

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0230151	(X3) Date Survey Completed 01/20/2022
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 January 20, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory technical consultant (TC) failed to document annual hematology competency assessments for Complete Blood Count (CBC) testing for four (4) of five (5) testing personnel (TP) in calendar years 2020 and 2021. Findings include: 1. Review of the CMS 209 form and personnel files revealed that the Laboratory Director (LD) qualified/served as the TC and identified 5 TP (A-E) as responsible for performing patient CBC testing during the twenty-six (26) months reviewed (timeframe October 2019 to 1/20/22). See Personnel Code Sheet. 2. Review of the following laboratory personnel files revealed 2020 and 2021 competency assessments for CBC testing: TP B - CBC Skills Check List performed/signed by TP A TP C - CBC Skills Check List performed/signed by TP B TP D - CBC Skills Check List performed/signed by TP B TP E - CBC Skills Check List performed/signed by TP B The inspector noted that TP A and B did not meet the qualification requirements for TC duties and requested to review competency assessment documentation evaluated by the director (as TC) for the 2020 and 2021 records outlined above. The documentation was not available for review. The office manager and assistant office</p>

manager stated at approximately 11:00 AM on 1/20/22: "We were not aware that the lab director should be the person evaluating the competency assessments for the testing staff." 3. An exit interview with the office manager and assistant office manager on 1/20/22 at approximately 11:30 AM confirmed the above findings.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:
Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical consultant (TC) failed to document annual hematology competency assessments that included evaluation of problem solving skills for five (5) of 5 testing personnel (TP) in calendar years 2020 and 2021. Findings include: 1. Review of the CMS 209 revealed that the lab director (LD) performs the duties of TC and 5 TP qualified/responsible for patient hematology testing during the review timeframe of October 2019 to 1/20/22. 2. Review of the 2020 and 2021 laboratory personnel files revealed no Horiba ABX hematology analyzer competency assessments that included the competency procedure of problem solving skills for TP A-E. (See Personnel Code Sheet.) The inspector noted the personnel files included a Complete Blood Count (CBC) Skills Check Sheet for each TP outlining direct observation of CBC testing and requested to review additional competency procedures documentation. No additional documentation was available for review. 3. An exit interview with the office manager and assistant office manager on 1/20/22 at approximately 11:30 AM confirmed the above findings.