

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1000156	(X3) Date Survey Completed 03/14/2024
Name of Provider or Supplier Jefferson Dermatopathology	Street Address, City, State 33 A 9th Street, Suite 745, Philadelphia, 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 Testing Personnel (TP) #2, the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 Fisher Scientific Safety Flow Fume Hood used for Histopathology testing from 07/26/2022 to the day of survey. Findings include: 1. On the day of survey 03/14/2024 at 10:07 am, during the laboratory tour, the surveyor observed a sticker indicating a maintenance date of 12/27 /2018 and a due date of 12/31/2019 for 1 of 1 Fisher Scientific Safety Flow Fume Hood (serial number 93-609Q). 2. The laboratory could not provide maintenance /function check records after December of 2019 for the Fisher Scientific Safety Flow Fume Hood. 3. TP #2 confirmed the findings above on 03/14/2024 at 10:20 am. *REPEAT DEFICIENCY</p>
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (CMS 209), personnel</p>

qualification records and interview with Testing Personnel (TP) #2, the laboratory failed to ensure that each individual performing High Complexity testing (1 of 3) have the minimum qualifications required for grossing and inking. Refer to D6171
*REPEAT DEFICIENCY

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, competency assessment records and interview with Testing Personnel (TP) #2, the laboratory failed to ensure that each individual performing High Complexity testing (1 of 3) have the minimum qualifications required for grossing and inking from 07/26/2022 to 03/14/2024. Findings include: 1. On the day of survey, 03/14/2024 at 9:15 am, review of the personnel qualification records revealed 1 of 3 TP (CMS 209 personnel #3) did not meet the minimum qualifications to perform grossing and inking for High Complexity testing in Histopathology from 07/26/2022 to the date of survey. 2. On 03/14/2024 at 9:20 am, the laboratory provided the following documents for TP #3: - Community College of Philadelphia Associates in Arts Diploma. Degree awarded on 12/18/2021. - Community College of Philadelphia Associates in Arts (Health Care Studies) transcripts. - Hartford Community College Histotechnology Certificate Program Diploma. 3. On 03/20/2024 at 1:32 pm, the laboratory provided the following documents for TP #3: - ASCP Board of Certification Histotechnician certificate valid April 2012 through April 2015. 4. On 03/20/2024 review of the personnel qualification documents revealed that TP #3 did not have the minimum qualifications. 5. Competency assessment records revealed that TP #3 has been performing high complexity testing since January of 2022. 6. The laboratory reported an annual test volume of 21,000 in Histopathology. (CMS 116) 7. TP #2 confirmed the findings above on 03/14/2024 at 10:20 am.

*REPEAT DEFICIENCY