| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 14D0871989 | 05/06/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dermatology & Skin Surgery | 10100 West 191st Street, Mokena, 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 |
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| **D3043** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(7)<br><br>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records and interview with the technical supervisor; the laboratory failed to retain pathology slides for 6 or 6 patients who had frozen tissue pathology performed. Findings: 1. Review of patients' tests found for 6 of 6 patient test results reviewed, the laboratory failed to have the corresponding stained slides for review on the date of survey, May 6, 2021. Patient Identification Testing Date: P1 05 /29/2019 P2 07/31/2019 P3 10/30/2019 P4 05/27/2020 P5 11/18/2020 P6 03/17/2021 2. On survey date May 6, 2021 at 12:00 PM, the technical supervisor confirmed the surveyor's findings. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures manual and laboratory records; the laboratory failed to establish and follow written policies and procedures for specimen processing when it processed frozen tissue pathology specimens. Findings: 1. Review of the laboratory policy and procedure manual identified the policy for labeling specimens with 2 identifiers. 2. On survey date May 6, 2021 at 10:30 AM review of the patient testing log revealed two patient identifiers were not documented for 6 of 6 patients' specimens processed . Patient Identification Testing Date: P1 05/29 /2019 P2 07/31/2019 P3 10/30/2019 P4 05/27/2020 P5 11/18/2020 P6 03/17/2021 3. On survey date May 6, 2021 at 11:30 AM, the technical supervisor confirmed two patient identifiers were not used when processing patients' frozen tissue specimens. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records and interview with the technical supervisor; the laboratory test reports failed to indicate the name and address where frozen tissue pathology was performed for 6 of 6 patient test reports reviewed. Findings: 1. Review of patient test reports found for 6 of 6 patient test reports reviewed, the reports failed to indicate the name and address where frozen tissue pathology was performed. Patient Identification Testing Date: P1 05/29/2019 P2 07/31/2019 P3 10/30/2019 P4 05/27/2020 P5 11/18/2020 P6 03/17/2021 2. On survey date May 6, 2021 at 12:00 PM, the technical supervisor confirmed the name and address of the laboratory where frozen tissue pathology was performed was not documented on patients test reports. |