2021. The findings include: 1. A review of the laboratories KOH procedure identified that the laboratory performs initial training within two weeks of hire then six month and annual competency assessments. 2. A lack of training records identified two testing personnel listed on the CMS 209 hired since the last inspection on 3/4/2021 that failed to have documentation of initial training for KOH examinations. 3. A lack of competency assessment records identified two testing personnel listed on the CMS 209 hired since the last inspection on 3/4/2021 that failed to have documentation of a six month competency assessment for KOH examinations. 4. A lack of competency assessment records identified three testing personnel listed on the CMS 209 that failed to have an annual competency assessment for 2021 for KOH examinations. 5. An interview with the laboratory lead on 9/22/2022 at 2:11 pm confirmed the above findings. 6. The laboratory reports performing 67 KOH examinations annually. 7. This deficient practice was identified during the previous inspection on 3/4/21; failed to document initial training, six month and annual competency for testing personnel performing KOH examinations and was confirmed by interview with the laboratory lead on 03/04/21 at 2:00 PM.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on a lack of documentation and an interview with the laboratory lead on 9/22 /2022, the laboratory failed to document, at least twice annually, the verification of accuracy for potassium hydroxide (KOH) examinations since the last inspection . The findings include: 1. A lack of documentation for bi-annual verification identified that the laboratory failed to document verification of accuracy for KOH examinations at least twice annually since the last inspection on 3/4/2021. 2. An interview with the laboratory lead on 9/22/2022 at 2:11 PM confirmed that the laboratory has not performed bi-annual verification of KOH examinations. 3. The laboratory reports performing 67 KOH examinations annually 4. This deficient practice was identified during the previous inspection on 3/4/2021; failed to document bi-annual verification of KOH examinations from the time the laboratory opened in October of 2019 and was confirmed by interview with the laboratory lead on 03/04/2021 at 2:00 PM.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:
Based on a lack of documents and an interview with the laboratory lead on 9/22/2022, the laboratory failed to fulfill their responsibilities as a laboratory director. The laboratory director failed to ensure that testing personnel performing potassium

hydroxide (KOH) examinations had initial training and competency assessments (see D6079); that the laboratory perform bi-annual verification of KOH examinations (see D6088). Both are repeat deficient practices from the previous inspection on 3/4/2021 and there is no documentation of initial training, competency assessments or bi-annual verification for KOH examinations since the facility began testing in October 2019

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, an interview with the laboratory lead on 9/22/2022 and a lack of documentation, the laboratory director failed to ensure testing personnel were trained and competent for potassium hydroxide (KOH) examinations before patent testing in 2021. The findings include: 1. A lack of training records identified two testing personnel listed on the CMS 209 hired since the last inspection on 3/4/2021 that failed to have documentation of initial training for KOH examinations. 2. A lack of competency assessment records identified two testing personnel listed on the CMS 209 hired since the last inspection on 3/4/2021 that failed to have documentation of a six month competency assessment for KOH examinations. 3. A lack of competency assessment records identified three testing personnel listed on the CMS 209 that failed to have an annual competency assessment for 2021 for KOH examinations. 4. An interview with the laboratory lead on 9/22/2022 at 2:11 pm confirmed the above findings. 5. The laboratory reports performing 67 KOH examinations annually. 6. This deficient practice was identified during the previous inspection on 3/4/21; failed to document initial training, six month and annual competency for testing personnel performing KOH examinations and was confirmed by interview with the laboratory lead on 03/04/21 at 2:00 PM.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on a lack of documentation and an interview with the laboratory lead on 9/22 /2022, the laboratory director failed to ensure that bi-annual verification of accuracy for potassium hydroxide (KOH) examinations was performed since the last inspection . The findings include: 1. A lack of documentation for bi-annual verification identified

that the laboratory failed to document verification of accuracy for KOH examinations at least twice annually since the last inspection on 3/4/2021. 2. An interview with the laboratory lead on 9/22/2022 at 2:11 PM confirmed that the laboratory has not performed bi-annual verification of KOH examinations. 3. The laboratory reports performing 67 KOH examinations annually 4. This deficient practice was identified during the previous inspection on 3/4/2021; failed to document bi-annual verification of KOH examinations from the time the laboratory opened in October of 2019 and was confirmed by interview with the laboratory lead on 03/04/2021 at 2:00 PM.