

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2037153	<b>(X3) Date Survey Completed</b>  10/03/2024
<b>Name of Provider or Supplier</b>  Advanced Pathology Solutions Llc	<b>Street Address, City, State</b>  5328 Northshore Cove, North Little Rock, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Through a review of proficiency activities of 2023 and 2024, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to document review of proficiency testing results for histopathology. Survey findings follow: A. The surveyor requested documentation of review of histopathology proficiency testing activities, no documentation was provided. B. Review of histopathology proficiency testing activities records provided did not demonstrate documented review of the results. C. In an interview on 10/3/2024 at 2:40 pm, laboratory director confirmed that no systemic review of proficiency testing activities was documented to ensure all histopathology testing personnel were participating in proficiency activities twice annually.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p>

Observation, review of temperature records, lack of documentation and interview demonstrated that the laboratory failed to monitor the temperature on each day of operation in one of two rooms in which equipment with temperature and humidity requirements were stored. Findings follow: A) During a tour of the laboratory on 10/3/24 at 9:35am the surveyor observed two separate rooms (Histology Laboratory and Molecular Laboratory) containing laboratory items with a temperature storage requirement. B) During a review of the laboratory's temperature records it was noted that no temperature and humidity measurements of the molecular lab were recorded for 3 of 21 days in September of 2023, 2 of 22 days in October of 2023, 1 of 23 days in November of 2023, 8 of 21 days in March of 2024, and 9 of 22 days in September of 2024. C) During a tour of the laboratory on 10/3/24 at 2:50 p.m. the surveyor observed a Quant Studio 12K Flex instrument in the molecular lab and noted it's operating temperatures of 15-30C and humidity of 20-80% (Quant Studio 12K Flex Real-Time PCR System User Guide, Maintenance and Administration. Publication #4470689, Rev D). D) In an interview on 10/3/2024 at 3:30 pm, the general supervisor confirmed that no temperature and humidity records for the molecular lab were available for the above dates.

**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:  
Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 10/3/24 at 2:47 pm, one (of one) unopened container of QuantStudio Digital PCR plates (Applied Biosystems, lot 4603632, REF 4470186, expiration date 3/27/24) was observed in the laboratory, available for use beyond the expiration date. B) During a tour of the laboratory on 10/3/24 at 2:48 pm, one (of one) opened container of Apex Bond Superior Adhesive Slides(Leica, lot 4900063898, REF 3800040 White, expiration date 4/2023) was observed in the laboratory, available for use beyond the expiration date C) During a tour of the laboratory on 10/3/24 at 2:50 pm, one (of one) opened container of Gold Chloride Solution, 0.1% w/v (Histology Connections, lot 2324002, Item # HCSS4562-1L, expiration date 9/3/24) was observed in the laboratory, available for use beyond the expiration date. C) In an interview on 10/3/24 at 2:50 pm the general supervisor, confirmed that the items, identified above, had exceeded the expiration date and were available for use.

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Through a lack of documentation and interviews with laboratory staff, it was determined the laboratory director failed to ensure an approved corrective action plan

is followed for unacceptable proficiency test results. Survey findings follow: A. Upon request, no histopathology proficiency testing policy including an approved corrective action plan was provided. B. In an interview on 10/3/24 at 2:40 the lab director confirmed the lack of an approved corrective action plan policy for histopathology proficiency testing activities.