

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0929322	(X3) Date Survey Completed 07/28/2023
Name of Provider or Supplier Rheumatology Associates Of Balto Llc	Street Address, City, State 1220b East Joppa Rd #310, Baltimore, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has four TP listed on the "Laboratory Personnel Report" (CMS-209) who perform hematology, chemistry, and immunology testing. Three of the four TP have performed laboratory testing since 2021. One TP recently ceased testing in the laboratory and was not included on the current CMS-209, but was employed during the PT testing events reviewed in 2022 and 2023. 2. A review of hematology, chemistry, and immunology PT attestation worksheets from 2022 and 2023 showed that PT was performed by the same TP who recently left the lab for four of four events in hematology, five of five events in chemistry, and four of four events in immunology. 3. During an interview on 07/20/2023 at 1:30 PM, the TC confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on quality control (QC), instrument, and patient record review and interview with the technical consultant (TC), the laboratory failed to retain analytic systems and patient records for at least two years. Findings: 1. A review of analytic records showed that the laboratory did not have instrument printouts and intermediate records of all QC and patients run in the last two years. During an interview at 1:30 PM on the day of the survey, the TC stated that the laboratory discards the instrument printouts after keeping them for a few weeks. 2. Upon investigation the TC stated that the hematology instrument printouts for patients and QC were available for May 2023 to present. The hematology analyzer maintained an electronic copy of QC and patient runs from January 2023 to present. No record of individual QC and patient runs were available before January 2023. 3. The TC also stated that the chemistry instrument printouts for QC and calibrations performed were available for May 2023 through present, however that the chemistry analyzer did not print out individual patient runs. The TC stated that the chemistry analyzer's internal memory was capable of storing 2000 reports, but did not store patient records for at least two years due to the volume of testing performed in the laboratory. 4. A review of chemistry reagent logs showed that the lab had one "Reagent Log" which documented the lot numbers and expirations dates of reagents used to perform chemistry testing from 07/17/2023 to 07/20/2023. In an email communication dated 07/28/2023 the TC stated, "I have not yet found out how long the data on the lot numbers of the controls are kept in the Chemistry Analyzer." 5. During an interview on 07/20/2023 at 1:30 PM, the TC confirmed that the laboratory did not retain all analytic systems records for at least 2 years.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
 Based on observation and interview with the technical consultant (TC), the laboratory did not ensure that hematology controls were labeled with the date that they are put in to use or expire. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the opened and in use "Cell-Dyn 18 Plus" hematology controls in the laboratory refrigerator (lot # L3149, expiration date 09/15/2023) were not labeled with the date that they were put in to use or with the expiration date. A review of manufacturer instructions showed that the hematology controls expire 8 days after opening. 2. During an interview on 07/20/2023 at 1:30 PM, the TC confirmed that the in-use hematology controls were not labeled with the opened or expiration date.

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 instrument maintenance record review and interview with the technical consultant (TC), the laboratory did not ensure that monthly maintenance was performed and documented on the hematology and chemistry analyzers as recommended by the manufacturer. Findings: 1. The laboratory uses a Cell-Dyn Emerald hematology analyzer to perform CBC (complete blood cell count) analysis. The monthly "Emerald CBC Maching" maintenance log shows that every month the laboratory should perform "Monthly Bleaching/cleaning." 2. A review of monthly hematology analyzer maintenance records from January through June 2023 showed that monthly instrument cleaning was not documented for four out of six months. 3. The laboratory uses an ACE Axcel chemistry analyzer to perform chemistry testing. The monthly "ACE Axcel Clinical Chemistry System Maintenance Log" shows that every month the laboratory should perform four maintenance tasks. 4. A review of monthly chemistry analyzer maintenance records from January through June 2023 showed that four out of four monthly tasks were not documented for two out of six months. 5. During an interview on 07/20/2023 at 1:30 PM, the TC confirmed that monthly hematology and chemistry analyzer maintenance was not documented as recommended by the manufacturer.