Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1000156	07/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson Dermatopathology	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
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on lack of documentation, observation of the laboratory, and interview with the Testing Personnel (TP#2), the laboratory failed to monitor the room temperature of paraffin blocks storage to ensure proper conditions for preservation from 11/05/2019 to 07/26/2022. Findings include: 1. On the day of survey, 07/26/2022 at 10:30 a.m., the surveyor observed paraffin blocks were stored at room temperature in the histopathology laboratory and a storeroom next to the laboratory. 2. The laboratory could not provide room temperature records from 07/01/2020 to 07/26/2022 for the following: - Histopathology laboratory. - Storeroom . 3. TP #2 confirmed the findings above on 07/26/2022 at 10:35 a.m.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of maintenance records and interview with the Testing Personnel (TP#2), the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 4 of 4 Fisher Scientific timers and 1 of 1 Fisher Scientific Safety Flow Fume Hoods used for Histopathogy testing in the

	laboratory from 07/01/2020 to the date of survey. Findings Include: 1. On the day of survey, 07/26/2022 at 10:30 am, the laboratory could not provide maintenance /function check records for the following used from 07/01/2020 to 07/26/2022 : A: 4 of 4 Fisher Scientific Timers -S/N: 230142356 - Due: 06/30/2005 -S/N: 90854625 - Due: 04/08/2011 -S/N: 90854724 -Due: 04/08/2011 -S/N: 91065474 -Due: 04/08 /2011 B: 1 of 1 Fisher Scientific Safety Flow Fume Hood -Model: 93-609Q - Due 12 /31/2019. 2. TP# 2 confirmed the findings above on 07/26/2022 around 10:50 am.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of staining quality control (QC) records and interview with the Testing Personnel (TP#2), the laboratory failed to document a negative staining reactivity every day of patient testing for 4 of 4 stains used in histopathology from 11 /05/2019 to 07/26/2022. Findings include: 1. On the day of survey 07/26/2022 at 10: 10 a.m., review of the laboratorys' special/immunohistochemical stains QC records revealed, that a negative control was not documented for Acid-Fast Bacteria (AFB), Fite, Gram, and Immunohistochemical (IHC) stains from 11/05/2019 to 07/26/2022. 2. The laboratory performed the following number of special stains from 07/01/2020 to 06/30/2022: - AFB: 70 stains - Fite: 17 stains - Gram: 71 stains - IHC: 369 stains 3. TP# 2 confirmed the findings above on 07/26/2022 around 10:50 a.m.
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 's Laboratory Personnel Report (Form CMS-209), review of personnel 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
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 (Form CMS-209), review of personnel qualification records, review of competency assessment records and interview with the 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 06/07/2020 to 07/26/2022. Findings Include: 1. On the day of survey, 07/26/2022 at 09:35 a.m, review of the personnel qualification records revealed 1 of 3 TP (CMS 209 form personnel #3) did not meet the minimmum qualifications to perform grossing and inking for High Complexity testing in Histopathology from 06/07/2020 to the date of survey. 2. On 7 /26/2022 at 09:40 am, the laboratory provided the following documents for TP#3: - Community College of Philadelphia Associates in Arts Diploma . Degree conferred on 12/18/2021. - Community College of Philadelphia Associates in Arts (Health Care Studies) Transcripts. - Harford Community College Histotechnology Certificate Program Diploma. (Non-Credit Continuing Education) 3. On 7/27/2022 at 12:48 pm, the laboratory provided the following documents for TP#3: -Harford Community College Histotechnology Certification Program Transcripts. 4. On 7/29/2022 at 08:41 am, the laboratory provided the following documents for TP#3: -Brightwood College Medical Assisstant Transcripts. 5. On 07/29/2022, review of personnel qualification documents revealed that TP#3 did not have the minimum qualifications. 6. Competency assessment records revealed that TP # 3 started performing high complexity testing on 06/07/2020. 7. The laboratory performed 21,500 Histopathology examinations in 2021. 8. TP # 2 confirmed the findings above on 07 /26/2022 at 09:45 am.