

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2083982	(X3) Date Survey Completed 10/16/2024
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the technical supervisor (TS), the laboratory's procedures did not include instructions for the most current labeling practices employed for general immunology specimens. Findings: 1. Patient specimens stored in the refrigerator for general immunology testing were labeled with a green sticker. 2. The TS explained that all the general immunology specimens were labeled with the green sticker to ensure that if additional testing was performed on the specimens, for example chemistry, the personnel would be sure to store the specimen for general immunology testing. 3. During the survey on 10/09/2024 at 2:00 PM, the TS confirmed that although the labeling procedure for immunology specimens was written up as a corrective action, the laboratory's procedure manual was not updated.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.</p>

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's procedure, review of temperature records, and interview with the technical supervisor (TS), the laboratory failed to ensure that incubation temperatures for rheumatoid factor (RF) immunoglobulin G (IgG) testing were within the manufacturer's acceptable range. Findings: 1. The manufacturer's instructions stated "For the measurement of RF-IgG, the sample is first digested with pepsin. This enzyme destroys RF-IgM and a large portion of RF-IgA activity." The instructions then stated that samples with pepsin should be "placed in a 37C incubator or water bath for 2-3 hours." 2. The "Monthly RF3 Incubator Temperature Log" (temperature log) listed the acceptable incubation temperature range as 35-40C. 3. Temperature logs for 2023 were reviewed and showed that the incubator temperatures were outside of the acceptable range on 29 of 29 days documented. 4. During the survey on 10/09/2024 at 2:15 PM, the TS confirmed that the incubation temperature for RF-IgG samples was increased after working with the manufacturer to optimize the assay. The TS also confirmed that there was no written update to the manufacturer's procedure and the laboratory did not update the template for their temperature log.

D5427

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(c)

(c) Documentation. The laboratory must document all activities specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the chemistry validation documentation and interview with the technical supervisor (TS), the laboratory failed to ensure there were written procedures for the validation activities performed when a new chemistry analyzer was installed. Findings: 1. The laboratory installed and validated a new chemistry analyzer in 10/2023. 2. All the raw data was maintained in a binder, but there was no documentation explaining how the validation was performed, what the acceptability criteria for each performance specification was, and whether the laboratory's validation results met the acceptability criteria. 3. During the survey on 10/09/2024 at 2:00 PM, the TS confirmed that there was no written documentation detailing how the chemistry validation was performed, what the acceptance criteria was, and whether the laboratory's results met acceptance criteria.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical supervisor (TS), the laboratory director failed to ensure that quality assessment (QA) activities

were able to be performed in a timely manner to ensure the quality of laboratory testing. Findings: 1. Review of corrective action forms showed that even though events from 09/2023 were resolved in real-time, the forms were not completed until 06/2024. 2. Review of proficiency testing (PT) records showed that PT results from the 1st event released at the end of 03/2024 and the 2nd event released at the end of 06/2024 were not reviewed until 09/2024. 3. Linearity for general immunology testing is required every 6 months. The linearity performed in 2023 was performed late so that it was 8 months after the previously performed linearity and 9 months prior to the next performed linearity (which was performed on time). 4. The laboratory employed one part-time testing person and one full-time testing person who was also the TS and the general supervisor. All QA activities were performed by the TS and then presented to the laboratory director for review. 5. During the survey on 10/09/2024 at 2:50 PM, the TS confirmed that they performed and documented QA activities when they were able to designate time outside of testing patient samples and that as a result, some of the QA activities were not completed in a timely manner.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the technical supervisor (TS), the laboratory failed to ensure that competency assessments were performed and were performed by qualified personnel. Findings: 1. The laboratory performed moderate complexity testing for chemistry and hematology and high complexity testing for general immunology. 2. The Laboratory Personnel Report (CLIA form CMS-209) listed two testing personnel (TP). TP #1 performed moderate and high complexity testing and was listed as the TS and general supervisor. TP #2 performed moderate complexity testing only. 3. The last competency assessment performed for TP #1 for general immunology testing was completed on 12/15/2021. There was no documentation of a competency assessment performed for general immunology for 2022 or 2023. 4. The competency assessments performed on TP #1 in 2022 and 2023 for chemistry and hematology testing, were performed by TP #2. 5. Credential documentation received via email on 10/16/2024 showed that TP #2 was not qualified to perform the moderate complexity competency assessments as a technical consultant. 6. During the survey on 10/09/2024 at 10:30 AM, the TS confirmed that a competency assessment for general immunology was not performed in 2022 or 2023 because there were no other personnel qualified to perform the competency assessment for high complexity testing.