| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 04D2037153 | 02/21/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Advanced Pathology Solutions Llc | 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.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of proficiency test documentation for 2021 and 2022, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to maintain a copy of attestation sheets signed by the director and testing personnel. Survey findings include: A. The surveyor reviewed proficiency test documentation for 2021 and 2022. The laboratory documented participating in the 1st, 2nd, and 3rd Microbiology Proficiency Testing Event of 2021 and the 3rd Microbiology Proficiency Testing Event of 2022. B. In an interview at 3:13 p.m. on 2/21/2023, the surveyor requested signed attestation sheets for the proficiency testing events in 2021 and 2022. C. At 3:40 p.m. on 2/21/23, the surveyor was provided attestation sheets for the proficiency events in 2021 and 2022. All attestation sheets provided to the surveyor lacked director and testing person signatures. At that time, the microbiology supervisor (#34 from the Form CMS-209) confirmed that there were no other attestation sheets available other than the unsigned ones that she had presented to the surveyor. |
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| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of laboratory temperature records for January through December 2022 and January 2023, and through interviews with laboratory staff, it was determined the laboratory failed to document corrective actions when temperatures were outside of the specified performance specifications. Survey findings include: A. A review of temperature logs for the Histopathology laboratory revealed the acceptable temperature and humidity ranges were as follows: Embedder Paraffin 54 to 64 degrees Celsius; Refrigerators 2 to 4 degrees Celsius; Oven #1 59 to 65 degrees Fahrenheit; Room Temperature 55 to 89 degrees Fahrenheit; Room Humidity 25% to 80%; and Freezer -20 to -30 degrees Celsius. B. Through a review of Histopathology temperature logs for January through December 2022, it was determined that in January 2022, Refrigerator temperatures were unacceptable on one of twenty days for Refrigerator #1 and twelve of twenty days for Refrigerator #2. Room Humidity was documented outside of acceptable range on fourteen of twenty days. In February 2022, Refrigerator temperatures were unacceptable on one of sixteen days for Refrigerator #1 and two of seventeen days for Refrigerator #2 and Room Humidity was documented outside of acceptable range on nine of seventeen days. In August 2022 the temperatures for Refrigerator #2 were documented outside of the specified ranges on three of twenty-three days. In December 2022 the temperatures documented for Oven #1 were outside of the specified ranges on three of twenty-one days documented. Corrective actions were not documented for any of the failures. C. During an interview at 12:20 on 2/21/2023, laboratory employee #12 (as listed on the form CMS-209) confirmed that the temperatures and humidity were documented outside of specified acceptable ranges and that no corrective actions were documented. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. |

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| | This STANDARD is not met as evidenced by:<br>Through a review of the CMS-209 form presented at the time of the survey, a review of personnel records for sixteen randomly selected personnel (designated testing personnel) listed on the form CMS-209, and through interviews with laboratory staff, it was determined four of sixteen failed to have documented training on the test systems used by the laboratory. Survey findings include: A. Through a review of the CMS- 209 form, it was determined that all personnel (39 of 39) were designated as testing personnel. B. A review of personnel records for sixteen randomly selected personnel listed on the form CMS-209 revealed that four of sixteen failed to have training documented on the test systems in use, prior to testing patient samples. Employees #34, #35, #36, and #37 did not have documented training prior to testing patient samples. C. In an interview at 3:13 on 2/21/2023, employee #34 (listed as general supervisor as well as testing personnel) confirmed that the laboratory did not have documented training for employees performing molecular testing. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of the CMS-209 form presented at the time of the survey, a review of personnel records for sixteen personnel (designated testing personnel) listed on the form CMS-209, and through interviews with laboratory staff, it was determined four of sixteen failed to have written authorization to perform testing without direct supervision. Survey findings include: A. Through a review of the CMS- 209 form, it was determined that all personnel were designated as testing personnel. B. A review of personnel records for sixteen personnel listed on the form CMS-209 revealed that four of sixteen failed to have written authorization to perform testing without direct supervision. Employees #34, #35, #36, and #37 did not have a written authorization to perform testing without direct supervision. C. In an interview at 3:13 on 2/21/2023, employee #34 (listed as general supervisor as well as testing personnel) confirmed that the laboratory did not have documented authorization for testing for employees performing molecular testing. |
| **D6047** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b(8)(i)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. |

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| | This STANDARD is not met as evidenced by:<br>Through a review of personnel records for four testing personnel performing molecular testing in the microbiology laboratory, and lack of documentation, it was determined the laboratory failed to document competency by direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. Survey findings include: A. A review of the personnel file for employee #35 revealed the only evaluation in the file was a Performance Evaluation dated 2/14/2022 but was not a Competency Assessment for the actual test system in use and did not have documentation of the method used to assess the performance of the employee. B. A review of documents titled "Competency Assessment" for laboratory employee #36 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel included the name of laboratory employee #36 but had no date. Competency Assessment: Nail Panel and Competency Assessment: StoolDX had no name or date anywhere on the form. C. A review of documents titled "Competency Assessment" for laboratory employee #37 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel and Competency Assessment: Nail Panel included the name of laboratory employee #36 but had no date. The Competency Assessment: StoolDX had no name or date anywhere on the form. D. Personnel records for employee #34 included documentation, in the form of "APS Bloodborne Pathogens Training" that was dated 7 /24/2020. Although the documentation indicated employee #34 had been working in the laboratory since 7/24/2020, there were no competency assessments in the file. |
| **D6048** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(ii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of personnel records for four testing personnel performing molecular testing in the microbiology laboratory, and lack of documentation, it was determined the laboratory failed to document competency by monitoring the recording and reporting of results. Survey findings include: A. A review of the personnel file for employee #35 revealed the only evaluation in the file was a Performance Evaluation dated 2/14/2022 but was not a Competency Assessment for the actual test system in use and did not have documentation of the method used to assess the performance of the employee. B. A review of documents titled "Competency Assessment" for laboratory employee #36 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel included the name of laboratory employee #36 but had no date. Competency Assessment: Nail Panel and Competency Assessment: StoolDX had no name or date |

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| | anywhere on the form. C. A review of documents titled "Competency Assessment" for laboratory employee #37 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel and Competency Assessment: Nail Panel included the name of laboratory employee #36 but had no date. The Competency Assessment: StoolDX had no name or date anywhere on the form. D. Personnel records for employee #34 included documentation, in the form of "APS Bloodborne Pathogens Training" that was dated 7 /24/2020. Although the documentation indicated employee #34 had been working in the laboratory since 7/24/2020, there were no competency assessments in the file. |
| **D6049** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of personnel records for four testing personnel performing molecular testing in the microbiology laboratory, and lack of documentation, it was determined the laboratory failed to document competency by review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. Survey findings include: A. A review of the personnel file for employee #35 revealed the only evaluation in the file was a Performance Evaluation dated 2/14/2022 but was not a Competency Assessment for the actual test system in use and did not have documentation of the method used to assess the performance of the employee. B. A review of documents titled "Competency Assessment" for laboratory employee #36 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel included the name of laboratory employee #36 but had no date. Competency Assessment: Nail Panel and Competency Assessment: StoolDX had no name or date anywhere on the form. C. A review of documents titled "Competency Assessment" for laboratory employee #37 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel and Competency Assessment: Nail Panel included the name of laboratory employee #36 but had no date. The Competency Assessment: StoolDX had no name or date anywhere on the form. D. Personnel records for employee #34 included documentation, in the form of "APS Bloodborne Pathogens Training" that was dated 7 /24/2020. Although the documentation indicated employee #34 had been working in the laboratory since 7/24/2020, there were no competency assessments in the file. |
| **D6050** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iv) |

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| | The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of personnel records for four testing personnel performing molecular testing in the microbiology laboratory, and lack of documentation, it was determined the laboratory failed to document competency by direct observation of performance of instrument maintenance and function checks.. Survey findings include: A. A review of the personnel file for employee #35 revealed the only evaluation in the file was a Performance Evaluation dated 2/14/2022 but was not a Competency Assessment for the actual test system in use and did not have documentation of the method used to assess the performance of the employee. B. A review of documents titled "Competency Assessment" for laboratory employee #36 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel included the name of laboratory employee #36 but had no date. Competency Assessment: Nail Panel and Competency Assessment: StoolDX had no name or date anywhere on the form. C. A review of documents titled "Competency Assessment" for laboratory employee #37 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel and Competency Assessment: Nail Panel included the name of laboratory employee #36 but had no date. The Competency Assessment: StoolDX had no name or date anywhere on the form. D. Personnel records for employee #34 included documentation, in the form of "APS Bloodborne Pathogens Training" that was dated 7/24/2020. Although the documentation indicated employee #34 had been working in the laboratory since 7/24 /2020, there were no competency assessments in the file. |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of personnel records for four testing personnel performing molecular testing in the microbiology laboratory, and lack of documentation, it was determined the laboratory failed to document competency by assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Survey findings include: A. A review of the personnel file for employee #35 revealed the only evaluation in the file was a Performance Evaluation dated 2/14/2022 but was not a Competency Assessment for the actual test system in use and did not have documentation of the method used to |

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| | assess the performance of the employee. B. A review of documents titled "Competency Assessment" for laboratory employee #36 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel included the name of laboratory employee #36 but had no date. Competency Assessment: Nail Panel and Competency Assessment: StoolDX had no name or date anywhere on the form. C. A review of documents titled "Competency Assessment" for laboratory employee #37 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel and Competency Assessment: Nail Panel included the name of laboratory employee #36 but had no date. The Competency Assessment: StoolDX had no name or date anywhere on the form. D. Personnel records for employee #34 included documentation, in the form of "APS Bloodborne Pathogens Training" that was dated 7 /24/2020. Although the documentation indicated employee #34 had been working in the laboratory since 7/24/2020, there were no competency assessments in the file. |
| **D6052** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(vi)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of personnel records for four testing personnel performing molecular testing in the microbiology laboratory, and lack of documentation, it was determined the laboratory failed to document competency by assessment of problem solving skills. Survey findings include: A. A review of the personnel file for employee #35 revealed the only evaluation in the file was a Performance Evaluation dated 2/14 /2022 but was not a Competency Assessment for the actual test system in use and did not have documentation of the method used to assess the performance of the employee. B. A review of documents titled "Competency Assessment" for laboratory employee #36 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel included the name of laboratory employee #36 but had no date. Competency Assessment: Nail Panel and Competency Assessment: StoolDX had no name or date anywhere on the form. C. A review of documents titled "Competency Assessment" for laboratory employee #37 (as listed on the form CMS-209) revealed one set of documents which were Checklists without documentation of the method of evaluation. The Competency Assessments were documented separately for each panel and labeled Competency Assessment: Wound Panel, Competency Assessment: Nail Panel, and Competency Assessment: StoolDX. The Competency Assessment: Wound Panel and Competency Assessment: Nail Panel included the name of laboratory employee #36 but had no date. The Competency Assessment: StoolDX had no name or date anywhere on the form. D. Personnel records for employee #34 included documentation, in the form of |

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| | "APS Bloodborne Pathogens Training" that was dated 7/24/2020. Although the documentation indicated employee #34 had been working in the laboratory since 7/24 /2020, there were no competency assessments in the file. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of personnel records for four testing personnel performing molecular testing in the microbiology laboratory, and lack of documentation, it was determined the laboratory failed to document competency annually. Survey findings include: A. A review of the personnel file for employee #35 revealed he had been a testing person since 6/29/20 and the only evaluation in the file was a Performance Evaluation dated 2/14/2022. This was not a competency assessment for the actual test system in use and did not have documentation of the method used to assess the performance of the employee. B. Personnel records for employee #34 included documentation, in the form of "APS Bloodborne Pathogens Training" that was dated 7 /24/2020. Although the documentation indicated employee #34 had been working in the laboratory since 7/24/2020, there were no competency assessments in the file. C. In an interview, at 3:13 p.m. on 2/14/2023, laboratory employee #34 confirmed there were no other competency assessments available. |