Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2116100	10/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Beaird Dermatology S C	4885 Hoffman Blvd Ste 407, Hoffman Estates, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals; patient test records; quality control records; and interview with the technical supervisor, the procedures manuals did not include control procedures for its Periodic acid-Schiff and Alcian Blue staining process. Findings include: 1. Review of the laboratory's procedures manuals revealed that there were 2 different sets of procedures. There was one procedure for frozen tissue sections (Mohs) and another procedure for permanent tissue sections (Biopsies). Procedures show that the laboratory started performing staining on biopsy specimens in September 2020. 2. There were no written procedures that described the

	laboratory process for determining the quality of its Periodic acid- Schiff and Alcian Blue staining procedures used for permanent tissue specimens. 3. At 12:30 PM on October 13, 2020, the surveyor requested 1 patient's test record where a Periodic acid-Schiff stain was performed and 1 patient where Alcian Blue staining was performed. 4. Review of corresponding quality control (QC) records revealed the following: a. manufacture control slide from StatLab was used as QC material for QC of the Periodic acid -Schiff stain b. There was a QC slide labeled patient QC used as the QC material for the QC of Alcian Blue staining. There was no documentation to show what patient specimen was used as the QC material. 5. At 1:00 PM on October 13, 2020, the technical supervisor confirmed the surveyor's findings.