| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 01D2180231 | 12/08/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Southeastern Dermatology Group, Pa | 44 Hughes Road, Suite 1100, Madison, AL | |

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 |
|---|---|
| **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 lack of accuracy verification (Peer Review) records before September 2022, and interviews with the current Laboratory Director, Medical Assistant #1 and Medical Assistant #2, the laboratory failed to insure the previous Laboratory Director performed and documented verification activities for the specialty of Histopathology. The findings include: 1. During the entrance tour on 12/8/2022 at 9:15 AM, the current Laboratory Director and Medical Assistant #1 explained the scope of service in the laboratory had changed. Until September 2022, the clinic had a "Read-only" laboratory, with on-site reading and interpretation of processed slides from Dermatopathology cases. 2. Then in September 2022 the laboratory began producing Histopathology slides from frozen sections collected during MOHS surgical procedures, and a new physician assumed the role of Laboratory Director. The previous Laboratory Director now has a "Read-only" laboratory in her home, and obtained a new CLIA number. 3. After a review of the current laboratory procedures, the surveyor requested records for the "Read-only" laboratory from January 2021 through September 2022. During an interview on 12/8/2022 at 11:45 AM, Medical Assistant #2 stated she was unable to locate any accuracy verification (Peer Review) records performed by the previous Laboratory Director, and stated she believed the previous Director may have taken those records with her. The surveyor explained each CLIA laboratory should retain records for a minimum of two years. The records belong to a specific CLIA number and address, not a specific Laboratory Director. . |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b) |

| | |
|---|---|
| | 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. (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 a reviews of environmental charts and the Environmental Specifications in the Avantik QS12 Cryostat Operators Manual, and an interview with the MOHS Technician and Medical Assistant #1, the laboratory failed to specify acceptable temperature and humidity ranges for the room in which the Avantik QS12 Cryostat was located for four of four months of use in 2022. The findings include: 1. A review of the environmental charts revealed the MOHS technician recorded the room temperature and humidity in the room where the Avantik QS12 Cryostat was used, however the charts failed to specify acceptable ranges for each parameter. 2. During an interview on 12/8/2022 at 10:35 AM the MOHS technician confirmed she did not know the acceptable environmental ranges for operation of the cryostat; she was also unable to locate the operator's manual. 3. As the interview continued at 10:40 AM, Medical Assistant #1 provided a copy of the Operator's Manual for the Avantik QS12 Cryostat. The surveyor noted the following: "Environmental Specifications" ... "Temperature (Recommended Operation) +15 degrees C [Celsius] to +30 degrees C (+59 to +86 degrees F [Fahrenheit]) Note Performance may deteriorate when operated outside this range." ... "Relative Humidity Max. [Maximum] 60% RH" [Relative Humidity] The MOHS Technician and Medical Assistant #1 confirmed the acceptable ranges for temperature and humidity should be included on the charts. . |
| **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 a review of the Daily Slide Quality Control Log sheets, and interviews with the current Laboratory Director, Medical Assistant #1 and Medical Assistant #2, the laboratory failed to insure the quality of the Hematoxylin and Eosin (H&E) stains were evaluated and documented each day of patient testing from January 2021 to September 2022. The findings include: 1. During the entrance tour on 12/8/2022 at 9: 15 AM, the current Laboratory Director and Medical Assistant #1 explained the scope of service in the laboratory had changed. Until September 2022, the clinic had a "Read-only" laboratory, with on-site reading and interpretation of processed slides from Dermatopathology cases. 2. Then in September 2022 the laboratory began producing Histopathology slides from frozen sections collected during MOHS surgical procedures, and a new physician assumed the role of Laboratory Director. 3. A review of Daily Slide Quality Control Log sheets revealed the previous Laboratory |

| | |
|---|---|
| | Director failed to document the acceptability of the H&E staining each day of patient testing from 1/5/2021 through 9/27/2022. The surveyor further noted "Evaluated by _____" was blank on all the forms. 4. During an interview on 12/8/2022 at 11:45 AM, Medical Assistant #2 reviewed the Daily Slide Quality Control Log sheets and confirmed the above findings. SURVEYOR ID# 32558 Licensure and Certification Surveyor |