Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 53D2265113	**(X3) Date Survey Completed** 03/18/2026
Name of Provider or Supplier Sage Dermatology	**Street Address, City, State** 204 Mccollum St, 107, Laramie, WY	
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	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 review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel and laboratory records, and staff interview, the laboratory failed to ensure initial, 6-month, and annual competency assessments were completed for 2 of 2 testing personnel (MD #1, PA #1) as required for 2 of 2 years reviewed (2024, 2025). In addition, the laboratory failed to develop a policy and procedure for assessing the competency of testing personnel which included the six required elements. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed MD #1 and PA #1 were listed as testing personnel. In addition, the laboratory director also acted as the technical and general supervisor. The following concerns were identified: a. Review of the potassium hydroxide (KOH) preparation patient testing log sheet showed beginning on 4/11/24 MD #1 evaluated 11 KOH preparation slides in 2024 and evaluated 35 slides in 2025. Beginning on 8/29/24 PA #1 evaluated 14 KOH preparation slides in 2024 and 37 slides in 2025. b. Review of personnel files showed no evidence the required competency assessments had been completed. c. Review of the laboratory's policy and procedure binder showed no evidence a policy and procedure had been developed. 2. Interview with the laboratory manager on 3/18/26 at 11 AM confirmed a policy and procedure had not been developed and no further documentation was available. 3. Review of the "LABORATORY DIRECTOR" job description, provided by the laboratory, showed the laboratory director was to "11. 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. 12. 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. Also, whenever necessary, identify the need for remedial training or continuing education to improve skills." 4. Review of the "GENERAL SUPERVISOR" job description, provided by the laboratory, showed the general supervisor was "4. Responsible for the annual evaluation and documentation of all laboratory personnel." A box was checked on the form which indicated the laboratory director would perform this function.
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 lack of documentation, staff interview, and review of policy and procedures, the laboratory failed to ensure potassium hydroxide (KOH) preparations for the observation of fungal elements was verified for accuracy at least twice annually for 2 of 2 years reviewed (2024, 2025). The laboratory performed approximately 75 KOH preparations in 2025. The findings were: 1. Review of the facility's documentation showed no evidence the accuracy of KOH preparations had been verified twice yearly as required. 2. Interview with the laboratory manager on 3/18/26 at 10:03 AM confirmed the accuracy of the KOH preparations for observation of fungal elements had not been completed as required. 3. Review of the Potassium Hydroxide (KOH) Skin Preparation policy, signed by the laboratory director on 3/21/24, showed "REPORTING OF RESULTS Report the presence or absence of yeast or hyphae. (2 positive cases must have a secondary review by a separate provide (sic) at least once a year for KOH..."
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 new test method verification study review, lack of documentation, and staff interview, the laboratory failed to ensure the verification study was complete for 1 of 1 (potassium hydroxide (KOH) skin preparation) new test system reviewed. The laboratory performed approximately 75 KOH skin preparations per year. The findings were: 1. Review of the Quality Control Program policy showed "It is the policy of [laboratory director's name] laboratory (sic) to maintain a Quality Control Program to

	insure (sic) accuracy of results reported. All employees of this laboratory must be familiar with and adhere to all the policies herein stated with regard to quality control. The Quality Control Program involves monitoring the facilities; test methods and equipment, reagents, materials and supplies; procedure manual; method verification; equipment maintenance; calibration and calibration verification; control procedure; remedial actions; and maintenance of quality control records...Test Methods...The laboratory Director (sic) will be responsible for making the final decision on the test system, equipment and methodologies used in the laboratory. The Laboratory Director will ensure that proper test validation has been performed on all tests performed in the laboratory before reporting any patient test results. The Laboratory Director will decide the number of tests performed to validate the instrument or test system... Verification of Method Performance Specifications...The laboratory will verify the performance specifications for each new method base on: 1) Accuracy; 2) Precision... The laboratory will document verification of applicable test performance specifications and will maintain such documentation for the life of the methodology plus five years..." The following concerns were identified: a. Review of the laboratory's documentation showed the laboratory began performing KOH preparations on 4/11/24. Prior to testing, MD #1 participated in a Medical Laboratory Evaluation (MLE) proficiency testing event on 2/6/24 using slides provided by MLE. There was no evidence the facility had performed a verification study which included accuracy and precision using the Potassium Hydroxide (KOH) Skin Preparation procedure on patient samples which was signed by the laboratory director on 3/21/24. 2. Interview with the laboratory manager on 3/18/26 at 11:30 AM revealed no further documentation was available.
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 new test method verification study review, lack of documentation, review of the Centers for Medicare and Medicaid Services 209 Laboratory Personnel Report, staff interview, review of personnel files, review of laboratory records, and review of policy and procedures, the laboratory director failed to ensure the verification study was complete for 1 of 1 (potassium hydroxide (KOH) skin preparation) new test method reviewed (D6086); failed to ensure KOH preparations for the observation of fungal elements was verified for accuracy at least twice annually (D6089); failed to ensure initial, 6-month, and annual competency assessments were completed as required (D6102); and failed to ensure a policy and procedure was established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing (D6103).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

	This STANDARD is not met as evidenced by: Based on new test method verification study review, lack of documentation, and staff interview, the laboratory director failed to ensure the verification study was complete for 1 of 1 (potassium hydroxide (KOH) skin preparation) new test system reviewed. The laboratory performed approximately 75 KOH skin preparations per year. Refer to D5421.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on lack of documentation, staff interview, and review of policy and procedures, the laboratory director failed to ensure potassium hydroxide (KOH) preparations for the observation of fungal elements was verified for accuracy at least twice annually for 2 of 2 years reviewed (2024, 2025). Refer to D5217.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel and laboratory records, and staff interview the laboratory director failed to ensure initial, 6-month, and annual competency assessments were completed for 2 of 2 testing personnel (MD #1, PA #1) as required for 2 of 2 years reviewed (2024, 2025). Refer to D5209.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 review of the laboratory's policy and procedure binder and staff interview, the laboratory director failed to ensure a policy and procedure was established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing. Refer to D5209.