

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1057101	(X3) Date Survey Completed 02/10/2020
Name of Provider or Supplier Annapath, Inc	Street Address, City, State 4801 Tesla Dr Suite H J K L & M, Bowie, MD	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM), the "MICS OVEN" worksheets in use and interview with the general supervisor (GS), the laboratory did not ensure that the SOPM included the limits of acceptability for the "Slide Oven Temperature", all the revisions to the "MICS OVEN" worksheets, and the current worksheet. Findings: 1. Review of the "MICS OVEN" worksheet in the SOPM and in use in the laboratory showed that there were no limits of acceptability defined for the "Slide Oven Temperature." The worksheet defined the temperature as set to 80 degrees Celsius with no limits of acceptability defined. 2. The "MICS</p>

OVEN" worksheet in the SOPM did not match the one being used by the histotechnologists in the laboratory. 3. Review of the "MICS OVEN" worksheets in the log book from January 2019 through January 2020 showed that three different versions of the worksheet had been in use. The SOPM did not include a copy of each of the versions of the "MICS OVEN" worksheet used over the last two years. 4. During the survey on 02/10/2020 at 1:30 PM the GS confirmed that the SOPM did not include limits of acceptability for the "Slide Oven Temperature" worksheet and a copy of each version used over the last two years.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patients final reports and interview with the general supervisor (GS), the laboratory did not ensure that the final test report listed the name of each client that used the laboratory information system (LIS) provided by the staining laboratory. Findings: 1. According to the GS the laboratory has 8 clients that have contracted by the laboratory being surveyed to perform the grossing and staining /technical processing of the tissue being analyzed by the pathologists at another location. 2. The laboratory being surveyed also provides the LIS for documenting the "final pathologic diagnosis" of the tissue stained and the final reports provided to the physicians who ordered the test from the pathologists. 3. The GS stated that the final report for only one of the eight pathologists indicates that the "final pathologic diagnosis" was performed at the address where the slides were interpreted. The final reports did not include the address of the other seven pathologist who performed the "final pathologic diagnosis" at their laboratory. 4. During the survey on 02/10/2020 at 1:30 PM the GS confirmed that the LIS did not include the address of each pathologist that performed the "final pathologic diagnosis" at the location where the slides were interpreted.

D6148

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463(a)(4)

The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

This STANDARD is not met as evidenced by:
I. Based on review of the waterbath records for "Cutting Station No. 4" and interview with the general supervisor (GS), the GS did not ensure that the histotechnologists were completing the forms are required. Findings: 1. Review of the waterbath records for "Cutting Station No. 4" for January 2019 through January 2020 showed that the waterbath temperature was not recorded for during January 2020. The form had been

reviewed on "31Jan2020" but there was no follow-up with the histotechnologist who failed to document the required temperatures for the month of January 2020. 2. During the survey on 02/10/2020 at 1:30 PM the general supervisor confirmed that the waterbath temperatures had not been recorded as required and that there had been no follow-up with the histotechnologist. II. Based on review of the "MICS OVEN" worksheets in use and interview with the general supervisor (GS), the laboratory did not ensure that the histotechnologists were completing the forms are required. Findings: 1. The "MICS OVEN" worksheets from January 2019 through January 2020 were reviewed. The worksheet defined the "Slide Oven Temperature" as set to 80 degrees Celsius (C) with no limits of acceptability. 2. The worksheet from January 2020 showed that the temperature was recorded as 79 C on on 3 of 22 days of operation with no follow-up with the histotechnologist. 3. During the survey on 02/10/2020 at 1:30 PM the general supervisor confirmed that the there was no no limits of acceptability for the "Slide Oven Temperature."

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 "Laboratory Personnel Report (CLIA) (CMS-209)", education records and training records the laboratory failed to ensure that the grossing personnel met the qualification requirements (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 "Laboratory Personnel Report (CLIA) (CMS-209)", education records, training records, and interview with the general supervisor, the laboratory failed to ensure that the histology technicians performing grossing, inking and marking met the minimum qualification requirements for high complexity testing under 493.1489. Findings: 1. The CMS-209 form that was reviewed on 02/10/2020 showed 4 testing personnel who perform the grossing at the laboratory. The education records were not available for 2 of the 4 persons listed on the CMS-209, therefore, they do not meet the minimum requirements for 493.1489. 2. There was letter that was shown to the surveyor that may grandfather one of the testing persons listed on the CMS-209. The name on the letter did not match the name listed on the CMS-209. There was no documentation showing that the educational credentials for the two testing personnel were equivalent to a high school diploma or higher. 3. During the survey on 02/10/2020 at 1:30 PM the general supervisor confirmed that the educational records were not complete.