| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 53D2276004 | 03/29/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| South Lincoln Medical Center | 711 Onyx St, Kemmerer, WY | |

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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| **D3013** | FACILITIES<br>CFR(s): 493.1101(e)<br><br>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and staff interview, the laboratory failed to arrange a secure area for the storage of histopathology slides to ensure the proper preservation of specimens. This failure affected 16 patients which had undergone a Mohs procedure on 2/24/23. The findings were: 1. Observation of the laboratory on 3/29/23 at 10:45 AM showed the histopathology slides were stored in an under-the-counter cupboard in thin plastic storage trays, which were not enclosed, and stacked on top of each other. 2. Interview with the office manager on 3/29/23 at 10:50 AM confirmed the slides were not stored in a secure manner. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, manufacturer's instruction for use, and staff interview, the laboratory failed to follow the manufacturer's instructions to ensure the Avantik QS11 Cryostat was at the proper temperature prior to performing MOHs surgical procedures. This failure affected 16 patients which had undergone a Mohs |

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| | procedure on 2/24/23. The findings were: 1. Review of the laboratory's records showed 16 Mohs surgical procedures were performed on 2/24/23. Review of the Cryostat and Laboratory quality control log sheet showed the box to record the temperature of the cryostat was left blank. 2. Review of the Avantik Cryostat QS11 manufacturer's instructions showed "Before sectioning, the microtome chamber should be at a stable temperature around the desired cutting temperature. The temperature of the knife is determined by the cooling of the microtome chamber. All tools which are necessary to take off sections or to manipulate the specimen must also be cooled, as the section will stick to them...The optimal cutting temperature of a specimen depends on the respective characteristics of the tissue especially on the fat content..." The manufacturer's instructions described temperature ranges from minus 10 to minus 60 degrees Celsius depending on the tissue type. 3. Interview with the office manager on 3/29/23 at 10:45 AM confirmed the temperature of the cryostat had not been recorded on the quality control log sheet. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Mohs surgery log, the "Solution and Control-Date Check" log sheet, policy and procedure review, and staff interview, the laboratory failed to document the results of the hematoxylin and eosin quality control slide for its intended reactivity prior to patient testing on 2/24/23. Sixteen cases of Mohs surgery were performed on 2/24/23. The findings were: 1. Review of the "Solution and Control-Date Check" log sheet showed the lot numbers and expiration dates of the hematoxylin and eosin stains and a quality control slide, noted as M23-001, were recorded; however, there was no documentation the laboratory director had evaluated the quality control slide prior to patient testing. 2. Review of the Mohs surgery log showed 16 patients had undergone the Mohs procedure on 2/24/23. 3. Review of the "Histopathology-Mohs Surgery" policy and procedure showed "...A control slide will be made and evaluated each day that a frozen section is prepared..." 4. Interview with the office manager on 3/29/23 at 10:45 AM confirmed there was no further documentation available. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure manual review, lack of documentation, and staff interview, the laboratory director failed to ensure the laboratory had established a quality assessment plan for general laboratory, pre-analytic, analytic, and post-analytic systems for the |

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| | specialty of histopathology. The findings were: 1. The laboratory procedure manual failed to include a quality assurance plan that included the items the laboratory reviews, the frequency of review, and the method they used to document the review in the following areas: a. General laboratory tasks which include proficiency testing review, testing personnel competency procedures, and complaint documentation and resolution. b. Pre-analytic tasks which include specimen collection, patient identification verification, specimen labeling, storage, and transportation. c. Analytic tasks which include review of quality control, instrument preventive maintenance, reagent replacement and test record logs. d. Post-analytic tasks which include test report accuracy. 2. Interview with the office manager on 3/29/23 at 10:45 AM confirmed the laboratory had not established a quality assessment plan. |