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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>14D1093233                   | <b>(X3) Date Survey Completed</b><br><br>05/06/2021 |
| <b>Name of Provider or Supplier</b><br><br>Ab Dermatology  | <b>Street Address, City, State</b><br><br>3060 N Arlington Heights Rd, Arlington Heights, IL |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D5609</b>              | <p><b>HISTOPATHOLOGY</b><br/>CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and an interview with testing personnel (TP1), the laboratory failed to document all control procedures performed, as specified in the specialty of Histopathology for 49 patients. Findings Include: 1. The laboratory manual, Mohs accession logs, and quality control (QC) sheets were reviewed. 2. The patients for Mohs procedures are documented on the Mohs accession logs. The following dates were selected for QC record review: *02/14/2019; *05/23/2019; *08/01/2019; *12/12/2019; *03/26/2020; *06/18/2020; *09/24/2020; *01/21/2021 and *04/08/2021; 3. The QC worksheets showed the laboratory failed to document the following information on the above (finding #2) selected test dates: *The lot numbers and expiration dates of the reagents and stains used in the performance of the Hematoxylin and Eosin (H &amp; E) tissue staining procedure; and *Record the date prepared and/or opened when reagents and stains are put into use. 4. Further review of the Mohs accession logs revealed the laboratory processed 49 patients' tissue during the selected dates. 5. The laboratory manual and QC worksheet failed to include a written method that would ensure the required information for its reagents and stains are documented each day of tissue processing and staining. 6. On a Recertification survey conducted on 05/06/2021 at 12:45 PM, TP1 confirmed the above findings.</p> |