

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1013449	(X3) Date Survey Completed 10/26/2020
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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's procedures manual, patients' test reports, and interview with the laboratory director, the test report did not indicate the name and address of the laboratory location where the test was performed. Findings include: 1. Review of the laboratory's procedures revealed that the laboratory sent biopsied tissue specimens to Consolidated Pathology Group for processing and staining. The stained slide is sent back to Dermatology & Dermatologic Surgery laboratory for interpretation (diagnosis). 2. On October 26, 2020 at 10:30 AM, the surveyor selected 10 patients test reports along with their corresponding slides. 3. Patients' test reports revealed that Consolidated Pathology Group performed the interpretation of the patient's slide for 1 of 10 patients' test reports reviewed. The address of Consolidated Pathology Group was not documented on the test report. 4. The laboratory director of Dermatology & Dermatologic Surgery signed and dated the final report. Not Consolidated Pathology Group. 5. On October 26, 2020 at 10:40 AM, the laboratory director confirmed the surveyor's findings.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p>

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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of patients' test reports and interview with the laboratory director, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, correct problems identified in the post analytic systems specified 493.1291. Findings: 1. There were no written procedures that describe the process the laboratory follows when there is a need to correct problems in the postanalytical systems. 2. Review of patients' test results revealed 1 of 10 patients test results was performed by a different laboratory. 3. Review of 10 patients' test results revealed, the name and address location of the laboratory performing the test was not documented on the final report for 1 of 10 patients test results reviewed. 4. On October 26, 2020 at 10:30 AM, the surveyor asked the laboratory director if any other patients tests are missing the name and address location, as well as the signature and date of the person interpreting the results. The laboratory director told the surveyor that there may be quite a few. 5. There is no documentation to show a corrected report was issued. 6. On October 26, 2020 at 10:40 AM, the laboratory director confirmed the surveyor's findings.