Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2120577	04/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology, Sc	2394 N Alma School Rd, Chandler, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual for Mohs and interview with the facility personnel, the laboratory director failed to approve, sign and date the Mohs test procedure before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been listed as laboratory director since 12/02/2022. 2. The Mohs policy and procedure manual presented for review during the survey conducted on 04/30/2024 was not approved, signed and dated by the current laboratory director. 3. The facility personnel interviewed on 4/30.2024 at 10:30 AM confirmed the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director. 4. The laboratory performs patient testing in conjunction with the Mohs procedure under the subspecialty of Histopathology with a reported annual test volume of 244.
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 Quality Assessment (QA) documentation, review of post-analytic QA policies, review of electronic test records, and interview with the facility personnel, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory performs patient testing in conjunction with the Mohs procedure under the subspecialty of Histopathology with a reported annual test volume of 244. 2. The laboratory performs a chart audit on a monthly basis and documents identified errors and corrections made on a "Lab Error and Corrections" log. 3. During the survey, review of the above log from February 2024 and the corresponding surgical notes in the EHR, revealed the laboratory failed to document the corrections noted from the log onto the patients' surgical note. (Accessions: C22-027, C24-035, C24-036, C24-045, C24-048). 4. Review of the established QA policies shows the laboratory failed to establish a policy and procedure for correcting patient reports including: documenting the correction, issuing the corrected report, and promptly notifying the authorized individual ordering the test of the correction. 5. The facility personnel interviewed on 4/30/2024 at 10:45 AM confirmed that the laboratory failed to establish QA policies and procedures, to monitor, assess and correct problems identified with the postanalytic systems.