

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2083982	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Arthritis Care Specialist Of Md	Street Address, City, State 6350 Stevens Forest Rd Suite 101, Columbia, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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 the manufacturer's product insert, patient worksheets, and interview with the technical consultant (TC), the laboratory failed to follow the manufacturer's instructions for testing general immunology specimens within the required 14 days of collection. Findings: 1. The manufacturer's product insert for the "Thera Test Labs Innovations in Immunoassays" for "EL-ANA Profiles" states "Serum samples may be stored at 2-8C [degrees Celsius] for up to 14 days prior to testing." 2. The patient worksheets were reviewed. On 04/27/2021 a specimen was collected and the serum was stored at 2-8C until 05/05/2021 when it was tested. The documentation included some questions about the validity of the test result and the specimen was stored at 2-8C until it was retested on 05/13/2021. The specimen was tested and the results released 19 days after collection. 3. During the survey on 02/08/2023 at 12:30 PM, the TC confirmed that the specimen was tested and the results released after the 14 day limit required by the manufacturer and there were no procedures in effect to ensure that a specimen that needed to be retested was not held and retested past the 14 day limit.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and</p>

identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patients' final reports and interview with the technical consultant (TC), the laboratory failed to ensure that the final test report listed the date the test was performed. Findings: 1. The TC explained that some of the immunology and chemistry specimens that are collected are batched and the testing is performed up to 14 days after collection. 2. During the survey patient results were pulled from the electronic medical record (EMR) to review the final report with the patients test results. Review of the reports showed that the final report failed to include the date that the testing was performed for immunology and chemistry specimens not tested on the day of collection. 3. During the exit interview on 02/08/2023 at 12:30 PM, the TC confirmed that the final report failed to include the date that the testing was performed for immunology and chemistry specimens not tested on the day of collection.