

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0230151	(X3) Date Survey Completed 10/18/2023
Name of Provider or Supplier Arthritis And Rheumatic Diseases Pc	Street Address, City, State 329 Mclaws Circle, Williamsburg, VA	
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
D0000	An announced CLIA recertification survey was conducted at Arthritis and Rheumatic Diseases, PC on October 17, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The inspection included an offsite interview and review of records with the practice manager on 10/18/23. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of hematology proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to record evaluation for eight (8) of 8 Complete Blood Count (CBC) analyte parameters scored/ reported as unsatisfactory on challenge sample #HD-2 by Medical Laboratory Evaluation (MLE) for 2022 Event M1. Findings include: 1. Review of three MLE 2022 PT events (M1-M3) revealed the following 8 analyte parameters reported as unacceptable on Event M1 challenge sample #HD-2: Lymphocyte Percent (%) reported as 42.5 outside acceptable range 8.6-15.6; Monocyte % reported as 17.6 outside acceptable range of 2.6-4.3; Granulocyte % reported as 39.9 outside acceptable range 80.8-88.2; White Blood Cell reported as 2.0 outside acceptable range 17.2-23.4; Red Blood Cell reported as 2.19 outside acceptable range 5.38-6.08; Hemoglobin reported as 5.8 outside acceptable range 17.1-19.8; Hematocrit reported as 15.4 outside acceptable range 48.2-54.4; Platelet reported as 69 outside acceptable range 409-683. 2. The inspector requested to review documentation that the laboratory evaluated the 8 unacceptable challenge results outlined above. Documentation was not available for review. 3. An interview with the practice manager on 10/17/23 at 1:30 PM confirmed the above findings.</p>

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of procedures, hematology quality control (QC) records, lack of documentation, and interviews, the laboratory failed to perform an evaluation of statistical analysis to identify possible shifts and trends for Complete Blood Count (CBC) testing on the Horiba ABX hematology instrument for twenty-one (21) of 21 months reviewed during timeframe of January 2022 to the date of the inspection on October 17, 2023. Findings include: 1. Review of the laboratory procedure manual revealed: Manufacturer's Quality Control and Peer Group Program protocol (dated 11/22/19) that outlined, "The QC Program will improve the management of QC using Horiba instrument. The Horiba QC Peer program includes automatic QC data uploaded in real time, peer review statistics by instrument, proactive monitoring and auto notification based on Westgard violations, easily identify data that is out of specification on demand peer and Levey-Jennings reports". Quality Assurance Procedure (dated 3/2/21) that stated, "End of Month Report- after the last day of the month, log into Horiba QC website to print monthly QC reports, attach to the maintenance log, turn into lead tech for Lab Director's signature". 2. A review of 2022 and 2023 hematology Horiba instrument's Tri Level QC materials (levels 1-3) revealed no available documentation of statistical analysis for the parameters of CBC testing (White Blood Cell, Red Blood Cell, Hemoglobin, Hematocrit, Platelet, Lymphocyte, Monocyte, Granulocyte Neutrophil) during the timeframe of January 2022 to the date of the inspection 10/17/23. The inspector requested documentation. No records were available. The practice manager stated on 10/17/23 at 1:00 PM: "I would defer to our lead lab tech for this issue. I am not sure why the Levey Jennings charts are missing for those months." In a follow up interview on 10/18/23 at 4:55 PM, the practice manager stated, "I was able to contact Horiba and found that the QC data was uploaded. They helped me to access the reports." 3. The inspector reviewed QC Levey Jennings charts provided by the practice manager via an email scan on 10/18/23. The ten reports provided did not include date of assays nor were the review /date attestation pages signed by the lab director. 4. An exit offsite interview with the practice manager on 10/18/23 at 5:15 PM confirmed the above findings