Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1025249	06/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Osteoporosis Clinic Of East Texas Pa	1212 Clinic Dr, Tyler, TX	

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
D0000	Based on the survey conducted 06-15-2018, the laboratory was found to be out of compliance with the following conditions of 42 CFR: 493.803 Successful Participation 493.807 Reinstatement of Nonwaived Laboratories 493.1403 Moderate Complexity Laboratory Director 493.1409 Technical Consultant-Moderate Complexity .
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2016, 2017 and 2018, the laboratory failed to participate successfully in the specialty of hematology. Refer to D 2121 I-IV.

D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: . Based on review of API PT documentation for testing in hematology for 2016, 2017 and 2018, the laboratory failed to participate successfully in testing for the following analytes: Analyte Event Score 0765 WBC diff 3rd 2016 0% 1st 2017 0% 1st 2018 0% 0775 RBC count 1st 2017 0% 2nd 2017 20% 1st 2018 0% .
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2016, 2017 and 2018 and staff interview, the laboratory failed to attain scores of at least 80% for each analyte in hematology testing using the Abbott Cell-Dyn Emerald analyzer in the 3rd event 2016, 1st event 2017, 2nd event 2017 and 1st event 2018. Findings: I. API 3rd Event 2016 A. Review of API PT documentation for the 3rd event of 2016 showed scores of 0 for percent granulocytes, percent lymphocytes and percent monocytes/mids on all samples (HEM-11, HEM-12, HEM-13, HEM-14 and HEM-15), resulting in a score of 0 for analyte 0765, Cell identification or WBC differential. B. In an interview at the site on 06-15-2018, the laboratory technical consultant (CMS form 209) stated the scores were the result of a clerical error. Examination of testing results from the instrument, dated 11-18-2016, showed that the operator had entered the results for the total number of cells in a given category as opposed to the percentage of the whole. A self-check is noted in performance review and corrective action documentation dated 06-13-2017. C. When compared to the expected results, all values fell within acceptable range as follows: Percent Granulocytes Sample Reported Actual Result Expected HEM-11 2.7 80.3 75.7-85.8 HEM-12 0.9 44.8 40.7-48.4 HEM-13 16.1 83.3 82.1-85.3 HEM-14 9.4 81.1 77.3-84.1 HEM-15 5.5 70.1 67.7-72.0 Percent Lymphocytes Sample Reported Actual Result Expected HEM-11 0.4 12.9 9.2-17.3 HEM-12 1.0 52.0 46.7-55.9 HEM-13 2.6 13.7 11.9-14.6 HEM-14 1.3 10.8 9.9-12.8 HEM-15 2.1 26.4 24.0-28.7 Percent Monocytes/Mids Sample Reported Actual Result Expected HEM-11 0.2 6.8 3.4-8.4

	HEM-12 0.1 3.2 1.4-6.6 HEM-13 0.6 3.0 2.0-4.1 HEM-14 0.9 8.1 5.2-10.6 HEM-15 0.3 3.5 2.4-5.1 II. API 1st Event 2017 A. Review of API PTdocumentation for the first event of 2017 showed scores of 0% for the following analytes, marked "failure to participate": 0760 Hematology 0% 0765 Cell ID or WBC diff 0% 0775 RBC 0% 0785 HCT (non-waived) 0% 0795 HGB (non-waived) 0% 0805 WBC 0% 0815 Platelets 0% B. In an interview at the site on 06-15-2018, the technical consultant stated that proficiency testing for that event had been performed on 03-22-2017 by an individual no longer employed at the facility and the results held for electronic submission. For unknown reasons, the submission date, 03-31-2017, passed without the results being submitted. III. API 2nd Event 2017 A. Review of API proficiency testing documentation for second event 2017 showed a score of 20% for Erythrocyte Count. Results for the individual testing samples were as follows: Red Cell Count (Hem-3) 10^9 per liter Sample Reported Expected HEM-01 1.99 2.03-2.31* HEM-02 4.76 4.83-5.46* HEM-03 4.98 4.88-5.52 HEM-04 3.86 3.93-4.44* HEM-05 5.56 5.68-6.41 * * indicates result out of expected range B. Examination of instrument printouts showed no clerical errors in the results submitted. Attestation statements were signed and dated 07-18-2017. No documentation of review or corrective action was found or could be offered. IV. API 1st Event 2018 A. Review of API PTdocumentation for the first event of 2018 showed scores of 0% for the following analytes, marked "failure to participate": 0760 Hematology 0% 0765 Cell ID or WBC diff 0% 0775 RBC 0% 0785 HCT (non-waived) 0% 0795 HGB (non-waived) 0% 0805 WBC 0% 0815 Platelets 0% B. In an interview at the site on 06-15-2018, the technical consultant stated proficiency testing was performed by testing person 1 before the due date (03-30-2018) and results recorded on manual sheets held for electronic submission, but forgotten until the due date had passed. This information is also noted on the performance review and corrective action form for that event. .
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for 2017 and 2018 and staff interview, the laboratory failed to participate in hematology testing for the first event 2017 and the first event 2018, resulting in unsatisfactory PT performance. I. API 1st event 2017 A. Review of API PTdocumentation for the first hematology event of 2017 showed scores of 0% for all analytes, marked "failure to participate": B. In an interview at the site on 06-15-2018, the technical consultant stated that proficiency testing for that event had been performed on 03-22-2017 by an individual no longer employed at the facility and the results held for electronic submission. For unknown reasons, the submission date, 03-31-2017, passed without the results being submitted. C. An examination of the instrument printouts showed the results within acceptable ranges as follows: White Cell Count (Hem-3) 10^9 per liter Sample Reported Expected HEM-

	01 7.4 6.5-8.9 HEM-02 2.1 1.7-2.5 HEM-03 19.5 16.9-23.0 HEM-04 11.5 10.2-13.9 HEM-05 18.0 15.9-21.7 Red Cell Count (Hem-3) 10^12 per liter Sample Reported Expected HEM-01 3.98 3.86-4.36 HEM-02 2.08 2.03-2.30 HEM-03 5.03 4.89-5.52 HEM-04 4.96 4.77-5.39 HEM-05 3.58 3.40-3.85 Hematocrit (Hem-3) % Sample Reported Expected HEM-01 35.2 34-39 HEM-02 17.7 17-20 HEM-03 47.2 45-52 HEM-04 43.5 41-47 HEM-05 30.4 28-32 Hemoglobin (Hem-3) grams per deciliter Sample Reported Expected HEM-01 11.5 10.9-12.7 HEM-02 5.6 5.3-6.2 HEM-03 15.9 15.1-17.5 HEM-04 13.9 13.2-15.3 HEM-05 9.7 9.4-10.9 Granulocytes (Hem-3) % Sample Reported Expected HEM-01 67.4 66.0-70.5 HEM-02 44.3 38.9-46.6 HEM-03 83.6 81.6-84.8 HEM-04 81.2 77.3-82.9 HEM-05 68.2 66.1-69.8 Monocytes/Mids (Hem-3) % Sample Reported Expected HEM-01 5.0 3.1-7.7 HEM-02 5.4 1.0-10.1 HEM-03 3.3 2.7-4.8 HEM-04 7.3 6.0-9.0 HEM-05 5.7 3.8-7.9 Lymphocytes (Hem-3) % Sample Reported Expected HEM-01 27.6 23.0-29.7 HEM-02 50.3 45.2-57.1 HEM-03 13.1 11.3-14.7 HEM-04 11.5 10.6-14.2 HEM-05 26.1 23.1-29.0 Platelet Count (Hem-3) 10^9 per liter Sample Reported Expected HEM-01 223 165-276 HEM-02 65 48-80 HEM-03 513 387-647 HEM-04 131 95-159 HEM-05 335 267-446 II. API 1st event 2018 A. Review of API PTdocumentation for hematology in the first event of 2018 showed scores of 0% for all analytes, marked "failure to participate." B. In an interview at the site on 06-15-2018, the technical consultant stated proficiency testing was performed by testing person 1 before the due date (03-30-2018) and results recorded on manual sheets held for electronic submission, but forgotten until the due date had passed. This information is also noted on the performance review and corrective action form for that event. C. An examination of the instrument printouts and manual submission worksheets showed results for testing performed 03-19-2018 as follows: White Cell Count (Hem-3) 10^9 per liter Sample Reported Expected HEM-01 2.2 1.8-2.6 HEM-02 8.2 6.8-9.3 HEM-03 21.1 17.2-23.3 HEM-04 19.0 16.1-21.9 HEM-05 3.6 3.0-4.2 Red Cell Count (Hem-3) 10^12 per liter Sample Reported Expected HEM-01 1.84 2.06-2.33* HEM-02 3.56 3.89-4.39* HEM-03 4.59 4.85-5.48 * HEM-04 3.10 3.41-3.86* HEM-05 5.39 5.85-6.61* * indicates result out of expected range Hematocrit (Hem-3) % Sample Reported Expected HEM-01 15.2 16-19* HEM-02 31.0 32-38* HEM-03 41.8 43-50* HEM-04 26.1 27-32* HEM-05 47.1 49-56* * indicates result out of expected range Hemoglobin (Hem-3) grams per deciliter Sample Reported Expected HEM-01 5.4 5.1-6.0 HEM-02 11.0 10.7-12.4 HEM-03 15.3 14.5-16.8 HEM-04 9.6 9.2-10.7 HEM-05 16.6 16.0-18.5 Granulocytes (Hem-3) % Sample Reported Expected HEM-01 45.8 42.1-49.9 HEM-02 69.1 67.5-72.5 HEM-03 84.5 82.4-86.2 HEM-04 70.0 68.4-71.8 HEM-05 82.0 76.5-85.7 Monocytes/Mids (Hem-3) % Sample Reported Expected HEM-01 3.9 1.1-8.2 HEM-02 3.6 2.1-5.6 HEM-03 2.8 2.0-4.2 HEM-04 3.4 2.2-6.2 HEM-05 5.0 3.1-6.6 Lymphocytes (Hem-3) % Sample Reported Expected HEM-01 50.3 44.2-54.3 HEM-02 27.3 23.3-28.9 HEM-03 12.7 11.0-14.1 HEM-04 26.5 23.1-28.2 HEM-05 13.0 10.3-17.5 Platelet Count (Hem-3) 10^9 per liter Sample Reported Expected HEM-01 63 50-85 HEM-02 194 167-280 HEM-03 448 383-640 HEM-04 310 257-429 HEM-05 110 89-150 PT documentation showed no evidence of corrective or remedial action for out of range results for red cell count (0% acceptable) or hematocrit. (0% acceptable) .
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

	This STANDARD is not met as evidenced by: . Based on review of API PT documentation for 2017 and 2018 and staff interview, the laboratory failed to return hematology PT testing results to API within the acceptable time frame in the first event 2017 and the first event 2018, resulting in unsatisfactory PT performance. I. API 1st event 2017 A. Review of API PTdocumentation for the first event of 2017 showed scores of 0% for all analytes, marked "failure to participate": Refer to D 2121 II . II. API 1st event 2018 A. Review of API PTdocumentation for the first event of 2018 showed scores of 0% for all analytes, marked "failure to participate": Refer to D2121 IV.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of API PT testing performance in hematology for 2016, 2017 and 2018, the laboratory failed to achieve satisfactory performance for the following analytes in the specialty of hematology for two out of three consecutive testing events: Analyte Event Score 0760 Hematology 1st 2017 0% 1st 2018 0% 0765 WBC diff 3rd 2016 0% 1st 2017 0% 1st 2018 0% 0775 RBC count 1st 2017 0% 2nd 2017 20% 1st 2018 0% 0785 HCT 1st 2017 0% 1st 2018 0% 0795 HGB 1st 2017 0% 1st 2018 0% 0805 WBC 1st 2017 0% 1st 2018 0% 0815 Platelets 1st 2017 0% 1st 2018 0% .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of quality control (QC) documentation for 2017 and 2018, surveyor observation and staff interview, the laboratory failed to employ control procedures to monitor the accuracy of test performance in hematology over time. Findings: 1. Review of hematology QC records for 2017 and 2018 showed from 02-13-2017 to the time of the survey, documentation consisted of individual instrument printouts of daily QC only. A cumulative report dated 02-13-2017 including a graphic representation of results for the previous control lot (Levy-Jennings plot) was found; when requested, cumulative reports for subsequent lot numbers were not offered. 2. In an interview at the site on 06-15-2017, the technical consultant stated that a testing person no longer employed at the laboratory had printed the cumulative QC records at

	lot change on 02-13-2017, and since that time the practice had ceased. 3. Review of representative QC results for Cell-Dyn 18 Plus hematology controls lot 7352, in use 01-08-2018 to 03-29-2018, revealed that the control values for erythrocyte count (RBC) and hematocrit (HCT) in levels low (L) normal (N) and high (H) were below the manufacturer's assay means when initially put in use and trended lower through the time they were in use. 4. Review of instrument printouts for testing of API PT samples in the first event of 2018 dated 03-19-2018 showed the laboratory's results for RBC and HCT (HEM-01, HEM-02, HEM-03, HEM-04 and HEM-05) were all out of expected range low. Refer to D 2123 (C). .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on surveyor observation and review of quality control and proficiency testing documentation, the laboratory director failed to fulfill his responsibilities regarding adherence to PT reporting deadlines and PT result review and evaluation. Refer to D 6017 and D 6018. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: . Based on review of API PT documentation for 2017 and 2018, confirmed by staff interview, the laboratory director failed to ensure that proficiency testing results for hematology were returned within the program's established timeframes. Refer to D 2127 I, II. .
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: . Based on review of API PT documentation for hematology testing in the second event 2017 and first event 2018, the laboratory director failed to ensure that proficiency testing reports were reviewed and evaluated to identify problems requiring corrective action. Refer to D2121 (B) and D2123 (C). .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of hematology quality control documentation for 2017 and 2018, surveyor observation and staff interview, the laboratory technical consultant failed to fulfill her responsibilities regarding establishment of a quality control program that ensured acceptable levels of analytic performance. Refer to D 6042. .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: . Based on review of hematology quality control documentation for 2017 and 2018, surveyor observation and staff interview, the laboratory technical consultant failed to establish a quality control program that ensured acceptable levels of analytic performance. Refer to D 5441.