Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0963550	(X3) Date Survey Completed 09/01/2022
Name of Provider or Supplier Pinnacle Dermatology, Sc	**Street Address, City, State** 13640 N 99th Ave Ste 300, Sun City, AZ	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on lack of written policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures for specimen/slide labeling. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology, with an approximate annual test volume of 918. The laboratory reads and interprets slides in conjunction with Mohs testing and frozen biopsy testing. 2. No documentation was presented for review during the survey to indicate the laboratory had established policies in place for slide labeling with regard to Mohs testing. 3. No documentation was presented for review during the survey to indicate the laboratory had established policies in place for slide labeling with regard to Frozen Biopsy testing. 4. The facility personnel confirmed that the laboratory did not have the above referenced policies and procedures in place at the time of the survey conducted on September 1, 2022.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to establish policies and procedures for signing off on pathology test reports in a timely manner. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the sub-specialty of histopathology, with an approximate annual test volume of 918. The laboratory utilizes an electronic medical record (EMR) system to maintain patient records, including Mohs test reports which are electronically signed by the physician who made the diagnosis. 2. Review of Mohs test report for case# 22-041 indicated the date of service as 1-17-2022, and the test report was electronically signed by the physician who made the diagnosis on 2-13-2022. 3. No documentation was presented for review during the survey to indicate the laboratory established a policy to indicate the acceptable amount of time the physician has to electronically sign the final Mohs test report. 4. On 9-01-2022 at approximately 11:00am, the facility personnel interviewed confirmed that the Mohs test report indicated above was not signed in a timely manner by the physician who made the diagnosis, and confirmed that the laboratory failed to establish a policy to indicate the acceptable timeframe for electronically signing off on Mohs test reports.