

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1013449	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier Skinmd - Bielinski Dermatology Group Llc	Street Address, City, State 1001 Health Park Drive - Ste 470, Brentwood, TN	
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
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, review, and interview; the laboratory failed to properly manage and evaluate the overall quality of the general laboratory systems and correct problems specified in 493.1239 for it Histopathology testing. Findings: 1. The laboratory failed to perform bi-annual evaluation of testing for histopathology. See D5217 2. The laboratory failed to have a comprehensive procedures manual that includes preanalytic, analytic, and post analytic instructions for histopathology testing. See D5403 3. The laboratory failed to have quality control procedures for its histopathology testing. See D5601</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual, proficiency testing (PT) records, patients' test records and interview; the laboratory failed to perform bi-annual</p>

method accuracy evaluations for histopathology testing for January 2017 through April 2018. Findings: 1. There were no procedures that described the laboratory's process for how it performs bi-annual verification of the accuracy of its histopathology procedures. 2. Review of PT records revealed that there is a form titled, "Proficiency Testing: Derma pathology." The following information is documented on the form: a. Patient ID #; b. Lab # ; c. Date; d. Physician Reading (Laboratory Director); Consultation; e. Score (+/-); and f. Date Completed. There was no documentation to show that bi- annual method verification procedures were performed in 2017 and at least once between January to April 2018. 3. Review of patient's test records identified 9 of 9 patients' test records from 2017 through April 2018 for histopathology testing but no corresponding method accuracy evaluations were documented for the following records reviewed: a. P1 Biopsy Date 02/03/2017 b. P2 Biopsy Date 06/21/2017 c. P3 Biopsy Date 07/05 2017 d. P4 Biopsy Date 09/01 /2017 e. P5 Biopsy Date 11/21/2017 f. P6 Biopsy Date 12/22/2017 g. P7 Biopsy Date 01/31/2018 h. P8 Biopsy Date 02/28/2018 i. P9 Biopsy Date 03/07/2018 4. During survey date 05/09/18, the laboratory director 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 procedure manual did not include the following: *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. *Microscopic examination, including the detection of inadequately prepared slides. *Control Procedures. *The laboratory's system for entering results in the patient record and reporting patient results. *Description of the course of action to take if a test system becomes inoperable. Findings: 1. There were no procedures that described requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection 2. There were no procedures that described microscopic examination, including the detection of inadequately prepared slides 3. There were no procedures that described Control Procedures. 4. There were no procedures that

described the laboratory's system for entering results in the patient record and reporting patient results. 5. There were no procedures that described the course of action to take if a test system becomes inoperable. Note: Histopathology procedures were removed with procedures that had been previously retired. The laboratory's current procedures consisted of quality assessment reviews. 6. During survey date 05/09/18, the laboratory director confirmed the surveyor's findings.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review and interview, the laboratory failed to document control procedures for histopathology staining. Findings: 1. Review of the laboratory's procedures manual revealed that there were no procedures that described the laboratory's process for quality control of stained slides. 2. Review of 9 patients' test records and specimen slides revealed that there was no documentation to show that the quality of staining procedures was performed for 9 of 9 patients tests reviewed for the following: a. P1 Biopsy Date 02/03/2017 b. P2 Biopsy Date 06/21/2017 c. P3 Biopsy Date 07/05 2017 d. P4 Biopsy Date 09/01/2017 e. P5 Biopsy Date 11/21/2017 f. P6 Biopsy Date 12/22 /2017 g. P7 Biopsy Date 01/31/2018 h. P8 Biopsy Date 02/28/2018 i. P9 Biopsy Date 03/07/2018 3. During survey date 05/09/18, the laboratory director confirmed the surveyor's findings.