

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1057101	(X3) Date Survey Completed 04/17/2024
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual, manufacturer's specifications, and maintenance record review and interview with the general supervisor (GS), the laboratory did not ensure that the procedure for performing function checks on the fume hoods was up to date and followed by the testing personnel (TP). Findings: 1. The procedure, "Safety Equipment," Section 3.3, "Quality Control and procedure" states, "Safety hoods are monitored daily and results are documented on the Temperatures and Safety Equipment Maintenance Log." Section 3.3.1, "Hemco ducted fume hood for coverslipping" states, "Ideal airflow should read 100 lfm (linear feet per minute)"; and 2. A review of the "UniFlow CE Specification" sheet for the Hemco fume hood showed that it is "Recommended that hoods be used with sash open with face velocity of 80-100 FPM" (feet per minute). 3. A review of the "Automatic Coverslipper" maintenance log from February 2024 showed that the "Ideal Velocity" of the automatic coverslipper (Hemco) fume hood was listed as "40-60" FPM, which does not match the manufacturer ' s acceptable range or the one written in the procedure manual. The "Velocity ft/min" for the Hemco fume hood was documented on the maintenance log as "60" on 21 of 21 days used in February 2024 which is outside the manufacturer ' s recommended acceptable range. 4. Section 3.3.2, "Misonix ductless fume hood workstation for grossing" and section 3.3.3, "Misonix ductless fume hood workstation for non-gyn" of the "Safety Equipment" procedure state that the "ideal airflow should read 50 lfm." During an interview on 04/17/2024 at 1:15 PM, the GS stated that the workstations are no longer "ductless" and that the</p>

procedure manual had not been updated. Maintenance record review showed that at the time of the survey there was no documentation that the Misonix fume hoods were checked daily for adequate airflow. The GS confirmed that the laboratory did not measure and document the airflow of the Misonix fume hoods. 5. During an interview on 04/17/2024 at 2:30 PM, the GS confirmed that the procedure for performing function checks on the fume hoods was not up to date and followed by the TP.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on record review and interview with the general supervisor (GS), the laboratory failed to document the lot numbers and expiration dates of stains and reagents used for histology testing to ensure that they were not used when they had exceeded their expiration date, had deteriorated, or were of substandard quality. Findings: 1. A review of "Processing Station" and "Staining Station" maintenance logs from January through March 2024 showed that the laboratory documented the lot number and expiration date of the stains and reagents used for histology slide staining on the top right portion of the logs. 2. During an interview on 04/17/2024 at 12:30 PM, the GS stated that the electronic file used for documenting the lot numbers and expiration dates of histology stains and reagents before January 2024 was corrupted and that the information was no longer accessible. A review of maintenance logs from January 2023 showed that the lot numbers and expiration dates of 17 out of 19 stains and reagents used were not documented on the logs. 3. The lot number and expiration date of the distilled water used for staining was not documented on the maintenance logs from January 2023 through March 2024. During an interview on 04/17/2024 at 12:30 PM, the GS stated that the laboratory did not document the lot number and expiration date of the distilled water and confirmed that the laboratory did not ensure that the lot numbers and expiration dates of histology reagents were documented.

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 surveyor observation, procedure manual review, and interview with the general supervisor (GS), the laboratory did not perform and document routine preventive maintenance checks on the fume hoods. Findings: 1. The procedure, "Facilities," section 3, "Ventilation", subsection 3.3, "Certification" states, "A licensed ventilation specialist will perform an annual testing and certification of the hood. The certification label is posted on the equipment." 2. The laboratory uses three "Misonix WS-6 Downflow Work Stations" (hood #191310-L1, #191310-L4, and #191310-L5) to perform the technical component (grossing) of the histopathology testing. 3. During a tour of the laboratory on 04/17/2024 at 1:20 PM it was observed that the fume hoods

at three of three "Misonix WS-6 Downflow Work Stations" were labeled with a sticker which stated that the maintenance had been performed October 2021. During an interview at the same time, the GS confirmed that maintenance had not been performed on the fume hoods since that date.