

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0897250	(X3) Date Survey Completed 11/08/2022
Name of Provider or Supplier Advanced Dermatology Care	Street Address, City, State 4480 Centerville Rd, White Bear Lake, MN	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish a written competency assessment procedure for Histopathology testing personnel. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:10 p.m. on 11/08/22. 2. A competency assessment procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a competency assessment procedure upon request. 3. In an interview at 2:50 p.m. on 11/08/22, TP1 confirmed the above finding. .</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed to ensure 21 of 25 bottles of Histopathology dyeing materials were not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory</p>

performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:10 p.m. on 11/08/22. 2. One of five bottles of tissue marking dye observed as present and available for use during the tour of the laboratory was in use beyond the expiration date. See below. Cancer Diagnostics Tissue Marking Dye Color Lot Expiration Green 20300 10/31/22 3. Five of five bottles of tissue marking dye observed as present and available for use in four of four surgical rooms were in use beyond the expiration date. See below. Advantek Tissue Marking Dye Color Lot Expiration Blue 092713 01/31/22 Yellow 093731 12/31/21 Orange 092597 12/31/21 Green 092598 01/31/22 Black 092707 01/31/22 4. Expiration dates were to be checked during monthly Quality Assurance meetings as established in the Mohs Procedure Manual procedure found in the Mohs Procedure Manual and Chemical Hygiene Plan manual. 5. The laboratory performed approximately 1,176 Mohs procedures annually as indicated on the Form CMS-116 completed for the 11/08/22 survey. 6. In an interview at 1:15 p.m. on 01/08/21, TP1 confirmed the above finding. .

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
 . Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to assess competency at least annually for two of two tenured Mohs' Histopathology testing personnel in 2021 and 2022. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:10 p.m. on 11/08/22. 2. Five of five testing personnel performed tissue inking for Mohs micrographic surgery as indicated on the CMS-209 and confirmed by laboratory personnel at 1:30 p.m on 11/08/22. 3. Training documentation reviewed on date of survey indicated two of five testing personnel were trained on inking procedures more than one year ago. See below. -TP1 was trained on 12/2019. -Testing Personnel 2 (TP2) was trained on 1/27/21. The other three testing personnel were trained within the past six months and were not due for a competency evaluation. 4. Annual competency assessment documentation for TP1 and TP2 was not found for 2021 or 2022. 5. The laboratory was unable to provide the missing records upon request. 6. In an interview at 2:50 p.m. on 11/08/22, TP1 and TP2 confirmed the above finding. .

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

. Based on review of education documents and interview with laboratory personnel, the laboratory failed to ensure personnel performing high complexity testing meet the qualification requirements of 493.1489. Findings are as follows: The laboratory failed to ensure two of five Histopathology testing personnel met the qualification criteria to perform high complexity testing. See D6171 .

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 document review and interview with laboratory personnel, the laboratory failed to ensure two of five Histopathology testing personnel met the qualification criteria required to perform high complexity testing. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:10 p.m. on 11/08/22. 2. Laboratory records indicated the following testing personnel were deemed as trained to perform high complexity tissue inking procedures as follows: -TP1 in December of 2019. -Testing Personnel 5 (TP5) in August 2022. 3. Testing personnel education credentials for were not found on date of survey, 11/08/22. The laboratory was given five business days to provide the credentials. 4. In an interview at 2:57 p.m. on 11/08/22, Testing Personnel 2 confirmed the above finding and indicated the testing personnel perform inking procedures on approximately 5% of the Mohs Micrographic surgery cases. 5. In an email received at 4:01 p.m. on 11/14/22, TP1 provided education credentials for testing personnel 1, 2, 3 and 4. TP1 did not have the required education to perform high complexity testing. TP1's transcript did not include 24 semester hours of science based classes. TP5's education credentials were not received.