| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 13D1084633 | 01/17/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Idaho Skin Surgery Center | 1906 S Vista Ave, Boise, ID | |

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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| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on an observation of patient specimens, a procedure manual review, and an interview with the laboratory director, the laboratory failed to specify in writing a procedure for labeling histopathology specimens and skin scrapings for fungal and parasite specimens since the last survey on May 30, 2017. Findings: 1. An observation of 2 patient histology specimens in the laboratory on January 19, 2019 at 9:15 A.M., revealed the 2 skin biopsy specimens received in 2 separate petri dishes failed to be labeled with at least the patient ' s name or a unique identifier. 2. The laboratory performs approximately 877 histological examinations from Mohs procedures and 75 microscopic examinations for the presence of fungi and parasites. 3. A review of the procedure manual revealed the procedures for histology and fungal examinations failed to include a written procedure or policy for labeling and identifying patient specimens. 4. An interview on January 17, 2019 at 9:45 A.M., with the laboratory director, confirmed the procedures failed to include specimen labeling. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform |

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| | test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on a procedure manual review and an interview with the laboratory director, the laboratory director failed to ensure a quality assessment program for the laboratory was established to detect errors in all phases of microscopic examinations from histopathology specimens and skin scrapings for fungal and parasite presence since the last survey on May 30, 2017. Findings: 1. A record review revealed the laboratory director failed to establish and write polices or procedures for a system to monitor, assess, and correct problems in the preanalytic, analytic, and post-analytic processes in the laboratory. 2. An interview on January 17, 2019 at 10:05 A.M., with the laboratory director, confirmed the laboratory failed to establish and write policies and procedures for a system to monitor all quality assessments activities for the laboratory's microscopic examinations. |