| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D2117782 | 12/12/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Chattanooga Skin & Cancer Clinic Cleveland | 3891 Adkisson Dr Nw, Cleveland, 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 |
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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies and procedures, proficiency testing logs, and staff interviews, the laboratory failed to verify the accuracy of micrographically oriented histographic surgery (MOHS) testing at least twice annually in 2023 and 2024. The findings include: 1. A review of the laboratory's policy titled "Comparison of Test Results" revealed the following statement: - "test systems not enrolled in proficiency testing, split-specimen testing will be implemented to evaluate the correlation of the results." When asked what "split-specimen testing" means for MOHS testing, the Laboratory Consultant explained that the laboratory sends cases to another pathologist or MOHS surgeon to compare test results. 2. A review of the laboratory's "Proficiency Testing" logs revealed the laboratory sent cases for comparison once in 2023 (05/02/2023) and none in 2024. 3. An interview with the laboratory consultant on 12/12/2024 at 1:00 p.m. confirmed that the laboratory has not sent MOHS cases for a comparison of test results since May 2023. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. |

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| | (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory observation, review of the manufacturer's instructions for use, lack of documentation, and staff interview, the laboratory failed to monitor ambient temperature and humidity where patient tissue processing occurred in 2023 and 2024 (18 of 18 months reviewed). 1. Observation of the laboratory on 12/12/2024 at 10:00 a.m. revealed a Leica CM 1950 cryostat and Linistat Linear Stainer used for processing patient tissue samples removed during MOHS procedures. 2. A review of the manufacturer's instructions for use revealed the following environmental specifications: - The Leica CM 1950 requires an operating temperature of 18 to 35 degrees Celcius (C) with 20 - 60% relative humidity. - The Linistat Linear Stainer requires 5C to 40C operating temperature with a maximum relative humidity of 80%. 3. No laboratory temperature and humidity monitoring records were available for review from June 2023 to December 2024. 4. An interview with the laboratory consultant on 12/12/2024 at 1:00 p.m. confirmed the laboratory did not monitor laboratory temperature and humidity from June 2023 to December 2024. |
| **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 laboratory observation, a review of patient test records, quality control (QC) records, and staff interviews, the laboratory failed to document daily Hematoxylin and Eosin (H&E) staining QC for one of the four testing days reviewed in 2023 and 2024. The findings include: 1. Observation of the laboratory on 12/12/2024 at 10:00 a.m. revealed a Linistat Linear Stainer using Hematoxylin (Lot: 144470) and Eosin (Lot: 145250) reagents for the staining of patient tissues removed from the micrographically oriented hectographic surgery (MOHS) procedure. 2. A random review of patient test records revealed the laboratory performed H&E staining on tissues obtained during MOHS procedures on 12/27/2022 (ID: 234840), 09/15/2023 (ID:206974), 01/10/2024 (ID:245064), and 11/26/2024 (ID:215539). 3. A review of the daily H&E QC records revealed no documented QC recorded for 09/15/2023. 4. An interview with the laboratory consultant on 12/12/2024 at 1:00 p.m. confirmed that the laboratory did not perform H&E stain QC on 09/15/2023. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of laboratory policies, lack of records, and staff interviews, the laboratory director failed to ensure the laboratory maintained the quality assessment program in 2022, 2023, and 2024. The findings include: 1. A review of the laboratory's quality assessment policy revealed the following: - "We will perform periodic quality assessment monitoring and review the results with the laboratory director or technical consultant for their approval. The laboratory director or consultant will initial and date our written reviews and actions." - "The records of our quality assessment monitoring are filed in the QA Monitoring section of this manual." - "Signatures below document that the current laboratory director has reviewed and approved this Quality Assessment policy initially and each year." 2. No signatures were present on the quality assessment policy indicating the lab director's review and approval. There were no records in the "QA Monitoring" section of the manual indicating the laboratory conducted periodic quality assessments. 3. An interview with the laboratory consultant on 12/12/2024 at 1:00 p.m. confirmed the laboratory did not maintain the quality assessment program in 2022, 2023, and 2024. |