Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2171439	10/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ada West Dermatology	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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of laboratory records and an interview with the Mohs lead on 10/24 /2024, the laboratory failed to enroll in proficiency testing (PT) for dermatophyte fungi cultures in 2024. The findings include: 1. A lack of laboratory PT records identified that the laboratory failed to enroll and participate in PT for dermatophyte fungi cultures performed by the laboratory since March of 2024. 2. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed that the laboratory failed to enroll and participate in PT for dermatophyte fungi cultures since March of 2024. 3. The laboratory reports performing 73 dermatophyte fungi cultures annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, competency assessment records and an interview with the Mohs lead on 10/24/2024, the laboratory failed to follow written policies and procedures to assess testing personnel performing dermatophyte fungi cultures in 2024. The findings include: 1. A review of the CMS 209 form identified four (4) testing personnel performing dermatophyte fungi cultures. 2. A review of competency assessment records identified the laboratory failed to have documentation of six month competency assessments for four (4) of four (4) testing personnel in 2024. 3. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed the above findings. 4. The laboratory reports performing 73 dermatophyte fungi cultures annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual and an interview with the Mohs lead on 10/24/2024, the Laboratory Director failed to approve, sign and date the dermatophyte fungi culture policy prior to patient testing beginning in March 2024. The findings include: 1. A record review of the laboratory policy and procedure manual identified that the Laboratory Director failed to approve, sign and date the "DTM Policy- Ten Mile Clinic" used for dermatophyte fungi cultures prior to patient testing beginning in March 2024. 2. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed that the Laboratory Director had not approved the "DTM Policy- Ten Mile Clinic" policy prior to patient testing. 3. The laboratory reports performing 73 dermatophyte fungi cultures annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure for dermatophyte fungi culture, the manufacturer's instructions for use (IFU), laboratory records and an interview with the Laboratory Director on 10/24/2024, the laboratory failed to follow the manufacturer's IFU for interpretation of results for dermatophyte fungi cultures. The findings include: 1. A review of the laboratory procedure for dermatophyte fungi culture,"DTM Policy-Ten Mile Clinic," identified that the laboratory was interpreting and resulting dermatophytes and yeast from the Dermatophyte Testing Medium (DTM). 2. A review of the Hardy Diagnostics IFU for DTM used in dermatophyte cultures identified interpretation of results to be positive or negative for dermatophytes. 3. A review of the laboratory's internal proficiency testing quiz identified that the laboratory failed to follow the manufacturer's IFU and result only positive or negative

	for dermatophytes from cultures using the Hardy Diagnostics DTM. 4. An interview with the Laboratory Director on 10/24/2024 at 10:33 am confirmed the above findings. 5. The laboratory reports performing 73 dermatophyte fungi cultures annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for use (IFU), laboratory records and an interview with the Mohs lead on 10/24/2024, the laboratory failed to document testing temperatures as required by the manufacturer for dermatophyte fungi cultures. The findings include: 1. A review of the IFU for Hardy Diagnostics Dermatophyte Test Medium (DTM) identified that the inoculated medium is to be incubated at room temperature (15-30 C) for up to 14 days. 2. A review of the laboratory's temperature log identified that the laboratory failed to document room temperature in the locations that dermatophyte fungi cultures were incubating. 3. An interview with the Mohs lead on 10/24/2024 at 10:35 confirmed that the laboratory fail to document incubation temperatures for dermatophyte fungi cultures. 4. The laboratory reports performing 73 dermatophyte fungi cultures annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a lack of documentation for verification of performance specifications for dermatophyte fungi cultures and an interview with the Mohs lead on 10/24/2024, the laboratory failed to ensure test performance specifications were established and verified before patient testing began in March 2024. The findings include: 1. A lack of documentation for the verification of performance specifications for dermatophyte fungi cultures identified that the laboratory failed to establish accuracy of the testing method prior to performing patient testing in March 2024. 2. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed that the laboratory failed to verify manufacturer's performance specifications prior to beginning patient testing. 3. The laboratory reports performing 73 dermatophyte fungi cultures annually.

D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the Mohs lead on 10/23/2024, the laboratory failed to check each lot of prepared medium for its ability to support and inhibit growth for dermatophyte fungi cultures since March 2024. The findings include: 1. A lack of microbiology quality control (QC) records identified that the laboratory failed to perform and document quality control (QC) to show the ability of the prepared Hardy Dermatophyte testing medium (DTM) to support growth since beginning testing in March 2024. 2. A lack of microbiology quality control (QC) records identified that the laboratory failed to perform and document QC to show the ability of the prepared Hardy DTM to inhibit growth of selected organisms since beginning testing in March 2024. 3. A lack of microbiology quality control (QC) records identified that the laboratory failed to perform and document QC to show the ability of the prepared Hardy DTM to differentiate organisms since beginning testing in March 2024. 4. An interview with the Mohs lead on 10/23/2024 at 10:35 am confirmed that the laboratory failed to to perform QC on the DTM. 5. The laboratory reports performing 73 dermatophyte fungi cultures annually.
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 review of the Centers for Medicare and Medicaid (CMS) personnel form 209, the manufacturer's instructions for use, a lack documents and an interview with the Mohs lead on 10/24/2024, the Laboratory Director failed to ensure that new test verifications were performed, that testing personnel had training and were competent to provide accurate and reliable patient results, that PT was ordered and performed that the laboratory was following the manufacturer's testing instructions and that the laboratory had a quality control plan for dermatophyte fungi culture. See D6086, D6087, D6088, D6093 and D6102.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on a lack of documentation for verification of performance specifications for dermatophyte fungi cultures and an interview with the Mohs lead on 10/24/2024, the Laboratory Director failed to ensure test performance specifications were established and verified before patient testing began in March 2024. The findings include: 1. A lack of documentation for the verification of manufacturer performance specifications for dermatophyte fungi cultures identified that the Laboratory Director failed to ensure test method accuracy was adequate prior to performing patient test in March 2024. 2. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed that the laboratory failed to verify manufacturer's performance specifications prior to beginning patient testing. 3. The laboratory reports performing 73 dermatophyte fungi cultures annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure for dermatophyte fungi culture, the manufacturer's instructions for use (IFU), laboratory records and an interview with the Mohs lead on 10/24/2024, the Laboratory Director failed to ensure that the laboratory was following the manufacturer's IFU for accurate interpretation of results for dermatophyte fungi cultures. The findings include: 1. A review of the laboratory procedure for Dermatophyte fungi Culture, the Hardy Diagnostics IFU for DTM used in dermatophyte cultures and the laboratory's internal proficiency testing quiz identified the laboratory failed to follow the manufacturer's IFU for interpretation of results to result only positive or negative for dermatophytes. See D5411 2. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed the above finding. 3. The laboratory reports performing 73 dermatophyte fungi cultures annually.
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 review of laboratory records and an interview with the Mohs lead on 10/24 /2024, the Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing (PT) for dermatophyte fungi cultures in 2024. The findings include: 1. A review of laboratory records identified that the laboratory failed to enroll and participate in PT for dermatophyte fungi cultures performed by the laboratory since March 2024. 2. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed that the Laboratory Director failed to ensure that the laboratory was enrolled and participated in PT for dermatophyte fungi cultures since March 2024. 3. The laboratory reports performing 73 dermatophyte fungi cultures annually.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a lack of quality control (QC) documentation and an interview with the Mohs lead on 10/24/2024, the Laboratory Director failed to ensure that the laboratory had an acceptable QC plan for dermatophyte fungi cultures that was followed by testing personnel. The findings include: 1. A lack of a QC policy and QC documentation for dermatophyte fungi cultures identified that the laboratory failed to perform and document acceptable QC since beginning testing in March 2024. See D5447 2. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed that the Laboratory Director failed to ensure QC was performed. 3. The laboratory reports performing 73 dermatophyte fungi cultures 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, a lack of documentation, an interview with the Mohs lead on 10/24 /2024, the Laboratory Director failed to ensure that testing personnel performing dermatophyte fungi cultures had the training to accurately perform and report patient testing. The findings include: 1. A review of the CMS 209 identified four (4) testing personnel performing dermatophyte fungi cultures. 2. A lack of training documentation identified that the laboratory failed to have documentation of initial training for four (4) of four (4) testing personnel performing dermatophyte fungi cultures before beginning patient testing in March 2024. 3. An interview with the Mohs lead on 10/24/2024 at 10:35 am confirmed that there was no documentation of training. 4. The laboratory reports performing 73 dermatophyte fungi cultures annually.