Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D2147552	**(X3) Date Survey Completed** 04/05/2022
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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of 2021 laboratory policy and procedure manual, laboratory records, lack of documentation for 2021 verification of accuracy and interview with testing personnel (TP) #1 4/5/22, the laboratory failed to verify the accuracy of the testing performed on the Indiko Plus screening analyzer 2 of 2 times in 2021. Findings: Review of laboratory procedure manual revealed the procedure "Proficiency Testing Procedures" states "To satisfy CLIA regulations and accrediting organization criteria we are enrolled in the approved external Proficiency Testing programs for all regulated analytes and authorize that our PT results be forwarded to our accrediting agency if needed. In addition we perform split-sample analysis with other CLIA certified laboratories as an external validation of all non-regulated analytes not included in our approved proficiency testing program menus." Review of 2021 laboratory records revealed the laboratory tested patient samples on the Indiko Plus screening analyzer January of 2021 thru December of 2021, a period of approximately 12 months. Review of 2021 verification of accuracy records revealed no documentation the laboratory had performed a verification of accuracy for all analytes tested in 2021. Interview with TP#1 at approximately 3:30 p.m. confirmed the laboratory failed to perform a verification of accuracy 2 of 2 times in 2021 for the testing performed on the Indiko Plus screening analyzer due to machine problems.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)

	(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. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, 2020 proficiency testing (PT) records, and interview with testing personnel (TP) #1 4/5/22, the laboratory failed to retain documentation of the processing, reporting, and review of PT samples and results for the first and second toxicology events in 2020. Findings: Review of laboratory procedure manual revealed the procedure "Proficiency Testing Procedures" states "All records of external PT testing are kept for at least two years. This includes information about the PT specimens (date received, condition when received), the personnel who performed the analysis, the attestation form signed by the person doing the testing and the laboratory director and designee. The attestation form provides that the PT sample was treated and tested as a patient specimen in our laboratory, results submitted to the PT program, and the date the results from the PT programs are reviewed." Review of 2020 PT records revealed that the laboratory participated and was scored in the first and second toxicology events in 2020. Review of 2020 PT records revealed no documentation of the processing, reporting and review of results of the first and second toxicology events in 2020. Interview with TP#1 at approximately 3:00 p.m. confirmed the laboratory failed to document the first and second toxicology events in 2020 but that it was performed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, the manufacturer's instructions and interview with testing personnel (TP) #1 4/5/22, laboratory procedure manual was incomplete for the testing performed. The procedures for Amphetamine (AMP), Benzodiazepine (BENZ), Buprenorphine (BUP), Cocaine (COC), Methadone (MTD), Opiate (OPI), Oxycodone (Oxy) and specific gravity (SG) failed to include the laboratory's type and level of quality control (QC) reagents used for control procedures. Findings: Review of laboratory procedure manual revealed the procedure "DRI Amphetamines Assay" states "Refer to Indiko Plus laboratory procedures provided for Quality Control." Review of the manufacturer's instructions for "DRI Amphetamines Assay" revealed under the section "Quality Control and Calibration" "Use controls near the cutoff to validate the calibration. Control results must fall within established ranges, as determined by laboratory procedures and guidelines ... All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control frequency." Review of laboratory procedure manual revealed the procedure "Quality Control Policies and Procedures for Screening Instruments" states "Quality Control is performed with every patient run and consists of two levels of control. Acceptable levels of QC must be obtained before patient testing can be reported ...Selection of control materials for each analyte consist of control which falls below the cutoff and a second control which falls above the cutoff. " During interview with TP#1 at approximately 3:00 p.m. confirmed the procedure did not list the control materials for testing of QC and that she performs QC based on the information for QC from the laboratory information system (LIS).
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, review of calibration records, review of calibration verification records and interview with lab director (LD) and testing personnel (TP) #1 4/5/22, the laboratory failed to perform and document

	calibration verification at least once every six months during 2020 and 2021 on the Indiko Plus analyzer. Findings: Review of laboratory policy "Calibration and Calibration Verification" revealed " Calibration verification is intended to confirm the calibration setting. It requires a minimum of three specimens (low, mid-point and high) ...Calibration verification should be performed every 6 (six) months ..." Review of the calibration records revealed the laboratory performs 2-point calibrations for Amphetamine (AMP), Benzodiazepine (BENZ), Cocaine (COC), Methadone (MTD), Opiate (OPI), Oxycodone (Oxy) and specific gravity (SG) testing performed on the Indiko Plus screening analyzer. Review of calibration verification records failed to reveal the laboratory performed 3-point calibration verification on the Indiko Plus screening analyzer at least once every six months for 2020 and 2021. Interview with LD and TP #1 at approximately 3:00 p.m.confirmed the laboratory failed to perform and document calibration verification on the Indiko Plus screening analyzer at least once every six months for 2020 and 2021.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: See D2003.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: See D2015.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the

	system is functioning properly. This STANDARD is not met as evidenced by: Based on lack of documentation for 2022 laboratory refrigerator temperature records, and interview with TP #1 4/5/22, the LD failed to ensure temperatures of the laboratory refrigerator was monitored to assure laboratory systems were functioning properly for 3 of 3 months, January through March, in 2022. The LD failed to ensure the temperature of the laboratory refrigerator was monitored to assure laboratory systems were functioning properly for 3 of 3 months, January through March, in 2022. Findings: Review of 2022 laboratory temperature and humidity logs, refrigerator and logs revealed no log or documentation for the laboratory refrigerator temperatures for January, February and March of 2022. Interview with TP#1 at approximately 3:30 p. m. confirmed the laboratory had tested patient specimens from January 2022 thru March 2022, that reagents were stored in the laboratory refrigerator and there was no documentation available that the temperature was monitored for the laboratory refrigerator during this time period.