| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>51D2064579 | **(X3) Date Survey Completed**<br><br>12/19/2018 |
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| **Name of Provider or Supplier**<br><br>The Rheumatology Group Pllc | **Street Address, City, State**<br><br>4610 Kanawha Avenue Sw Suite 301, South Charleston, WV | |
| 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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| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing summary reports and interview with the General Supervisor and Testing Personnel, the laboratory failed to ensure that all General Immunology proficiency testing (PT) results were reviewed and evaluated for 2017 and 2018. Findings include: 1. The laboratory was enrolled and participating in College of American Pathologist (CAP) Special Immunology (S2) PT surveys for 2017 and 2018. The surveyor reviewed all challenges for 2017 and 2018. 2. The laboratory did not have documentation available demonstrating review and evaluation for the laboratory's PT results that received ungraded score (27 lack of consensus) or educational challenge (26) exception codes for Anti -DNA ds quant and Anti-Sm, quant. 3. Interview with the laboratory General Supervisor and Testing Personnel on 12/19/18 at approximately 11:30AM confirmed findings. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's quality assessment (QA) policy manual and |

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| | Quarterly QA Meeting documentation, and interview with testing personnel, the laboratory failed to establish an ongoing mechanism to monitor post-analytic systems for 2018. Findings include: 1. The surveyor reviewed the laboratory QA policies and corresponding QA documentation of Quarterly QA Meeting Summaries for 2018. While the laboratory did have evidence of monitors for the Pre-analytic System and Analytic systems, there was no documentation to support the laboratory had any policies or monitors in place that addressed assessment of the laboratory's post-analytic system. 2. Interview with the general supervisor on 12/19/2018 at approximately 11:45 AM confirmed the findings that a QA monitor was not in place to monitor testing reporting. The General Supervisor stated that once the test report was generated, it was handed off for the office staff to handle and chart. |