Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0683529	09/27/2018
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's manual, records and an interview with the laboratory staff, the laboratory failed to retain analytic systems records for the Mycology testing conducted on patients during the years of 2016 and 2017. Findings: 1. On 09/27/2018 at 9:45 AM, the surveyor requested the quality control records and patients' test logs for the fungal culture and Potassium Hydroxide (KOH) testing performed in the laboratory for the period of October 1, 2016 through 09/27/2018 (date of survey). In response, the laboratory staff stated that the new owner and laboratory director (LD) took over the practice on 12/15/2017 and that they could not find any test or quality control records from the previous owner/LD prior to that time. 2. The following documents were not available for review at the time of survey for patient testing performed prior to 12/15/2017: Patients' test logs for KOH and fungal cultures; Media check records for fungal media used in testing; Quality control records for fungal and KOH testing; The twice annual accuracy verification of the the Fungal testing and KOH procedure; and Environmental/maintenance records, (incubators, refrigerator, microscope, etc.) 3. On a Recertification survey conducted on 09/27/2018 at 11:30 AM, the laboratory staff confirmed the above findings.
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 the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's manual, records, and an interview with the laboratory staff; the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Potassium Hydroxide (KOH) preparations (Preps) and fungal testing, affecting 4 out of 4 testing personnel (TP). Findings: 1. The CMS 209 lists 2 licensed practitioners and 2 licensed physicians performing fungal cultures using dermatophyte test media (DTM) and KOH Preps (a moderately complex test) in the laboratory. 2. The personnel documents revealed that 4 out of 4 TP had not received competencies or training since the new laboratory director (LD)/owner and new laboratory personnel began in December 15, 2017 thru the date of survey 09/27/2018, but were authorized to perform patient testing during this period. 3. The laboratory's manual does not include an established competency policy and step-by-step procedures for assessing TP performing fungal and KOH testing. 4. On a Recertification survey conducted on 09 /27/2018 at 11:30 AM, the laboratory staff confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's manuals, test records, and an interview with the laboratory staff; the laboratory failed to verify the accuracy of tests performed in the specialty of Microbiology at least twice annually. Findings: 1. The manual and test records reveal that the laboratory performs the following tests: Dermatophyte test media (DTM) fungal test, the Potassium Hydroxide (KOH) preparations (Preps), Swartz-Lamkins and Chlorazol Black E Preps. 2. The laboratory's manual does not define the method and procedure the laboratory will use to verify the accuracy of its fungal test, KOH, Swartz-Lamkins, and Chlorazol Black E Preps testing. 3. The records reveal that fungal cultures and KOH preps were performed on patients during the period of 12/15/2017 to 09/20/2018 by laboratory personnel. 4. On a Recertification survey conducted on 09/27/2018 at 11:30 AM, the laboratory staff confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's manual, final report, the Clinical Laboratory Improvement Amendments (CLIA) application (CMS 116), and an interview with the laboratory staff; the laboratory failed to ensure test reports include all information as specified in 493.1291(c)(1)- (c)(6), affecting 50 patients. Findings: 1. The laboratory's manual does not include a step-by-step process to manually enter patients' fungal and Potassium Hydroxide (KOH) prep results into the patients' chart in the electronic medical records (EMR) system. 2. The "final report" printed from selected patients' EMR chart fail to include the "date of testing" for the test performed. 3. On the CMS 116, the LD documents that 50 patients were tested during the year of 2017 to 09/20/2018. 4. On a Recertification survey conducted on 09/27/2017 at 11:35 AM, the laboratory staff confirmed the above findings.