

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2147552	(X3) Date Survey Completed 02/26/2025
Name of Provider or Supplier Arthritis And Rehab Medicine, PLLC	Street Address, City, State 320 Salter Path Road, Pine Knoll Shores, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and interview with testing personnel (TP) #1, 02/26/25, the laboratory failed to ensure expired calibration reagent was not available for use. Findings: At approximately 1:15 p.m. surveyor observed one bottle of "Buprenorphine 0 ng/mL Calibrator" reagent, Lot #74893999, with an expiration date of 11/30/24, available for use on the bottom shelf of the laboratory refrigerator. Interview with TP #1 at approximately 1:45 p.m. confirmed the calibration reagent was expired. They stated they had not used it for patient testing and the reagent was only used for troubleshooting if necessary. The calibration reagent was disposed of at time of survey.</p>
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, 2023 and 2024 testing personnel (TP) competency records, and interviews with laboratory director (LD) and TP #1, 02/26/25, the technical consultant (TC) failed to perform direct observations of patient test performance for 1 of 1 TP in 2023 and 2024. Findings: Review of laboratory policy,</p>

"Quality Assurance Program" revealed "5. External Proficiency testing...PT is used as competency assessment of personnel as noted.". Review of TP #1 competency records for 2023 and 2024 revealed a printed copy of the competency assessments. The copies of the assessments were signed by the TC. The competency record states "Performs patient testing on specimens submitted to the laboratory for analysis by adhering to the laboratory's quality control policies, documents all quality control activities, instrument and procedural calibrations and maintenance performed in accordance with the clinical laboratory's approval policies and procedures identified by the direct observation by the supervisor." This assessment is checked "Yes". During interview with LD at approximately 1:45 p.m., the LD stated the TC has not been on-site for over 2 years and that record review and competency assessments are sent electronically for the TC to review and sign off on. Interview with TP #1 at approximately 2:20 p.m. confirmed the TC had not been on-site to perform direct observations of routine patient test performance. They stated the competency assessment form is sent electronically for the TC to sign and return to the laboratory.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, 2023 and 2024 testing personnel (TP) competency records, and interviews with laboratory director (LD) and TP #1, 02/26 /25, the technical consultant (TC) failed to perform direct observations of instrument maintenance and function checks for 1 of 1 TP in 2023 and 2024. Findings: Review of laboratory policy, "Quality Assurance Program" revealed "5. External Proficiency testing...PT is used as competency assessment of personnel as noted.". Review of TP #1 competency records for 2023 and 2024 revealed a printed copy of the competency assessments. The copies of the assessments were signed by the TC. The competency records state "Performs patient testing on specimens submitted to the laboratory for analysis by adhering to the laboratory's quality control policies, documents all quality control activities, instrument and procedural calibrations and maintenance performed in accordance with the clinical laboratory's approval policies and procedures for instrumentation utilized identified by the direct observation by the supervisor." This assessment is checked "Yes". During interview with LD at approximately 1:45 p.m., the LD stated the TC has not been on-site for over 2 years and that record review and competency assessments are sent electronically for the TC to review and sign off on. Interview with TP #1 at approximately 2:20 p.m. confirmed the TC had not been on-site to perform direct observations of instrument maintenance and function checks. They stated the competency assessment form is sent electronically for the TC to sign and return to the laboratory.