

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2035409	<b>(X3) Date Survey Completed</b>  07/23/2025
<b>Name of Provider or Supplier</b>  Arthritis Care And	<b>Street Address, City, State</b>  15525 Pomerado Rd Ste E6, Poway, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with Testing Personnel (TP) on July 23, 2025, it was determined that the laboratory director failed to approve, sign, and date procedures and changes in procedures. The findings included: 1. It was the practice of the laboratory to perform high complexity testing in the subspecialty of general immunology. 2. On July 23, 2025, at approximately 10:00 a.m., the TP confirmed that the laboratory director did not sign and date the policies and procedure manuals. The procedures were only signed by the testing personnel, and some were signed by the previous laboratory director. 3. The laboratory's testing declaration form, signed by the laboratory director on July 21, 2025, stated that the laboratory performed approximately 7,000 general immunology tests annually.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals, manufacturer instructions, turnaround times for 100 specimens, and an interview with Testing Personnel (TP) on</p>

July 23, 2025, it was determined that the laboratory did not comply with the manufacturer's instructions regarding specimen storage conditions. The findings included: 1. It was the practice of the laboratory to measure IgM, IgG, and IgA Isotypes of Rheumatoid Factor (RF), single-stranded DNA (ssDNA), double-stranded DNA (dsDNA), Sm, RNP/Sm, SSA (Ro), SSB (La), Histone, Scl-70, Jo-1, Ribosomal Protein P, Centromere, and Chromatin (Nucleosomes) using test kits EL-ANA profiles TM and EL-RF/3TM from the manufacturer Thera Test Labs. According to the manufacturer manual, "Serum samples may be stored at 2-8C for up to 14 days prior to testing" for both panels. For EL-RF/3TM: "After 14 days, re-draw serum samples. DO NOT FREEZE unseparated blood." For EL-ANA profiles TM: "Freeze-thawing sera may cause variable loss of autoantibody activity." 2. The review of the random patient specimen log for 2023, 2024, and 2025 revealed that the laboratory failed to complete 40 of 100 tests within 14 days. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. Examples of randomly selected samples are shown below: ACC# Collection Date Analysis Date G278 12/11/2023 01/11/2024 H110 07/09/2024 07/30/2024 H039 12/12/2024 03/05/2024 1051 05/20/2025 06/28/2025 3. On July 23, 2025, at 11:00 a.m., the TP confirmed that samples were not analyzed within 14 days and were stored frozen during that time. 4. The laboratory's testing declaration form, signed by the laboratory director on July 21, 2025, stated that the laboratory performed approximately 7,000 general immunology tests annually.

**D5801**

**TEST REPORT**  
CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:  
Based on a review of the specimen log and turnaround times (TNT) for 100 specimens and an interview with Testing Personnel (TP) on July 23, 2025, it was determined that the laboratory did not ensure the tests were reported in a timely manner. The findings included: 1. It was the practice of the laboratory to perform general immunology testing. The laboratory manual stated, "TNT for all in-house labs can take up to 21 business days to process, not to exceed 30 days." 2. The review of the random patient specimen log for 2023, 2024, and 2025 revealed that the laboratory failed to process 24 of 100 tests within 21 days and 6 of 100 tests within 30 days. 3. The laboratory's testing declaration form, signed by the laboratory director on July 21, 2025, stated that the laboratory performed approximately 7,000 general immunology tests annually.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently,

and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on an interview with Testing Personnel (TP), review of policies and procedures manuals, manufacturer instructions, test report turnaround times on July 17, 2025, the laboratory Director (LD) failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings included: 1. The LD failed to ensure that laboratory procedures followed the manufacturer's specimen storage instructions. See D5411 2. The LD failed to approve, sign, and date procedures and changes in procedures. See D5407 3. The LD failed to ensure that the tests were reported in a timely manner. See D5801

**D6100**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(10)

(e)(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(5);

This STANDARD is not met as evidenced by:  
Based on an interview with Testing Personnel (TP) and a review of five (5) randomly selected patient testing records on July 23, 2025, it was determined that the laboratory director did not ensure that the general supervisor (GS) provided on-site supervision of high complexity tests performed by the TP. The findings included: 1. The laboratory operates as a physician office laboratory. It has been the practice of the laboratory to conduct high complexity testing during weekends using Non-CLS Testing personnel without licensed personnel supervision. 2. On July 23, 2025, at 11:30 a.m., the TP confirmed that he performed testing on the weekend without supervision by the general supervisor. 3. The laboratory's testing declaration form, signed by the laboratory director on July 21, 2025, stated that the laboratory performed approximately 7,000 general immunology tests annually.