Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0987642	10/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis And Pain Associates Of Pg County	7300 Hanover Drive Suite 201, Greenbelt, 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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that corrective action was taken and documented for failed PT. Findings: 1. A review of PT records from 2021 showed that the laboratory failed Ferritin PT (50%) for the 1st PT event of 2021. 2. The laboratory director signed the PT results page to show that the PT results had been reviewed, however no corrective action was documented for the failed PT. 3. During an interview on 10/24/2022 at 2:30 PM, the TC confirmed that there was no corrective action taken or documented for the failed PT.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's standard operating procedure manual (SOPM) and interview with the technical consultant (TC), the laboratory did not retire procedures that are no longer in use. Findings: 1. Review of the "General Laboratory Quality Assurance Procedure Manual" showed that the SOPM included 2 procedures for performing erythrocyte sedimentation rate (ESR) ("Seditainer Procedure," and "PolyMedico Sedimat 15 Procedure"), a "Microscope Maintenance" procedure, and a "Complete Blood Count (CBC) with Five-Part Differential" procedure which was for the Beckman Coulter MAXM hematology analyzer. 2. During an interview on 10/18 /2022 at 11:30 AM the TC stated that the laboratory stopped performing ESR testing in February 2022, and that the laboratory did not have a microscope or use a Beckman Coulter MAXM to perform hematology testing. The TC confirmed that these procedures were no longer in use and did not include the dates of initial use and discontinuance.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation, laboratory record review, and interview with the technical consultant (TC), the laboratory failed to retain all analytic systems records for at least 2 years. Findings: 1. A review of calibration records for the Horiba ABX Pentra XL-80 hematology analyzer from 2020 to 2022 showed that the instrument was calibrated 06/20/2020, 12/10/2020, and 09/08/2021. No other calibration records were available for review at the time of the survey. 2. During an interview on 10/24/2022 at 10:30 AM the TC stated that the hematology analyzer had been calibrated on 03/10 /2022 and provided a calibration log from the analyzer with the date, lot number, and expiration date of the calibration materials. There were no instrument printouts or other documentation available to show that the calibration was successful. 3. A review of calibration records for the Beckman Coulter Access 2 chemistry analyzer from 2021 to 2022 showed that calibration documentation for the test thyroid stimulating hormone was not available from 08/26/2021 to 06/09/2022. 4. During an interview on 10/24/2022 at 11:15 AM the TC stated that they were not working at the laboratory then and did not know where the documents were. They stated that calibration records were not stored on the analyzer for that time period. 5. During an interview on 10/24 /2022 at 9:15 AM the TC stated that calibration records for the Beckman Coulter AU480 chemistry analyzer were not printed out. They stated that all calibration records were stored on the analyzer, but that the analyzer did not have 2 years of calibration records for analytes which are calibrated daily. 6. Surveyor observation of calibration records on the AU480 confirmed that calibrations for the tests sodium, potassium, and chloride were available from 09/21/2022 to present; carbon dioxide from 05/26/2022 to present; and creatinine from 05/31/2022 to present. 7. The TC also stated at 9:15 AM that maintenance records for the AU480 were also stored on the analyzer and that there was no physical maintenance log to review. 8. Surveyor observation of maintenance records on the AU480 chemistry analyzer showed that under "Analyzer Maintenance," documentation of 7 of 8 required "Daily" tasks was available from 09/07/2022 to present; 1 of 8 "Daily" tasks was available from 09/12 /2022; 2 of 5 "Weekly" tasks was available from 04/04/2022 to present; 1 of 5 "Weekly" tasks was available from 04/12/2022; 2 of 5 "Weekly" tasks was available

	from 04/18/2022; and 9. Under "ISE (ion-selective electrode) Maintenance," documentation of 2 of 3 required "Daily" tasks was available from 09/07/2022 to present; 1 of 3 "Daily" tasks was available from 09/09/2022; 1 of 2 "Weekly" tasks was available from 04/11/2022 to present; 1 of 2 "Weekly" tasks was available from 08/26/2022; 1 of 2 "2 Weeks" tasks was available from 08/30/2021 to present; and 1 of 2 "2 Weeks" tasks was available from 10/25/2021. 10. During an interview on 10/24 /2022 at 2:30 PM, the TC confirmed that the laboratory failed to retain all analytic systems records for at least 2 years.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from 2021 showed that the attestation statement, instrument printouts, and results summary for 1 of 2 events for the DYNEX DSX Automated ELISA System were not present at the time of the survey. 2. During an interview on 10/24/2022 at 10:25 AM, the TC stated that they had to email the PT provider (Theratest) to obtain a copy of the PT results/scores and confirmed that PT documents were missing for the above listed PT event.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the technical consultant (TC), the laboratory did not ensure that written procedures for performing hematology testing accurately reflect the current practice in the laboratory. Findings: 1. Procedure manual review showed that the laboratory has 3 separate binders which each contain a different procedure for performing hematology testing. 2. There are 2 different procedures for parallel testing of new hematology controls. The "Procedure for Verifying New Lot of Controls for Pentra XL80" in the "Horiba Medical System Installation/Validation Pentra XL80" SOPM states, "The new lot should be run on 3 to 5 different days to verify and establish values." The "Difftrol II New Lot Installation and Verification: Horiba Pentra XL80" procedure in the "General Laboratory Quality Assurance Procedure Manual" SOPM states to run "all three levels of control" and to repeat "5-10 times across 2-3 days until at least 20 points are reached." 3. During an interview on 10/18/2022 at 10:00 AM the TC stated that a new lot number of hematology controls should be run on 3-5 different days which matches 1 of the 2 procedures. 4. There are 3 different procedures which specify the stability limits of blood specimens drawn for hematology testing. The "Complete Blood Count with Automated Differential" procedure in the "General

	Laboratory Quality Assurance Procedure Manual" SOPM states that "samples must be run within 24 hours of collection"; The "Horiba Pentra XL80 Procedure: Complete Blood Count With Automated Differential" procedure in the "Green Binder" SOPM states, "Lavender tube is stable for up to 48 hours in the refrigerator"; and the version of the "Complete Blood Count with Automated Differential" procedure in the "Horiba Medical System Installation/Validation Pentra XL80" SOPM states, "If the test is not performed on the lavender tube right away, it should be refrigerated" with hand-written instructions added that state, "up to 72 hours." 5. During an interview on 10/24 /2022 at 2:30 PM the TC confirmed that written procedures for performing hematology testing are not consistent and do not accurately reflect the current practice in the laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on procedure manual and temperature log record review, and interview with the technical consultant (TC), the laboratory failed to define the acceptable laboratory reagent freezer temperature to ensure proper reagent storage and reliable test system operation. Findings: 1. The procedure, "Temperature Monitoring" states that the "Normal Range" for the laboratory freezer is "-26 - 0 degrees C (celsius) / -15 - 32 degrees F (fahrenheit)." 2. Temperature log review showed that there was no temperature range defined on the freezer log. 3. During an interview on 10/18/2022 at 11:30 AM the TC stated that a new freezer was in place in the laboratory and that the acceptable range for the freezer was "-8 to -20 degrees C." The TC confirmed that the laboratory failed to define the acceptable freezer temperature for the new freezer.
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 hematology instrument maintenance record review and interview with the technical consultant (TC), the laboratory did not ensure that monthly maintenance was performed on the hematology analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses a Horiba ABX Pentra XL-80 hematology analyzer to perform CBC (complete blood cell count) analysis. The "ABX Pentra XL 80 Maintenance Log" lists 2 activities to be performed monthly: "Perform Concentrated Cleaning" and "Empty the Cap Piercing Filter." 2. A review of monthly hematology analyzer maintenance records from January through December, 2021 showed that 2 of

	2 monthly maintenance activities were not recorded 6 out of 12 months. 3. During an interview on 10/24/2022 at 2:30 PM, the TC confirmed that monthly hematology analyzer maintenance was not documented.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) and patient record review and interview with the technical consultant (TC), the laboratory did not ensure that QC results meet the laboratory's test system criteria for acceptability before reporting patient test results. Findings: 1. The laboratory uses a "Quality Control Review" log to document whether "all QC" is "in range" and "Troubleshooting/Action taken" for each day of testing. A review of the "Quality Control Review" log for January 2022 for the Beckman Coulter Access 2 chemistry analyzer showed that on 01/05/2022 the testing person (TP) wrote, "folate fail - 1 pt (patient) reported." 2. QC record review showed that on 01/05/2022 "IA-PLUS-QC1" (lot # 85231, expiration date 02/28/2022) QC failed for the test folate. The QC was repeated and was acceptable; and 3. "IA-PLUS-QC1" (lot # 85232, expiration date 02/28/2022) QC failed for the test folate. The QC was repeated 3 times but the QC did not meet the laboratory's criteria for acceptability. The TP wrote "NPR" (no patients reported) next to the QC results on both instrument printouts. 4. A review of Access 2 instrument printouts for 01/05/2022 showed that 2 patients were tested for folate. Patient record review showed that folate test results were reported for 2 of 2 patients tested. 5. During an interview on 10/24/2022 at 2:00 PM the TC confirmed that patient test results were reported when QC did not meet the laboratory's criteria for acceptability.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on procedure manual and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not ensure that all corrective actions were documented when hematology QC was unacceptable. Findings: 1. The laboratory uses a "Quality Control Review" log to document whether "all QC" is "in range" and "Troubleshooting/Action taken" for each day of testing. A review of the "Quality Control Review" log for January 2022 for the Horiba ABX Pentra XL-80 hematology analyzer showed that a check mark was documented under "All QC in range?" and no troubleshooting was documented for 20 out of 20 days of patient

	testing. 2. A review of the "Levey-Jennings" QC report for the "LO" level control (lot # PX433L, expiration date 03/05/2022), the "NOR" level control (lot # PX433N, expiration date 03/05/2022), and the "HI" level control (lot # PX433H, expiration date 03/05/2022) from 01/05/2022 through 01/31/2022 showed that on 01/06/2022 the "NOR" level of QC was out of the laboratory's range of acceptability for red blood cell (RBC), hemoglobin (HGB), and hematocrit (HCT); 3. On 01/07/2022 the "LO" level of QC was unacceptable for RBC, HGB, HCT, platelet (PLT), and absolute neutrophil count (NEUT#), and the "NOR" level of QC was unacceptable for RBC, HGB, HCT, and PLT; and 4. On 01/11/2022 the "NOR" level of QC was unacceptable for white blood cell count and NEUT#. 5. QC record review showed that QC was repeated and acceptable when QC was out of range but the laboratory did not document the corrective actions taken on the "Quality Control Review" log. 6. During an interview on 10/24/2022 at 2:30 PM, the TC confirmed that corrective actions had not been documented when hematology QC was out of range.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: The laboratory director did not ensure that corrective action was taken and documented for failed chemistry proficiency testing for 1st event, 2021. Cross-refer to D2094.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) plan and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that quality control (QC) and QA procedures monitored overall operation of the laboratory to identify immediate QC failures and ensure that effective corrective actions are taken when failures are identified. Findings: 1. The laboratory failed to ensure that corrective action was taken and documented for failed proficiency testing (PT). Cross-refer to D2094. 2. The laboratory did not retire procedures that are no longer in use. Cross-refer to D3029. 3. The laboratory failed to retain all analytic systems records for at least 2 years. Cross-refer to D3031. 4. The laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the

	date of the PT testing event. Cross-refer to D3037. 5. The laboratory did not ensure that written procedures for performing hematology testing accurately reflect the current practice in the laboratory. Cross-refer to D5401. 6. The laboratory failed to define the acceptable laboratory reagent freezer temperature to ensure proper reagent storage and reliable test system operation. Cross-refer to D5413. 7. The laboratory did not ensure that monthly maintenance was performed on the hematology analyzer as recommended by the manufacturer. Cross-refer to D5429. 8. The laboratory did not ensure that QC results meet the laboratory's test system criteria for acceptability before reporting patient test results. Cross-refer to D5481. 9. The laboratory did not ensure that all corrective actions were documented when hematology QC was unacceptable. Cross-refer to D5783. 10. During an interview on 10/24/2022 at 2:30 PM the TC confirmed that the laboratory's QA plan was not maintained to identify failures in quality as they occur.
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: The laboratory director failed to ensure that patient test results are reported only when the system is functioning properly. Cross-refer to D5481.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that policies and procedures were established and followed to monitor the competency of all personnel who conduct preanalytic, analytic, and postanalytic phases of testing. Findings: 1. The laboratory currently has 2 testing personnel listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). One of 2 TP have been testing for less than 6 months. 2. A review of competency assessment records from 2021 to 2022 showed that there were no competency assessment records for the TC (TP #1) for the duties they perform as a TP. 3. During

	an interview on 10/18/2022 at 1:00 PM the TC stated that they did not have a competency assessment because they were the one who wrote the quiz used for competency testing and it didn't seem "right" for them to take their own quiz. The other TP (TP #2) is not qualified as a TC therefore the LD must evaluate the TC's competency.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the laboratory's SOPM was current and approved by the LD. Findings: 1. A review of SOPMs in the laboratory showed that the "Horiba Medical System Installation /Validation," "Access 2," and the "Dynex DSX Procedure Manual" were not signed by the current LD, who started on 01/01/2021. 2. The laboratory has a SOPM they refer to as the "Green Binder" which contains a quality assurance procedure and one version of the procedure for the Horiba ABX Pentra XL-80 hematology analyzer. This SOPM was not approved or signed by the LD, nor was the "General Laboratory Quality Assurance Procedure Manual." 3. During an interview on 10/24/2022 at 2:30 PM, the TC confirmed that the LD failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.