Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0228831	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Consultants Of Tidewater	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 September 8, 2021 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 and include the Condition under 42 CFR part 493 CLIA Regulation: D6000 -42 CFR. 493.1403 Laboratory Director.
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 laboratory's 2019 Department of Health and Human Services Centers for Medicare and Medicaid Statement of Deficiencies and Plan of Correction form (CMS 2567), 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-seven (27) months reviewed. **REPEAT DEFICIENCY Findings include: 1. During pre-survey record review, the inspector noted the laboratory director's (LD) submitted CMS 2567 of the previous recertification (June 12, 2019) revealed the following statement: "ACT (Arthritis Consultants of Tidewater) has not taken the steps to require and implement the consistent rotation of all testing personnel in proficiency testing." 2. Review of the CMS 209 form revealed that the lab director identified three (3) testing personnel (TP) responsible for reporting patient CBC testing during the survey timeframe of June 2019 to September 2021. 3. Review of the laboratory's American Proficiency Institute

	(API) PT documentation, a total of seven (7) events, revealed: TP A performed 7 of the 7 reviewed API testing events (2019 Event 3, 2020 Events 1-3, 2021 Events 1-2). (See Personnel Code Sheet.) 4. In an interview with the primary testing personnel on 9 /8/21 at approximately 1:30 PM, the above findings were confirmed.
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 a review of quality control (QC) records, lack of documentation, and an interview, the laboratory failed to retain manufacturer's assay package inserts for ten (10) of 10 hematology QC lot numbers utilized for evaluating the precision/accuracy of the Complete Blood Count (CBC) analyzer in the twenty-seven (27) months reviewed. Findings include: 1. Review of the laboratory's Abbott Emerald analyzer QC records from June 2019 through the date of the survey on 9/8/21 revealed the following 10 Cell Dyn Plus QC lot numbers (#) and dates placed in use: #9126 (8/23 /19), #9294 (10/28/19), #9210 (11/15/19), #0013 (2/10/20), #0097 (6/30/20), #0181 (7 /6/20), #0265 (10/5/20), #0349 (12/22/20), #1067 (3/22/21), #1151 (6/11/21). 2. The inspector requested to review the Abbott assay information sheets for the 10 QC material lot numbers outlined above. The documentation was not available for review. 3. In an interview with the primary testing personnel on 9/8/21 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 2019 Department of Health and Human Services Centers for Medicare and Medicaid Statement of Deficiencies and Plan of Correction form (CMS 2567), Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and an interview, the laboratory director failed to ensure annual hematology competency evaluations were performed according to established plan of correction protocol for two of the three testing personnel in calendar year 2020 and 2021 (Cross reference D6054 *REPEAT DEFICIENCY).
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 laboratory's 2019 Department of Health and Human Services Centers for Medicare and Medicaid Statement of Deficiencies and Plan of Correction form (CMS 2567), 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 two (2) of three (3) testing personnel (TP) in calendar years 2020 and 2021. **REPEAT DEFICIENCY Findings include: 1. During pre-survey record review, the inspector noted that the laboratory director's (LD) submitted plan of correction for citations found during the previous recertification survey on June 12, 2019 revealed the following statement: "The LD recognizes the need for evaluating and documenting the competency performance of individuals responsible for moderate complexity testing at least annually by the LD for all TP". 2. Review of the CMS 209 form revealed that the LD also performed the duties of TC and 3 TP were identified as responsible for performing patient Complete Blood Count (CBC) testing during the review timeframe of June 2019 to September 2021. 3. Review of the laboratory personnel files revealed: TP A and TP B's annual hematology CBC competency evaluations completed in calendar years 2020 and 2021 were signed by the practice's licensed practical nurse. (See Personnel Code Sheet.) The inspector requested to review documentation that the director in his role as TC had participated in the competency evaluations per the accepted 2019 plan of correction outlined above. No record was available for review. 4. In an interview with the primary testing personnel on 9/8/21 approximately 1:30 PM, the above findings were confirmed.