Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0683529	05/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bielinski Dermatology Group, L L C/Skin Md	3900 W 95th St, Ste 12, Evergreen 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
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: Based on review of laboratory policies and procedures, laboratory records, CMS-209 (Laboratory Personnel Report), and interview with testing personnel (TP) #4; the laboratory failed to follow written policies and procedures regarding performance of bi-annual method accuracy evaluations for Provider-Performed Microscopy (PPM) testing at the laboratory facility for three of four TP in the years of 2023 through the date of survey, 05/23/2025, affecting 69 patients. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed four TP performing PPM testing of Potassium hydroxide (KOH) and scabies (TP #1, 2, 3, and 7) at the laboratory testing facility. 2. Review of laboratory policies and procedures revealed the procedure titled, "Potassium Hydroxide (KOH)", which stated, under "Quality Control Procedures:", "Semi-Annually - a visual test will be given to each provider." 3. Review of laboratory policies and procedures revealed the procedure titled, "Ectoparasites", which stated, under "Quality Control Procedures:", "A visual identification test will be given to each provider semi-annually." 4. Review of laboratory competency evaluation records revealed that three of four TP performing PPM testing (TP #1, 3, and 7) lacked documentation of bi-annual method accuracy evaluations performed at the testing laboratory. 5. Review of laboratory records revealed 69 KOH patients had been testing from 2023 through the date of survey, 05/23/2025. 6. Interview with TP #4 on 05/23/2025, at 10:22 am, confirmed the laboratory failed to follow written

	policies and procedures regarding performance of bi-annual method accuracy evaluations for PPM testing at the laboratory facility for three of four TP in the years of 2023 through the date of survey, 05/23/2025.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, patient test reports, and interview with testing personnel (TP) #4; the laboratory failed to accurately correlate pertinent information of patient specimen identification regarding the Mohs histopathology surgical specimen source for one of four patients reviewed between the specimen tracking log, the surgical map, and the final patient test report. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Policy on Quality Assurance and Procedure - Mohs Surgery", which stated, under "Procedure", "ii. The specimen is given an accession number and logged into the Mohs logbook with patient name, date, site, diagnosis, stage or layer, and number of quadrants per stage." 2. Review of laboratory records revealed the Mohs logbook, which stated, for patient EP25-126 (tested on 05/21/2025), under Specimen Source, "right inferior forehead". 3. Review of laboratory records revealed Mohs histopathology surgical map document for patient EP25-126, which indicated the location of Mohs surgical testing site as "left central temple". 4. Review of the patient test report for patient EP25-126, from 05/21/2025, revealed, under "Impression/Plan: .... located on the left central temple." 5. Interview with TP #4 on 05/23/2025, at 11:51 am, confirmed the laboratory failed to have a reliable system in place to ensure test results, including Mohs histopathology surgical specimen source, for one of four patients reviewed between the specimen tracking log, the surgical map, and the final patient test report.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, CMS-209 (Laboratory Personnel Report), and interview with testing personnel (TP) #4; the technical supervisor (TS) failed to ensure competency evaluations for three of four TP performing Provider-Performed Microscopy (PPM) testing and one of one TP performing histopathology tissue grossing were performed at the laboratory testing

	facility in the years of 2023 through the date of survey, 05/23/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Policy for Personnell Competency", which stated, under "Principle", "Personnel must not report test results for patient specimens until training is complete and competency is verified for each test procedure they perform." 2. Review of the CMS-209 (Laboratory Personnel Report) revealed four TP performing PPM testing of Potassium hydroxide (KOH) and scabies (TP #1, 2, 3, and 7) and one TP performing histopathology tissue grossing (TP #4). 3. Review of laboratory competency evaluation records revealed that three of four TP performing PPM testing (TP #1, 3, and 7) lacked documentation of competency evaluations performed at the testing laboratory. 4. Review of laboratory competency evaluation records revealed that one of one TP performing histopathology tissue grossing (TP #4) lacked documentation of competency evaluations performed at the testing laboratory. 5. Interviews with TP #4 on 05/23 /2025, at 09:31 am and 10:22 am, confirmed the TS failed to ensure competency evaluations for three of four TP performing PPM testing and one of one TP performing histopathology tissue grossing were performed at the laboratory testing facility in the years of 2023 through the date of survey, 05/23/2025.