

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2039532	<b>(X3) Date Survey Completed</b>  04/23/2024
<b>Name of Provider or Supplier</b>  Main Line Dermatology	<b>Street Address, City, State</b>  1246 Wrights Lane, West Chester, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, laboratory's Proficiency Testing manual review, and interview with testing personnel (TP) #2, the laboratory failed to verify twice annually the accuracy of dermatopathology microscopic examinations performed in 2022 and 2023. Findings include: 1. The laboratory's Proficiency Testing manual stated, "In compliance with 493.1709, this laboratory uses peer review in lieu of proficiency testing. Peer review will be conducted twice a year." 2. On the day of survey, 04/23/2024 at 11:45 am, the laboratory could not provide documentation of the semiannual verification of accuracy of dermatopathology microscopic examinations performed in 2022 and 2023. 3. TP #2 confirmed the findings above on 04/23/2024 at 12:45 pm.</p>
<b>D6106</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with the nursing supervisor (NS) and testing personnel (TP) #2, the laboratory director (LD) failed to ensure that all new and revised procedures were signed and approved for all aspects of the testing process from July 2022 to the date of survey. Findings include: 1. On the day of the survey, 04/23/2024 at 11:15 am, review of the laboratory's procedure</p>

manual, revealed that the LD did not sign and approve the following procedures currently in use from July 2022 to the date of the survey: -Competency Assessment Policy -Proficiency Testing Policy -Ongoing Assessment Policy -Employee Safety -Retention Policy 2. The NS and TP #2 confirmed the findings above on 04/23/2024 at 12:45 pm.

**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 (Form CMS-209), personnel qualification records, and interview with the nursing supervisor (NS) and testing personnel (TP) #2 (CMS 209), 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 07/14/2022 to 04/23/2024. 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 credentials, and interview with the nursing supervisor (NS) and testing personnel (TP) #2, 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 07/14/2022 to 04/23/2024. Findings Include: 1. On the day of the survey, 04/23/2024, review of personnel qualification records revealed 1 of 2 TP (CMS 209 personnel #2) did not meet the minimum qualifications of 493.1489 to perform High Complexity testing in Histopathology (grossing and inking) from 07/14/2022 to 04/23/2024. 2. On 04/23/2024 at 12:00 pm, the laboratory provided the following personnel credentials for TP #2: - Community College of Philadelphia Associates in Arts Diploma. - ASCP Board of Certification Histotechnician certificate valid 2024 through 12/2026. 3. Further review of TP#2's transcripts revealed that it did not have the minimum qualifications. 4. Competency assessment records revealed that TP #2 has been performing high complexity testing since 07/2022. 5. The NS and TP #2 confirmed the findings above on 04/23/2024 at 12:45 pm.