

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0972775	(X3) Date Survey Completed 09/01/2022
Name of Provider or Supplier Dermatology Specialists Pllc	Street Address, City, State 7730 Dannaher Drive, Powell, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of the laboratory's procedures, review of Cryostat daily maintenance logs, documentation on email of dates patient testing was performed, and interview with the lead nurse, determined the laboratory failed to follow their own written procedure for performing daily maintenance of the Cryostat instrument for 3 out of 138 days from September 1, 2021 through September 1, 2022. Findings included: 1. Review of the "Mohs' Accessioning, Processing and Reporting" policy and procedure, on page 3 stated, "9.2 The temperatures of the room and cryostats are documented each day testing is performed. Additionally the humidity is documented." 2. Review of Cryostat daily maintenance logs revealed daily maintenance was not performed on the following dates that patient testing was performed: 4-5-2022 7-29-2022 8-9-2022 3. Review of additional documentation received via email communication on 09.6.2022 from the lead nurse revealed Cryostat daily maintenance was not documented on 3 of 138 days that patient testing was performed from September 1, 2021 through September 1, 2022. 4. Interview with the lead nurse on September 1, 2022 at approximately 11:30 A.M. in the breakroom, confirmed the laboratory failed to follow their own written procedure for performing daily maintenance of the Cryostat instrument, as stated in the procedure, on all days of patient testing from September 1, 2021 through September 1, 2022. =====</p>
D6171	TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

===== Based on observation of the laboratory, review of testing personnel education documents, and interview with testing person number seven on the Center for Medicare and Medicaid Services Personnel Report (CMS-209), revealed testing person number seven listed on the CMS-209 failed to meet the high complexity regulatory education requirements for performing grossing of tissue removed during Histopathology procedures for September 1, 2021 through September 1, 2022. The findings include: 1. Observation of the laboratory on September 1, 2022 at 9:30 am revealed grossing stations in use for histopathology testing procedures. 2. Review of education documents for testing person number seven revealed that testing person number seven did not meet the minimum education requirements for performing high complexity testing for performing grossing of tissue removed during Histopathology procedures for September 1, 2021 through September 1, 2022. 3. Interview with testing person number seven on September 1, 2022 at 10:30 am confirmed the above findings.

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