Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0228831	**(X3) Date Survey Completed** 06/12/2019
Name of Provider or Supplier Arthritis Consultants Of Tidewater	**Street Address, City, State** 933 First Colonial Road Suite 100, Virginia Beach, VA	
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	An announced CLIA recertification survey was conducted at Arthritis Consultants of Tidewater on June 12, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, and an interview, the laboratory failed to rotate PT among personnel performing Complete Blood Count (CBC) patient testing during the twenty-four (24) months reviewed. Findings include: 1. Review of the CMS 209 form revealed three (3) testing personnel (TP) performed patient CBC testing. 2. Review of the laboratory's 2017 (Event 3), 2018 (Event 1, 2, 3), and 2019 (Event 1) American Proficiency Institute (API) PT documentation, a total of five (5) events, revealed that TP A performed 5 of the 5 reviewed testing events. (See Personnel Code Sheet.) 3. In an interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
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 a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel for one (1) of five (5) events reviewed. Findings include: 1. Review of the laboratory's 2017 (Event 3), 2018 (Event 1, 2, 3), and 2019 (Event 1) American Proficiency Institute (API) PT documentation, a total of five (5) events, revealed: 2019 Event 1: no signed attestation statements by LD or testing personnel. The inspector requested to review the attestations for the event listed above. No documentation was available for review. 2. In an interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
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 a review of manufacturer's hematology instrument operations manual, maintenance records, and an interview, the laboratory failed to perform and document a required semi-annual maintenance procedure for twenty-four (24) of 24 months reviewed. Findings include: 1. Review of the Abbott Emerald Operations Manual revealed semi-annual maintenance instructions that stated: "For optimal operation, the syringe pistons are to be lubricated every six months". 2. Review of the laboratory's Emerald hematology maintenance logs revealed no documentation of the semi-annual maintenance performed during the review timeframe of June 2017 to the date of the survey on 6/12/19. The inspector requested documentation of the semi-annual maintenance procedure. The primary testing personnel stated "We have never performed the semi-annual maintenance. I was not aware that it was required". 3. In an interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of policies and procedures, hematology monthly Quality Control (QC) records from October 2017 to May 2019, and an interview, the laboratory failed to follow their policy for QC statistics review in order to monitor, assess and correct problems with the Abbott Emerald analyzer and complete blood count (CBC) Cell Dyn 18 Plus QC materials for two (2) of nineteen (19) months reviewed. **Repeat Deficiency Findings include: 1. Review of the laboratory's policies and procedures revealed a Lab Services QA policy to monitor, assess and correct problems with the Abbott Emerald hematology analyzer that outlined that the laboratory director (LD) was to review Cell Dyn Plus QC data on a monthly basis. The QA policy in the procedure manual stated "the lab is to print the Emerald QC statistical data log on a monthly basis. The lab director will review and sign to document." 2. Review of the laboratory's monthly QC folders from October 2017 through May 2019, revealed no monthly QC data logs or LD signature indicating review for: April 2018, January 2019. The inspector requested to review the printed Levey-Jennings (LJ) data logs for the months outlined above. No LJ data log statistical reports were available for review upon request. 3. In an interview with the primary testing personnel at approximately 1: 30 PM, the above findings were confirmed.
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 a review of the laboratory's American Proficiency Institute proficiency testing (PT) results, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, and an interview, the laboratory director failed to: 1. document review of the laboratory's performance in hematology PT on two (2) of five (5) events during the twenty-four (24) months reviewed; 2. ensure annual hematology competency evaluations for one (1) of the three (3) testing personnel in calendar year 2018 was performed. See D6018, D6054. (**REPEAT DEFICIENCY)
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 a review of proficiency testing (PT) results and an interview, the laboratory director (LD) failed to document review of the laboratory's performance in

	hematology PT on two (2) of five (5) events during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's 2017 (Event 3), 2018 (Event 1, 2, 3), and 2019 (Event 1) American Proficiency Institute PT documentation revealed no documentation of review of results by the LD for: 2018 Event 2, 2019 Event 1. The inspector requested to review the documentation of review for the PT events outlined above. No record was available. 2. In an interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to perform annual hematology competency evaluations for one (1) of the three (3) testing personnel in calendar year 2018. **Repeat Deficiency Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performed the duties of TC and 3 testing personnel (TP) performed patient Complete Blood Count (CBC) testing. 2. Review of the laboratory personnel files revealed that testing personnel A lacked a 2018 annual hematology CBC competency evaluation. (See Personnel Code Sheet.) The inspector requested to review the 2018 annual competency assessment for TP A. No record was available for review. 3. In an interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.