

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0029144	<b>(X3) Date Survey Completed</b> 08/16/2023
<b>Name of Provider or Supplier</b> Jackson Clinic, Pa North Convenient Care, The	<b>Street Address, City, State</b> 2859 Highway 45 Bypass, 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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on observations of the laboratory, review of quality control (QC) records, and staff interview, the laboratory failed to retain the "MC ENTRY CARD" that comes in each box of reagent for the PATHFAST instrument resulting in the laboratory not being able to tie the box lot number (as printed on the control data sheet), and corresponding QC ranges, to the lot number on the QC printouts. The findings include: 1. Observation of the laboratory on 08/16/23 at 8:40 am revealed the Polymedco PATHFAST instrument in use for patient testing for Troponin I, B-Type Natriuretic Peptide (NT-ProBNP), and Fibrin Degradation Product (D-Dimer). 2. Observation of a box of test cartridge reagents on 08/16/23 at 1:30 pm revealed the following: Each box of reagent comes with a "MC ENTRY CARD" that has a unique lot number and expiration date which is scanned when setting up new lot numbers of reagent in the instrument. The box also comes with a control data sheet that includes lot specific QC ranges and references the Lot # that is on the outside of the box, which is different from the lot number on the MC ENTRY CARD. The lot number from the MC ENTRY CARD was not included on the manufacturer's control data sheet. 3. Review of quality control records for the Troponin I and NT-ProBNP performed on 05/05/23 revealed the following: The reagent lot number from the MC ENTRY card was printed on each of the QC printouts. The box lot number that is included on the control data sheet was not captured on the QC printouts. Troponin I QC revealed the use of reagent lot # 1102405654 on the QC printouts. The corresponding MC ENTRY CARD was not retained with the Control Range Data Sheet. NT-proBNP QC revealed the use of reagent lot # 1062407628. The MC ENTRY CARD was not retained with</p>

the Control Range Data Sheet. 4. Interview with technical consultant number one on 08/16/23 at 3:30 pm confirmed the laboratory failed to retain the MC ENTRY CARD that comes in each box of PATHFAST reagents, resulting in the laboratory not being able to tie the box lot number (and appropriate QC ranges) to the lot number (as scanned from the MC ENTRY CARD) on the QC instrument printouts. He confirmed there was no process in place to tie the reagent lot number on the MC ENTRY CARD to the box lot number and corresponding QC values on the control data sheet.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's testing personnel policy, testing personnel (TP) competency assessment records, patient test reports and staff interview, the laboratory policy for competency assessment was not followed when two of two established TP did not have annual competency assessments in 2022, and the competency forms in use did not include all six elements for each test performed by the TP in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's testing personnel policy revealed that TP competency assessments would be performed annually during the first year and then annually thereafter. It also indicated that the six required procedures would be included for each test the individual is approved to perform. 2. Review of personnel records revealed the following: a. No competency assessments were performed for testing personnel numbers one and two in 2022 (two of two established TP). b. The competency assessment forms in use did not include the following: Direct observation and record review was not included for manual differential. Direct observation and record review was not included for Potassium Hydroxide (KOH). Monitoring of test result recording and reporting did not specify which test(s). Blind testing did not specify which test(s). Assessment of problem solving skills did not specify which test(s). c. Competency assessments were performed using these forms in 2021, 2022, and 2023. d. The problem solving tests used for the 2023 competency for testing person number one were not graded. 3. Review of patient test reports revealed patient testing for manual differential performed 08/16/21 (patient 6152902), 09/16/22 (patient 99677318), and 08/15/23 (patient 99772098); KOH performed 09/04/21 (patient 3421112), 04/04/22 (patient 22045469), and 03/21/23 (patient 100163460). 4. Interview with technical consultant number one on 08/16/23 at 3:30 pm confirmed the laboratory did not follow its' own policy for competency assessment when competency assessments were not performed for TP numbers one and two in 2022, it failed to include all six elements for each test performed in 2021, 2022, and 2023, and the problem solving tests for TP number one for 2023 was not graded. He also confirmed the competency did not include direct observation and record review for manual differential and KOH in 2021, 2022, and 2023 with patient testing performed.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of manufacturers' operator's manual, lack of records, and staff interview, the laboratory failed to monitor humidity in the area where the Sysmex KX-21N Complete Blood Count with automated white blood cell differential (CBC w/Diff) instrument and the PASTFAST chemistry instrument were in use. The findings include: 1. Observation of the laboratory on 08/16/23 at 8:40 am revealed the Sysmex KX-21N (serial #F2734) in use for performing patient testing for CBC w/Diff and the PathFast instrument (serial # 1906D3548) in use for performing patient testing for Troponin I, B-type Natriuretic Peptide (BNP), and Fibrin Degradation Product (D-Dimer). No device for monitoring of humidity was observed in the laboratory. 2. Review of the manufacturers' operator's manuals revealed the following humidity requirements: Sysmex KX-21N CBC instrument = 30 - 85% PATHFAST Instrument = 20 - 80% Relative Humidity 3. There were no records for humidity monitoring. 4. Interview with technical consultant number two on 08/16/23 at 3:30 pm confirmed the laboratory did not monitor the humidity in the area where the Sysmex KX-21N CBC instrument and the PATHFAST chemistry instrument were in use.