Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1059373	11/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pathologists Diagnostic Laboratory, Pa	1800 South Hawthorne Road, Suite 100, Winston-Salem, NC	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2019, 2020, and 2021 CAP (College of American Pathologists) proficiency testing records 11/9 /21, the laboratory failed to ensure ungraded proficiency testing results were evaluated. Findings: The laboratory's "INTERLABORATORY COMPARISON PROGRAM FOR HISTOLOGY AND IMMUNOHISTOCHEMISTRY" policy states "... II. PROCEDURE ... G. All CAP results will be reviewed by the histology supervisor. Any incorrect responses will be investigated and corrective action taken if necessary. H. If the laboratory receives an error code on a PT challenge that was not graded because of lack of consensus, ... it will be investigated and documented by the histology supervisor and Section Director of Immunohistochemistry. ... J. When there is not clear consensus among the referees participating in the CAP Survey Program involving a particular slide, the result may not receive a formal evaluation. In this case, the result will be evaluated as to where our response fell amongst the referees by the section lab manager. Our percentage will be recorded." Review of 2019, 2020, and 2021 CAP proficiency testing records revealed the laboratory failed to document evaluation of ungraded results for the following events: 1. 2019: HER2-A, HER2-B, PM2-A, CHPV-A, CHPV-B, CHPV-C; 2. 2020: HER2-B, PM2-A, PM2-B, CHPV-C; 3. 2021: HER2-A, HER2-B, PM2-A, CHPV-A, CHPV-B.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on policy and procedure manual review and staff interview 11/9/21, the laboratory's histology procedure manual was not complete and current for testing performed. Findings: Review of the "IHC Quality Control and Quality Assurance" procedure revealed "... Daily Quality Control/ Batch Controls 1. After each run, the Slide Summary is printed. The tech checks each control slide and documents the controls stained properly on the printed Slide Summary before distributing to the pathologist. The records are maintained for a minimum of two years. ..." During interview 11/9/21 at approximately 3:30 p.m., the Director of Operations stated that the Slide Summary is no longer printed by the laboratory. She stated that vendor disconnected and disabled the printer and and the Slide Summary has not been printed since then.
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 laboratory policies and procedures, review of validation documentation, random review of daily 2021 work lists, and TP (testing personnel) interviews 11/9/21, the laboratory failed to check IHC (immunohistochemical) stains for negative reactivity each time of use. Findings: Review of laboratory procedure "IHC Quality Control and Quality Assurance" revealed "... 3. A positive control is processed for each IHC antibody and whenever possible the test sample tissue is placed on the slide with the control tissue. 4. A separate negative patient tissue control is processed with ER, PR, HER2NEU, EBER, and Kappa/Lambda ISH. ..." Review of laboratory policy "Summation Statement of IHC Negative Control Validation" revealed "After review of multiple immunohistochemical stains by the Medical Director, it is determined that the tests are free of background reactivity obviating the needs for a negative reagent control. As such, the negative controls shall be omitted from all immunohistochemical tests." Review of random 2021 daily IHC work lists revealed negative controls were not documented. Review of the daily worklist from 11/8/21 revealed there was no documentation that positive and negative controls were tested. During interview at approximately 2:35 p.m., TP #4 stated that controls are run daily and the positive controls are checked for reactivity. She stated that with the change to Biotin free products, they no longer use a separate negative fixitative and they omitted negative controls. During interview at approximately 2:45 p.m., TP #3 stated patient and control slides contain both positive and negative reactivity sections and the negative sections are not checked for non-reactivity.

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 personnel records 11/9/21 and the deficiency cited at D6171, the laboratory failed to verify that 1 of 4 testing personnel (TP #2) met the minimum education requirements for performing high complexity testing.
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 personnel records and interview with TP (testing personnel) 11/9/21, the laboratory failed to verify that 1 of 4 testing personnel (TP #2) met the minimum education requirements for performing high complexity testing. Review of personnel records for TP #2 revealed a high school diploma and an associate degree in funeral service. There were no other education records available. Review of personnel records for TP #2 also revealed a job description that included grossing. Review of TP #2's 2019, 2020, and 2021 competency assessments revealed the competency assessments included grossing. During interview at approximately 11:45 a.m., TP #4 confirmed that TP #2 does perform grossing. She stated they were not aware that TP #2 was not qualified to perform high complexity testing.