

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0910650	<b>(X3) Date Survey Completed</b>  03/27/2025
<b>Name of Provider or Supplier</b>  Jackson Clinic Pa South, The	<b>Street Address, City, State</b>  1893 South Highland Avenue, Jackson, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory procedure, laboratory personnel records, lack of records, final patient test reports, and staff interviews, the laboratory failed to follow the testing personnel (TP) competency assessment policy for two of two new TP reviewed in 2024. The findings include: 1. An observation of the laboratory on 03/27/2025 at 9:30 am revealed the following used for patient testing: Sysmex XP300 (Serial B3614) instrument used for Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) patient testing. Polymedco Pathfast (Serial 1906D3546) instrument used for Troponin I, N-terminal B-Type Natriuretic Peptide (NTproBNP), and fibrin degradation (D-dimer) patient testing. Microscope used for urine microscopy, vaginal wet prep, and manual White Blood Cell Differential (WBC Diff) patient testing. 2. A review of Form CMS-209 revealed two new testing personnel (TP three and TP four) since the previous survey, conducted on 01/23/2024. 3. A review of the laboratory Quality Assessment procedure in section six titled "Personnel Assessment" revealed that "The Technical Consultant, Technical Supervisor, and/or General Supervisor will evaluate and document competency of personnel responsible for testing at least semiannually during the first year the individual tests patient specimens." The "Aspect of Care: Training" section revealed that "Each technical position will have specified job duties and a checklist to ensure each duty or performance level is attained before releasing the employee from the department training program. The written result/checklist of the training will be filed</p>

in the individual's personnel file". 4. A review of the laboratory personnel records revealed the following: TP three: Documentation of training and semiannual competency assessments was not available for any test system for 2024 on the survey date (03/27/2025). TP four: Documentation of training and semiannual competency assessments was not available for any test system for 2024 on the survey date (03/27/2025). 5. A review of final patient test reports revealed the following: TP three reported urine microscopy test results on patient 5560420 on 07/29/2024 at 9:42 am. TP four reported urine microscopy test results on patient 157073 on 06/03/2024 at 12:04 pm. 6. An interview with the laboratory technical consultant on 03/27/2025 at 3:00 pm confirmed that the laboratory failed to follow the laboratory procedure in 2024 when TPs three and four performed patient testing and did not have documented training or semiannual competency assessments. Word Key: CLIA- Clinical Laboratory Improvement Amendments

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, lack of records, review of the final patient test report, and staff interviews, the laboratory failed to compare the White Blood Cell Differential (WBC Diff) performed using automated and manual methods in 2024. The findings include: 1. Observation of the laboratory on 03/27/2025 at 9:30 am revealed the following: Sysmex XP300 (Serial B3614) instrument used for automated WBC Diff patient testing. Microscope and stain used for manual WBC Diff patient testing. 2. Documentation for the WBC Diff performed by the automated method compared to the manual method in 2024 was not available on the survey date (03/27/2025). 3. A review of final patient test reports revealed the following: Automated WBC Diff reported for patient 2173375 on 04/12/2024 at 8:22 am. Manual WBC Diff reported for patient 4583530 on 09/09/2024 at 1:00 pm. 4. A telephone interview with the laboratory technical consultant on 03/31/2025 at 4:35 pm confirmed the survey findings.