Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2146684	03/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
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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 policies and procedures, lack of competency assessment records, and an interview with the laboratory personnel on March 30, 2026, the laboratory failed to establish and follow written policies and procedures to assess employee competencies in 2024 and 2025. The findings included: 1. It was practice of the laboratory to perform Mycology using Potassium Hydroxide (KOH) testing. The Physician Assistants (PA) were responsible for preparing Wet Mount and reporting the results. The laboratory had three testing personnel (TP) responsible for performing KOH skin preparations. 2. On March 30, 2026, at approximately 2:15 pm, the laboratory's office manager affirmed that the laboratory did not possess written policies or procedures regarding the assessment of employee competency. Furthermore, no documentation existed to demonstrate competency assessment for either of the two Physician Assistants (PA) who performed Potassium Hydroxide (KOH) testing. 3. The laboratory's testing declaration form, signed by the laboratory director January 15, 2026, stated that the laboratory performed approximately 90 microbiology tests annually.
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 the surveyor's review of Proficiency Testing (PT) records and an interview with the laboratory staff on March 30, 2026, it was determined that the Laboratory did not verify the accuracy of the Histopathology tests at least twice annually for the year 2024. The findings included: 1.It was the practice of the laboratory to perform Histopathology testing which is not listed in subpart I of the 42 CFR part 493. For test procedures not listed in subpart I, the laboratory must verify the accuracy of the test procedure twice annually. In accordance with the laboratory procedure manuals, the laboratory ensures the accuracy of its histopathology test procedures through a biannual verification process. Specifically, at least one case is selected and sent for peer review during each verification event. 2. On March 30, 2026, at approximately 1: 00 p.m., the surveyor conducted a review of the laboratory's peer review documentation associated with histopathology testing procedures. The documentation revealed that, for the second verification event in 2024, one case was sent out for accuracy verification. However, this case had not been initially reviewed by the laboratory itself. Instead, the initial review was performed by BARR dermatopathology and subsequently peer reviewed by a laboratory holding CLIA ID: 05D0870989. As a result, the laboratory did not perform the required accuracy verification for the second event in 2024, thereby failing to meet the biannual verification requirement for that year. 3. On March 30, 2026., at approximately 1:00 p. m., the laboratory staff confirmed that the laboratory did not verify the accuracy of the Histopathology testing twice annually for 2024. 4. The laboratory's testing declaration form, signed by the laboratory director on January 15, 2026, stated that the laboratory performed approximately 1000 histopathology tests annually.
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) (c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on review of specimen grossing records, an interview with the laboratory personnel and review of five (5) randomly selected patient test results on March 30, 2026, it was determined that the laboratory failed to ensure that the reference laboratory for specimen grossing maintains a current CLIA certificate. The findings included: 1. It was the practice of the laboratory to perform dermatopathology testing. 2. On March 30, 2026, at approximately 12:40 p.m., the laboratory personnel confirmed that specimen grossing is referred to Harris Histology Service. 3. Harris Histology Service does not possess a CLIA certificate to perform high complexity testing and, therefore, is not authorized to perform specimen grossing. 4. The laboratory's testing declaration form, signed by the laboratory director on January 15, 2026, stated that the laboratory performed approximately 1,000 histopathology tests including dermatopathology annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures and policies and an interview with the laboratory personnel on March 30, 2026. It was determined that the laboratory failed to maintain a written procedure manual and evidence of compliance including all necessary criteria relevant to the laboratory operations. This lack of documentation indicates that critical processes and standards required for consistent laboratory functioning were not adequately recorded or referenced. The findings included: 1. It was the practice of the laboratory to perform histopathology testing. 2. The laboratory failed to provide written policies and procedures outlining the step-by-step process for specimen processing, referral of specimens to reference laboratories for grossing, and specimen transportation tracking to ensure accountability. 3. The laboratory failed to provide written policies and procedures outlining the step-by-step process for entering results in the patient record and reporting patient results 4. On March 30, 2026, at approximately 2:00 p.m., the laboratory's office manager confirmed that the laboratory did not maintain additional procedure manuals containing all the necessary criteria relevant to laboratory operations. 5. The laboratory's testing declaration form, signed by the laboratory director on January 15, 2026, stated that the laboratory performed approximately 1,000 histopathology tests including dermatopathology annually.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of four (4) randomly selected patient test results for the Mohs procedure and interview with the laboratory staff on March 30, 2026, it was

	determined that the laboratory failed to have a reliable mechanism in place to confirm that the information received at the final destination matched the source report. These discrepancies highlight a lack of accuracy in the reporting of critical test parameters within the laboratory's documentation practices. The findings included: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery procedures. Upon completion of each Mohs procedure, the laboratory testing personnel manually documented the specifics of the test onto the designated Mohs map form. After this manual documentation, the laboratory staff transcribed and inputted the test data into the laboratory's electronic system 2. On the day of survey, the surveyor conducted a review of the lab patient test records pertaining to the Mohs Micrographic Surgery procedures. This review showed that 2 of 4 patients identified as patient with Mohs #24-080 and patient with Mohs#25-071 had electronic reports containing inconsistent and incorrect information regarding the Mohs defect size 3. On March 30, 2026, at approximately 1:45 p.m., laboratory personnel affirmed that incorrect data was entered into the laboratory's electronic system. 4. The laboratory's testing declaration form, signed by the laboratory director on January 15, 2026, stated that the laboratory performed approximately 1,000 histopathology tests including dermatopathology annually.
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 reapportions 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 the interview conducted with laboratory staff and a thorough review of records for competency assessments, proficiency testing, specimen referral, manual data entry and the laboratory's policy and procedure manuals, it was determined that the Laboratory Director (LD) failed to provide comprehensive management and direction as required under 493.1445 of this subpart. The findings included: 1.The laboratory director failed to ensure that personnel competency assessments were completed before employees began testing. See D5209 2. The laboratory director failed to ensure that the laboratory participated in the proficiency testing event at least twice annually for each year. See 5217 3. The laboratory director failed to ensure that the reference laboratory for specimen grossing maintains a current CLIA certificate. See 5315 4. The laboratory director failed to ensure that the laboratory maintains a comprehensive written procedure manual and evidence of compliance including all necessary criteria relevant to the laboratory operations. See 5403 5. The laboratory director failed to ensure that the laboratory had a reliable mechanism in place to confirm that the information received at the destination matched the source report. See 5801