Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2116100	09/24/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals, Laboratory Personnel Report (Form CMS 209), personnel records, and interview with the practice manager; the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency as specified in the personnel requirements is subpart M. Findings include: 1. Review of the laboratory's policies and procedures manuals revealed that the laboratory had 4 separate procedures manuals that included Potassium Hydroxide (KOH) ; a MOHS procedure from "Got MOHS"; the laboratory's own written procedures manual; and the Clinical Laboratory Improvement Amendments for Dermatology from the American Academy of Dermatology (AAD). The AAD's procedure even included a section that listed each positions responsibilities and duties, as well as for documenting the training and competency of laboratory personnel, which were not completed by the laboratory. 2. Review of Form CMS 209 revealed that the names of personnel were listed for the following positions in the laboratory: a. Laboratory Director b. Clinical Consultant (X2; with one of them being the laboratory director). c. Technical Supervisor d. General Supervisor e. Testing Personnel 3. Review of 9 personnel records revealed that there was no documentation to show that personnel listed on Form CMS 209 were assigned to their specific positions in the laboratory, nor what their duties or responsibilities were for 9 of 9 records reviewed. Also, there was no documentation to show training of personnel and their competency assessed for 9 of 9 personnel records reviewed. 4. At 10:00 AM on 09/24/18, the practice manager confirmed the surveyor's findings.

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 observation, review, and interview; the laboratory failed to have a comprehensive procedure manual that included instruction for performing preanlaytic, analytic, and postanalytic processes in the laboratory. Findings include: 1. At 10:00 AM on 09/24/18 the surveyor did a "walk-through" of the laboratory. The surveyor observed that the laboratory used the following equipment: a. Microscopes (X2) b. Potassium Hydroxide (KOH) Solution c. Computer System 2. Review of the laboratory's procedures manuals revealed that the laboratory had 4 sepatate procedures manuals that they used. The procedures included one for KOH; another for MOHS; the laboratory's written procedures manaul; and the last was the Clinical Laboratory Improvement Amendments for Dermatology form the American Academy of Dermatology (portions of the procedures that were supposed to be filled in by the laboratory director were left blank). None of the procedures included the following: a. 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. b. Microscopic examination, including the detection of inadequately prepared slides. c. Control procedures. d. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. e. Limitations in the test methodology, including interfering substances. f. 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. g. Description of the course of action to take if a test system becomes inoperable. 3. At 11:30 AM on 09/24/18, the practice manager confirmed the surveyor's findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which

	examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals, Laboratory Personnel Report (Form CMS 209), personnel records, and interview with the practice manager; the laboratory director failed to specify in writing the responsibilities and duties of each consultant, supervisor, and testing person engaged in the performance of all phases of testing; and whether supervision is required for specimen processing, test performance or result reporting. Findings include: 1. Review of the laboratory's policies and procedures manuals revealed that the laboratory had 4 separate procedures manuals which included Potassium Hydroxide (KOH); a MOHS procedure from "Got MOHS"; the laboratory's own written procedures manual; and the Clinical Laboratory Improvement Amendments for Dermatology from the American Academy of Dermatology (AAD). The AAD's procedure even included a section that listed each positions responsibilities and duties along with a form for assigning the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor d. General Supervisor c. Testing Personnel The surveyor noted that the laboratory director had not completed the forms for assignment of positions and duties. 2. Review of Form CMS 209 revealed that there were a total of 9 personnel listed as laboratory personnel which included the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor d. General Supervisor c. Testing Personnel 3. Review of 9 personnel records for persons listed on Form CMS 209, revealed that there was no documentation to show that the laboratory director assigned in writing personnel to their positions, responsibilities and duties in the laboratory for 9 of 9 personnel records reviewed. 4. At 10:30 AM on 09/24/19, the practice manager confirmed the surveyor's findings.