| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D0312538 | 07/10/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Rheumatology Consultants, Pllc | 4707 Papermill Dr, Suite 200, Knoxville, TN | |

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 |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form, the laboratory's policy, personnel records, and staff interview revealed the laboratory's policy failed to include initial training and semi-annual competency evaluation as required in Subpart M of the State Operations Manual (SOM) Appendix C and failed to have documentation of semi-annual competency for one of seven testing personnel. Findings included: 1. A review of the submitted CMS-209 form listed seven testing personnel for moderate complexity testing. 2. A review of the laboratory's Quality Assurance Plan policy revealed the policy failed to include initial training and semi-annual competency assessments for testing personnel performing moderate complexity testing. 3. A review of laboratory personnel records revealed the following: -No documented semi-annual competency assessment for testing personnel seven (TP7) of seven as listed on the CMS-209 4. An interview with the office manager on 07.10.2025 at 10:50 a.m. confirmed the above survey findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) |

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| | Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Citation One Based on laboratory observation, review of the manufacturer's user guide, lack of documentation, and staff interview, the laboratory failed to monitor ambient temperature where complete blood count (CBC) patient testing occurred in 2024 through the survey date (07.10.2025). The findings include: 1. Observation of the laboratory on 07.10.2025 at 08:30 a.m. revealed a Sysmex XP-300 (serial number: B4859) hematology analyzer used for CBC patient testing. 2. A review of the manufacturer's user guide revealed the following environmental conditions for operating: ambient temperature: 15C to 30C. 3. The laboratory could not provide records of ambient temperature monitoring for January 2024 through the survey date of 07.10.2025. 4. An interview with the laboratory lead on 07.10.2025 at 8:50 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius Citation Two Based on laboratory observation, review of the manufacturer's user guide, laboratory environmental records, and staff interview, the laboratory failed to ensure relative humidity was within operating specifications for the Sysmex XP-300 hematology analyzer for five of the eighteen months reviewed in 2024 and 2025. Findings included: 1. Observation of the laboratory on 07.10.2025 at 08:30 a.m. revealed a Sysmex XP-300 (serial number: B4859) hematology analyzer used for Complete Blood Count (CBC) patient testing. 2. A review of the Sysmex XP-300 manufacturer's user guide stated the following in the section titled "Operating Environment": "Relative humidity: 30% - 85%" 3. A review of the laboratory environmental records (01.01.2024 through 06.30.2025) titled "Lab Humidity" revealed that the laboratory did not have a defined acceptable relative humidity range. The review also revealed the following days in 2024 and 2025 when the relative humidity was NOT within the manufacturer's operating specifications of 30%-85%: 01.12.2024: 29% 01.15.2024: 26% 01.18.2024: 20% 01.22.2024: 20% 01.23.2024: 20% 02.05.2024: 29% 02.16.2024: 27% 02.19.2024: 27% 02.20.2024: 27% 02.21.2024: 27% 02.22.2024: 27% 02.23.2024: 28% 12.05.2024: 27% 12.06.2024: 25% 01.02.2025: 29% 01.07.2025: 29% 01.08.2025: 25% 01.09.2025: 26% 01.10.2025: 25% 01.13.2025: 25% 01.14.2025: 26% 01.15.2025: 26% 01.16.2025: 25% 01.17.2025: 24% 01.20.2025: 24% 01.21.2025: 23% 01.22.2025: 22% 01.23.2025: 22% 01.24.2025: 22% 01.27.2025: 25% 01.28.2025: 25% 01.29.2025: 26% 03.03.2025: 25% 03.04.2025: 25% The laboratory failed to ensure acceptable relative humidity was within operating specifications for the Sysmex XP-300. 5. An interview with the laboratory lead on 07.10.2025 at 8:50 a.m. confirmed the above survey findings. Word Key: % = percent |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on observation of the laboratory, review of the manufacturer control package insert, and interview with the laboratory lead, the laboratory failed to label three of three control vials used for performing quality control on the Complete Blood Count (CBC) hematology analyzer with an open date and a corrected expiration date on the date of the survey (07.10.2025). The findings include: 1. Observation of the laboratory on 07.10.2025 at 8:30 a.m. revealed the Sysmex XP-300 CBC analyzer (Serial Number B4859) used for patient testing, and three levels: low [lot 51050710], normal [lot 51050711], and high [lot 51050712] of EightCheck-3WP X-TRA Sysmex controls that were not labeled with an open date and corrected expiration date. 2. A review of the manufacturer's control package insert revealed the following: "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C after being re-capped." 3. An interview with the laboratory lead on 07.10.2025 at 8:35 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius |