Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2120895	07/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatopathology At Stony Point 9109	9109 Stony Point Drive, Richmond, VA	

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
D0000	An announced CLIA validation survey was conducted at Dermatopathology at Stony Point on July 26, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D6168 -42 CFR. 493.1487 Condition Testing Personnel.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of policies, patient test logs, histology slides, Mohs surgery map records, and interviews, the laboratory failed to follow their written policy for labeling patient Mohs slides for one (1) of five (5) random Mohs case numbers reviewed on the date of the survey, July 26, 2022. Findings include: 1. Review of the policy manual revealed a procedure for labeling and accessioning of patient Mohs slides (title: Collection, Identification, and Labeling of Mohs Specimens" Procedure Number 300) that stated, "Slides are labeled with the first initial of the surgeons last name, followed by assigned accession number, lesion number (if multiple lesions), and patient name". 2. During a review of the patient accession test logs, the inspector requested to review histology slides and surgical maps for the following 5 random case numbers: C363-21 done on 5/3/21; K1017-21 done on 10/29/21; C193-22 done on 3/10/22; C194-22 done on 3/10/22; K490-22 done on 7/1/22. The inspector noted for case C363-21 (performed on 5/3/21), eight (8) patient histology slides were processed. The inspector noted the mapping guide and six (6) of the 8 slides were

	labeled as accession "C363-51" compared to the patient log which identified the case as C363-21. The inspector noted that 2 slides were correctly labeled with accession "C363-21". The inspector inquired regarding the disparities in the patient identifier on the slides and mapping record. The Senior Histotechnologist stated at approximately 2: 30 PM, "It appears that the tech mislabeled an identifier on 6 of the slides. The last digits signify the year of the case and 51 is indeed an error. I am not sure why it was also mislabeled on the mapping record." 3. An interview with the Anatomic Pathology Quality/Education Supervisor, Senior Histotechnologist, and staff histotech on 7/26 /22 at approximately 4:00 PM confirmed the above findings.
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 a review of the CLIA Laboratory Personnel Report Form, available testing personnel (TP) files, lack of documentation, and an interview, the laboratory failed to ensure that one of five TP was qualified to perform high complexity testing from January 1, 2021 and up to the date of the inspection on July 26, 2022. 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 a review of the CLIA Laboratory Personnel Report Form (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and an interview, the laboratory failed to ensure that one (1) of five (5) TP was qualified to perform high complexity testing during the nineteen (19) month review timeframe (January 2021 and up to the date of the inspection on July 26, 2022). Findings include: 1. Review of the laboratory's CMS 209 form revealed that the lab director identified 5 TP as responsible for high complexity Mohs pathology patient tissue processing, grossing /mapping, and reading during the review timeframe of 1/1/21 to 7/26/22. 2. Review of the available laboratory personnel records for TP A revealed a foreign diploma (China). The inspector requested to review US education equivalency documentation. No records were available for review. (See Personnel Code Sheet attached.) 3. An interview with the Anatomic Pathology Quality/Education Supervisor, Senior Histotechnologist, and staff histotech on 7/26/22 at approximately 4:00 PM confirmed the above findings.