Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2140742	09/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	10720 W 165th St, Orland Park, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) (a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with testing personnel (TP) # 4; the laboratory failed to retain all documented histopathology slides for one of seven patients reviewed for ten years from the date of the Mohs micrographic surgery histopathologic examination. Findings include: 1. Review of the patient log for Mohs micrographic surgery histopathologic examination indicated a total number of three slides were created for the following patient: Date: Accession #: # of slides: 03/11/2024 OP24-0185 3 2. Upon review of patient testing on 09/22/2025, at 2:35 pm, surveyors observed the above mentioned patient only had one of three histopathology slides retained. 3. Interview with TP #3 on 09/22/2025, at 3:31 pm, confirmed the laboratory failed to retain all documented histopathology slides for one of seven patients reviewed for ten years from the date of the Mohs surgical histopathology examination.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.

	1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observation, review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, laboratory records, manufacturer operating instructions, lack of documentation, and interview with testing personnel #4; the laboratory failed to retain all documented histopathology slides for one of seven patients reviewed for ten years from the date of the Mohs micrographic surgery histopathologic examination (see D3043), failed to follow the written policy for bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for Mohs micrographic histopathology testing for five of five events and failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for 24 of 24 months (see D5291), failed to follow its policy and procedure for slide labeling for seven of seven Mohs micrographic surgery patients reviewed (see D5311), failed to document the discontinuance of seven of seven procedures not utilized at upon the date of survey (see D5409), and 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 laboratory preventative maintenance logs were documented and temperature and humidity was recorded for two of seven patient testing dates reviewed (see D5791) in the subspecialty of histopathology from 2023 through the date of survey, 09/22/2025.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: A) Repeat standard level deficiency from 08/24/2023 recertification survey. Based on review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #4; the laboratory failed to follow the written policy for bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for Mohs micrographic histopathology testing for five of five events from 2023 through the date of survey, 09/22/2025. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed three TP (TP #1, #2, and #3) performing Mohs micrographic histopathology testing. 2. Review of laboratory policies and procedures revealed the policy titled "Quality Assurance-Proficiency Testing", which stated, under "Procedure": "A. Proficiency Testing "1. Mohs Micrographic Surgery "a .... In compliance with section 493.1709, each Mohs surgeon will have 6 slides from each year (3 from Jan[uary]-June and 3 from July-Dec[ember]) in which Mohs surgery is performed pulled at random. These slides will be checked for accuracy ...." 3. Review of bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for Mohs micrographic histopathology testing revealed the following: i. July-December 2023 TP: # of cases reviewed: #1 0 #2 3 #3 3 ii. January-June 2024 TP: # of cases reviewed: #1 0 #2 6 #3 0 iii. July-December 2024 TP: # of cases reviewed: #1 4 #2 0 #3 1 iv. January-June 2025 TP: # of cases reviewed: #1 3 #2 0 #3 3 4. Interview with TP #4 on 09/22/2025, at 3:41 pm,

	confirmed the laboratory failed to follow the written policy for bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) for Mohs micrographic histopathology testing for five of five events from 2023 through the date of survey, 09/22/2025. B) Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #4; the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for 24 of 24 months in the subspecialty of histopathology from 2023 through the date of survey, 09/22/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Quality Assurance", which stated, "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist .... The lab director will also review and sign off the checklist monthly." 2. Review of laboratory records revealed the document titled "Job Description - Laboratory Director", which stated, "(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratories services provided and to identify failures in quality as they occur." 3. Review of laboratory records revealed a lack of documentation of monthly quality assurance checks performed in the laboratory for the previous 24 months reviewed. 4. Interview with TP #4 on 09/22/2025, at 3:01 pm, confirmed the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for 24 of 24 months in the subspecialty of histopathology from 2023 through the date of survey, 09/22/2025.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Repeat standard level deficiency from 08/24/2023 recertification survey. Based on review of the laboratory's Allegation of Compliance (AoC) response regarding citations from the 08/24/2023 recertification survey, direct observation, and interview with testing personnel (TP) #4; the laboratory failed to follow its policy and procedure for slide labeling in the subspecialty of histopathology for seven of seven Mohs micrographic surgery patients reviewed from 2023 through the date of survey, 09/22 /2025. Findings include: 1. Review of the laboratory's AoC response regarding citations from the 08/24/2023 recertification survey revealed the procedure titled "Mohs Slide Labeling", which stated, under "Current Policy", "All offices has been updated to the 'M' for mohs, the Year, dash and then the accession with four number sequence...Example 'M23-0001'". 2. Direct observation of Mohs micrographic surgical slides upon patient review on 09/22/2025, at 2:35 pm, revealed the following label on the seven patient slides reviewed: Date: Slide Label: 10/02/2023 OP23-0782 12/19/2023 OP23-1092 01/26/2024 OP24-0057 03/11/2024 OP24-0185 01/14/2025 OP25-0054 04/11/2025 OP25-0357 07/18/2025 OP25-0769 3. Interview with TP #4 on 09/22/2025, at 3:02 pm, confirmed the laboratory's policy and procedure for slide labeling was out of date and the most current procedure for slide labeling was not being followed up to the date of survey, 09/22/2025.

D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Repeat standard level deficiency from 08/24/2023 recertification survey. Based on review of laboratory policies and procedures, lack of documentation, and interview with testing personnel (TP) #4; the laboratory failed to document the discontinuance of seven of seven procedures not utilized at upon the date of survey, 09/22/2025. Findings include: 1. Review of laboratory policy and procedures manual revealed the following procedures of which the laboratory director (LD) failed to indicate the date of last use: i. "Ectoparasites [Scabies]" ii. "KOH [Potassium hydroxide]/Scabies Annual Competency Assessment" iii. "KOH/Scabies Initial Training Checklist" iv. "Mohs Slide Labeling" - dated 01/10/2020. v. "Slide Labeling" vi. "Frozen Section Procedure" vii. "Urine Pregnancy test" 2. Interview with TP #4, on 09/22/2025, at 3: 02 pm, confirmed the laboratory does not perform the above mentioned/outdated procedures found in the laboratory's policy and procedure manual but the LD failed to document when the procedures were discontinued.
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, manufacturer operating instructions, laboratory records, lack of documentation, and interview with testing personnel (TP) #4; 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 laboratory preventative maintenance logs were documented and temperature and humidity was recorded for two of seven patient testing dates reviewed in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the following procedures" i. "Daily Laboratory Maintenance", which stated the following: "8. Temperature charts, chemical, and other logs are checked daily or whenever in use. "9. Follow procedure for microscope care and document. "10. Follow procedure for eyewash and document. "11. Document that daily maintenance has been completed by initialing daily maintenance logs." ii. "Daily Routine", which stated the following: "1. Check and log temperature on cryostat.", "4. Check and log al[l] paperwork in log workbook.", "11. At the end of the day, clean cryostat according to maintenance log, and document.", "12. Wipe down counters and clean lab according to daily log and document." 2. Review of manufacturer operating instructions for the Leica CM Cryostat (Serial Number: 1156) revealed, under "Environmental specification", "Operating temperature 18[degrees Celsius] to 35[degrees Celsius]" and "Relative humidity [RH] (operation) 20 to 60 % RH non-condensing". 3. Review of laboratory records revealed the following preventative maintenance and temperature/humidity monitoring logs: i. "Cryostat Temperature Log and Maintenance Instructions" ii. "Microscope

	Maintenance" iii. "Eye Wash Station" iv. "Daily Routine Maintenance" v. "Room Temp[erature] & Humidity" 4. Review of above mentioned preventative maintenance and temperature/humidity monitoring logs revealed a lack of documentation on the following dates of patient testing: i. 10/02/2023 ii. 03/11/2024 5. Interview with TP #4 on 09/22/2025, at 3:38 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 by ensuring laboratory preventative maintenance logs were documented and temperature and humidity was recorded for two of seven patient testing dates reviewed in the subspecialty of histopathology.
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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #4; the laboratory director failed to follow the written policy for bi-annual method accuracy (proficiency testing /peer reviewed histopathology interpretations) for Mohs micrographic histopathology testing for five of five events reviewed (see D5219a) and failed to ensure the quality assurance program was maintained to assure the quality of laboratory services for 24 of 24 months in the subspecialty of histopathology from 2023 through the date of survey, 09/22/2025 (see D5291b).