

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2039545	(X3) Date Survey Completed 04/10/2024
Name of Provider or Supplier Pennsylvania Dermatology Partners, Inc	Street Address, City, State 2128 Penn Ave, 1st Floor, West Lawn, PA	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of maintenance records and interview with the Director of Training and Compliance (DTC), the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 Traceable thermometer/humidity monitor used in the Histopathology laboratory from 08/09/2022 to the day of survey. Findings Include: 1. On the day of survey, 04/10/2024 at 10:10am, during observation of the laboratory the surveyor discovered 1 of 1 Traceable thermometer/humidity monitor (serial number 221553655) with no expiration date. 2. The laboratory could not provide maintenance/function check records for the Traceable thermometer/humidity monitor. 3. Interview with the DTC on 04/10/2024 at 10:16am confirmed the Traceable thermometer/humidity monitor was used to record room temperature and relative humidity in the Histopathology laboratory from 08/09/2022 to 04/10/2024.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Director of Training and Compliance (DTC), the laboratory failed to follow an established policy to assess the competency of 1 of 2 testing personnel (TP) that performed macroscopic Histopathology examinations in 2022 and 2023. Findings include: 1. The laboratory's Competency evaluation policy states, "Assessment of competency will be done on an annual basis and is subject to change within the year if deemed necessary by the attending pathologist based upon performance." 2. On the day of survey, 04/10/2024, the laboratory could not provide documentation of the annual competency assessments for TP #2 (CMS 209 personnel #2) who performed grossing and inking in 2022 and 2023. 3. The laboratory reported an annual test volume of 2503 in Histopathology. (CMS 116) 4. The DTC confirmed the findings above on 04/10/2024 at 10:16 am.

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 the CLIA Laboratory Personnel Report (CMS 209), personnel qualification records and interview with the Director of Training and Compliance (DTC), the laboratory failed to ensure that 1 of 2 testing personnel (TP) that performed macroscopic Histopathology examinations met the minimum requirements of 493.1489 from 01/02/2020 to 04/10/2024. Refer to 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 review of the CLIA Laboratory Personnel Report (CMS 209), personnel qualification records and interview with the Director of Training and Compliance (DTC), the laboratory failed to ensure that 1 of 2 testing personnel (TP) that performed macroscopic Histopathology examinations met the minimum requirements of 493.1489 from 01/02/2020 to 04/10/2024. Findings include: 1. On the day of survey, 04/10/2024 at 9:07 am review of personnel qualification records revealed TP #2 (CMS 209 personnel #2) did not meet the minimum qualifications of 493.1489 to perform High Complexity testing in Histopathology (grossing and inking) from 01/02/2020 to 04/10/2024. 2. On 04/10/2024, the laboratory provided the following personnel qualification records for testing personnel (TP) #2: - Pennsylvania Homeschoolers-Home Education program High School diploma awarded on 06/30/2004. - National Society of Histotechnology-Mohs Micrographic technician training certificate awarded on 05/23/2012. 3. Competency assessment records revealed that TP #2 has performed high complexity testing since January 2, 2020. 4. The laboratory reported an annual test volume of 2503 in Histopathology. (CMS 116) 5. The DTC confirmed the findings above on 04/10/2024 at 10:16 am.