Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2031710	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	1985 Emancipation Highway, Fredericksburg, VA	

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
D0000	An announced CLIA recertification survey was conducted at Pinnacle Dermatology on November 13, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes the Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6076 -42 CFR. 493.1411 Laboratory Director, D6168 -42 CFR. 493.1487 Testing Personnel qualifications. .
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: A. Based on a review of the laboratory's policies and procedures, proficiency testing (PT) logs, lack of documentation, and interviews, the laboratory failed to follow their established policy and perform Mohs micrographic surgery and frozen section biopsy accuracy checks twice annually in calendar year 2024. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Assurance-Proficiency Testing" with the statements, "A. Proficiency Testing 1. Mohs Micrographic Surgery-In compliance with section 493.1709, each Mohs surgeon will have 6 slides from each year (3 from Jan-June and 3 from July-Dec) in which Mohs surgery is performed pulled at random...A reviewing Mohs surgeon will verify the diagnosis and sign off on the paperwork for proficiency testing ...2. Frozen Section Biopsy-Each Mohs surgeon will have 4 slides from each year (2 from Jan-June and 2 from July-Dec) in which Frozen Section Biopsies are performed pulled at random. The reviewing Mohs surgeon will verify the diagnosis and sign off on the paperwork. " 2. Review of the laboratory's PT records for calendar year 2024 revealed 3 Mohs cases and 2 frozen biopsy cases were reviewed from January 2024 until June 2024.

	The surveyor requested to review additional peer review cases reviewed in calendar year 2024. The laboratory provided no additional records to review. 3. In an exit interview with the Mohs Histotech on November 13, 2025 at 12:45 PM, the above findings were confirmed. B. Based on a review of the laboratory's policies and procedures, proficiency testing (PT) logs, lack of documentation, and interviews, the laboratory failed to follow their established policy and perform Potassium Hydroxide (KOH) accuracy checks twice annually in calendar year 2024. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Quality Assurance-Proficiency Testing" with the statements, "3. KOH Prep...Our policy is to have 2 cases of KOH prep ...per provider double checked by another physician within the practice per year." 2. Review of the laboratory's PT records for calendar year 2024 revealed a lack of documentation of KOH peer review for calendar year 2024. The surveyor requested to review KOH peer review cases reviewed in calendar year 2024. The laboratory provided no KOH peer records to review. 3. In an exit interview with the Mohs Histotech on November 13, 2025 at 12:45 PM, the above findings were confirmed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour, review of the laboratory's method validation documents, quality control records, Mohs logs, lack of documentation and interviews, the laboratory failed to: 1. validate the performance specifications of the BioSB MART-1/Melan A, A-103 Immuno-histochemical (IHC) stain method from September 5, 2025 until the date of the survey on November 13, 2025 (see D5423). 2. document daily Hematoxylin and Eosin (H&E) stain acceptability for three (3) days from February 2024 until the date of the survey on November 13, 2025 (see D5601).
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's survey Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116), laboratory's validation documentation, Mohs logs, Food and Drug Administration's (FDA) CLIA test categorization website, lack of documentation and interviews, the laboratory failed to validate the performance characteristics for their laboratory developed test (LDT) Immuno-histochemical (IHC) staining method utilizing the Bio SB MART-1/Melan A, A103 antibody with the BioGenex Super Sensitive Multi-link Detection System. The findings include: 1. Pre-survey review of the laboratory's survey CMS-116 Non-waived testing revealed the laboratory performed the high complexity MART-1 /Melan A Immuno-histochemical staining method.. 2. In an entrance interview with the Mohs Technician on November 13, 2025 at 9:00 AM, the surveyor inquired with the Mohs Histotech when the laboratory began performing IHC staining. They stated the laboratory began performing IHC staining utilizing the Bio SB MART-1 antibody and BioGenex detection system on September 5, 2025. 3. Review of the FDA's test categorization database review no listing or categorization for BioSB MART-1 IHC staining utilizing the BioGenex Super Sensitive Multi-link Detection System. 4. The surveyor requested to review the validation of the performance specifications for the BioSB MART-1 IHC staining method. The laboratory provided a document titled "Validation of Procedure for Mart-1/Melan-A Antibody" listing the "Antibody-Mart 1 /Melan A, A103; Manufacturer-Bio-SB; Species Mouse Monoclonal;Clone-A103." Further review of the document revealed column headers of "Date, Tumor Type & Mohs Case #, Antibody lot #, Detection Reagents Used & Lot #, Histotech Initials, Results & Comments, MD initials." The "Validation of Procedure for Mart-1/Melan-A Antibody" log was completed with eight (8) Mohs cases stained/resulted on 09/02 /2025 and one (1) Mohs cases stained/resulted on 09/05/2025. 5. During a discussion with the Mohs Histotech on November 13, 2025 at 9:30 AM, the Mohs technician stated they performed IHC staining of five known MART-1 negative cases and four known MART-1 positive cases with the new method. The surveyor requested to review documentation of the IHC method's precision/reproducibility, analytical sensitivity, and analytical specificity including interfering substances. The laboratory provided no further documentation for review. 6. Review of the laboratory's patient records revealed eighteen patient specimens were stained and resulted utilizing the MART-1 IHC staining method from September 5, 2025 until November 13, 2025. 7. In an exit interview with the Mohs Histotech on November 13, 2025 at 12:45 PM, the above findings were confirmed.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality control (QC) records, patient logs, and interview, the laboratory failed to document daily Hematoxylin and Eosin (H&E) stain acceptability for three (3) days with seventy-six (76) Mohs slides stained/processed/evaluated during the twenty-one (21) months reviewed from February 2024 until the date of the survey on November 13, 2025. The findings include: 1. Review of the laboratory's "Policy on Quality Control Slides",

	revealed the following statements, "A control slide will be made every day and label (sic) with the accession number, date and QC....The reviewing physician, examining patient tissue that day, will initial each Mohs day that QC has been made and whether the staining is appropriate." 2. Review of the QC records from February 2024 until November 13, 2025 revealed a lack of H&E control slide documentation for the following 3 dates: 06/17/2024, 06/18/2024 and 09/30/2025. 3. Review of the laboratory's Mohs patient logs revealed the following number of patient Mohs slides stained/ processed/evaluated on the 3 days lacking QC slide documentation: 06/17 /2024 - 24 patient slides, 06/18/2024 - 24 patient slides, 09/30/2025 - 28 patient slides, A total of 76 patients slides. 4. In an exit interview with the Mohs Histotech on November 13, 2025 at 12:45 PM, the above findings were confirmed.
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 the laboratory's pre-survey documents, policies and procedures, validation records, Mohs logs, Quality Control records, lack of documentation, and interviews, the laboratory director failed to ensure: 1. the validation of the performance characteristics for the MART-1/Melan A, A103 Immunohistochemical staining method prior to the testing of patients (see D6086). 2. the documentation of the stain acceptability each day of use for the Hematoxylin and Eosin (H&E) stain for three (3) days from February 2024 until the date of the survey on November 13, 2025 (see D6093).
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 a review of the laboratory's policies and procedures, method validation documents, Food and Drug Administration's (FDA's) CLIA test categorization website, Mohs logs, lack of documentation, and interviews, the laboratory director failed to ensure the performance specifications for the high complexity MART-1 Immunohistochemical stain utilizing the BioGenex Detection System were adequate and evaluated prior to processing/staining eighteen patients from September 5, 2025 until the date of the survey on November 13, 2025 (see D5423).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 review of the laboratory's quality control (QC) records, Mohs logs, lack of documentation, and interviews, the laboratory director failed to ensure the documentation of the stain acceptability each day of use for the Hematoxylin and Eosin (H&E) stain for three (3) days from February 2024 until the date of the survey on November 13, 2025 (see D5601).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's personnel files, policies and procedures, lack of documentation, and an interview, the Technical Supervisor (TS) failed to follow the established laboratory policy to perform a six-month competency evaluation for one (1) of two (2) personnel in calendar year 2024. The findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified themselves as the Technical Supervisor (TS). 2. Review of the laboratory's policies and procedures revealed a policy for competency evaluations of Mohs Histotechs /testing personnel (TP) "should occur every six months for the first year, and annually thereafter for all testing personnel." 3. Review of the laboratory's personnel files revealed two (2) individuals performing Mohs Histotech/TP duties (see personnel code sheet). Personnel A's file revealed an initial training in March 2024 and an annual competency evaluation in January 2025. The surveyor requested to review a six-month competency dated in September 2024. The laboratory provided no documentation for review. 4. In an exit interview with the Mohs Histotech on November 13, 2025 at 12:45 PM, the above findings were confirmed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's personnel files, policies and procedures, lack of documentation, and interview, the technical supervisor (TS) failed to follow their established policy to perform annual competency assessment evaluations for one (1) of two (2) testing personnel responsible performing high complexity Histopathology testing in calendar year 2024. The findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified themselves as Technical Supervisor (TS). 2. Review of the laboratory's policies and procedures revealed a policy for competency evaluations of Mohs Histotech/testing

	personnel (TP) "should occur every six months for the first year, and annually thereafter for all testing personnel." 3. Review of the laboratory's personnel files revealed two (2) individuals performing Mohs histotech/TP duties (see personnel code sheet). Personnel B's file revealed an initial training in July 2024, and an semi-annual competency evaluation in January 2025. The surveyor requested to review an annual competency dated in July 2025. The laboratory provided no documentation for review. 4. In an exit interview with the Mohs Histotech on November 13, 2025 at 12: 45 PM, the above findings were confirmed.
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 a review of the CLIA Laboratory Personnel Report Form (CMS-209), available testing personnel (TP) files, lack of documentation, and interview, the laboratory failed to retain education records to document the qualifications of one of two histopathology TP during the twenty-one months reviewed from February 2024 until November 13, 2025 (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 a review of the CLIA Laboratory Personnel Report Form (CMS-209), available testing personnel (TP) files, lack of documentation, and interview, the laboratory failed to ensure the education record met requirements for one (1) of two (2) Histopathology TP identified as qualified to perform high complexity testing procedures during the twenty-one months reviewed from February 2024 until the date of the survey on November 13, 2025. The findings include: 1. Review of the laboratory's CMS 209 form revealed that the laboratory director identified 2 Histopathology TP responsible for high complexity Mohs pathology patient tissue processing/grossing/IHC staining from February 2024 until November 13, 2025. 2. Review of the available Mohs Laboratory Histotech personnel records for TP B (see personnel code sheet) revealed a copy of an American Society of Clinical Pathologists (ASCP) certification card. The surveyor requested to review diploma(s), official transcript(s) or education records for TP B. The laboratory provided no further documentation for review. 3. In an exit interview with the Mohs Histotech on November 13, 2025 at 12:45 PM, the above findings were confirmed.