Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2129227	03/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	123 W Michigan St, Ottawa, IL	

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
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, patient test reports, and interview with the laboratory representative, the laboratory failed to accurately correlate pertinent information regarding patient specimen identification regarding the specimen source for two of six patients reviewed and the number of Mohs histopathology surgical stages for one of six patients reviewed between the specimen tracking log and the final patient test report. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Mohs Surgery and Specimen Processing Procedure", which stated, under "Specimen tracking log", "3. The histotechnician completes the specimen tracking log with all pertinent information ...." 2. Review of laboratory records and patient test reports revealed inconsistencies between the specimen tracking log and final patient test report. Date: Accession #: Specimen Log: Final Report: 10/25/2023 OTY23-0259 Right Temple Left Cheek 07/10/2024 OTT24-0133 Left Forearm Right Forearm 07/10/2024 OTT24-0133 2 Mohs Stages 1 Mohs Stage 3. Interview with the laboratory representative on 03/24/2025, at 12:27 pm, confirmed the laboratory failed to accurately correlate pertinent information regarding patient specimen identification between the specimen tracking log and the final patient test report.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems by ensuring microscope maintenance was documented for three of six days of patient testing reviewed, daily maintenance was documented for one of six days of patient testing reviewed, room temperature was recorded for two of six days of patient testing reviewed, and the Cryostat temperature was recorded for one of six days of patient testing reviewed in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Policy on Quality Assurance-Quarterly Checklist", which stated, under "Principle", "In the Mohs laboratory, quality assurance involves the entire testing process: pre-analytical, analytical (testing), and post-analytical processes. This policy is designed to monitor and evaluate the ongoing and overall quality of the total testing process." 2. Review of laboratory records revealed a lack of documentation on the following dates of patient testing: i) 10/25/2023 No microscope maintenance documentation. ii) 03/27/2024 No microscope maintenance documentation. No Cryostat temperature documentation. No room temperature documentation. iii) 07/10/2024 No room temperature documentation. iv) 12/11/2024 No microscope maintenance documentation. No daily maintenance documentation. 3. Interview with the laboratory representative on 03/24 /2025, at 12:27 pm, confirmed the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the technical supervisor (TS) failed to evaluate the competency of one of two testing personnel (TP) performing Mohs dermatopathology interpretations in the subspecialty of histopathology. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) form revealed two testing personnel (TP) performing Mohs dermatopathology interpretations (TP #1 and TP #2). 2. Review of laboratory policies and procedures revealed the policy titled, "Personnel Assessment", which stated, "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for Moderate or High

	Complexity testing." 3. Review of laboratory records revealed TP #2 performed Mohs dermatopathology interpretations and reported patients results on 10/25/2023 and 11 /01/2023. 4. Review of laboratory records revealed a lack of documentation of competency assessments for TP #2. 5. Interview with the laboratory representative on 03/24/2025, at 10:17 am, confirmed no competency assessment was performed on TP #2 performing Mohs dermatopathology interpretations in the subspecialty of histopathology.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory personnel records, and interview with the laboratory representative, the laboratory failed to ensure one of two histotechnologists were qualified for high complexity testing. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1),

	(2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory personnel records, and interview with the laboratory representative, the laboratory failed to ensure one of two histotechnologists were qualified for high complexity testing. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed two testing personnel (TP) performing high complexity specimen grossing testing in the subspecialty of histopathology (TP #3 and TP #4). 2. Review of personnel educational documentation revealed one of two histotechnologists (TP #4) failed to have qualifying documentation for high complexity histopathology specimen grossing testing. 3. Interview with the laboratory representative on 03/24/2025, at 10: 35 am, confirmed one of two histotechnologists failed to meet education requirements to qualify as a high complexity TP.