Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0029144	05/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic, Pa North Convenient Care, The	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	During a recertification survey performed on May 13, 2026, the laboratory was found out of compliance with the following condition: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) (a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on a review of new method validation records, and staff interview, the laboratory failed to retain the validation raw data for the high sensitivity cardiac Troponin I (hs-TnI) assay performed on the Polymedco Pathfast instrument (one of two new test systems reviewed). The findings include: 1. A review of new test validation records revealed that the hs-TNI performed on the Polymedco Pathfast instrument was put into use for patient testing on 11/10/25. The raw data that supported the validation summary dated 11/4/25, was not available on the survey date (comparisons, accuracy, precision, linearity). 2. Technical consultant one confirmed the survey findings during an interview on 05/13/26 at 4:45 p.m.
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 laboratory observation, a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), a review of testing personnel records, a review of the laboratory procedure manual, and staff interview, the laboratory failed to follow the policy for performing annual competency assessment for two of two testing personnel when it did not perform 2024 annual competency assessments for any test system, and failed to include manual differential in the 2025 annual competency assessments. The findings include: 1. Laboratory observation on 05/13/26 at approximately 8:10 a.m. revealed the following moderately complex test systems used for performing patient testing: the Sysmex XN-21 N for performing Complete Blood Count with automated White Blood Cell differential (CBC w/Diff), a microscope used for performing urine sediment examination, wet prep examination, Potassium Hydroxide (KOH) hair, skin, and nail examination, fecal white blood cell examination, and manual differential, a Polymedco PathFast used for performing fibrin degradation products (D-Dimer), N-terminal pro B-type natriuretic peptide (NT-proBNP) and high sensitivity cardiac Troponin I (hs-TnI), and an Alcor MiniiSED used for performing erythrocyte sedimentation rate (ESR). 2. A review of the FORM CMS-209 revealed two testing personnel. The same two TP were listed on the FORM CMS-209 from the previous survey completed on 09/17/24. 3. A review of testing personnel records (TP One and TP Two) revealed no documented annual competency assessments in 2024 for any test system, manual differential competency assessment was not performed in 2025. 4. A review of the laboratory personnel policy revealed that competency assessments were required initially, at 6 months, and annually thereafter. 5. Technical consultant two (as listed on the FORM CMS-209) confirmed the survey findings during an interview on 05/13/26 at approximately 10:35 a.m.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and a staff interview, on the survey date, the laboratory was not enrolled in a PT module for the examination of fungal elements in hair, skin, and nail specimens. The findings include: 1. Laboratory observation on 05/13/26 at approximately 8:10 a.m. revealed a microscope used for examination of hair, skin, and nails for fungal elements using Potassium Hydroxide (KOH) reagent. 2. A review of the laboratory's API PT 2026 enrollment revealed that the laboratory was not enrolled in a KOH PT module that included hair, skin, and nail specimens. 3. During an interview on 05/13/26 at approximately 12:30 p.m., technical consultant one stated that the laboratory used PT samples to verify the accuracy of fungal element detection in hair, skin, and nail specimens, and confirmed the laboratory was not enrolled in a module that included those specimen types.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each

	of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, and staff interview, the laboratory failed to have procedures for venipuncture blood collection, capillary blood collection, and specimen labeling on the date of the survey (05/13/26). The findings include: 1. Laboratory observation on 05/13/26 at approximately 8:10 a.m. revealed the following moderately complex test systems used for performing patient testing: the Sysmex XN-21 N for performing CBC w/Diff, a microscope used for performing urine sediment examination, wet prep examination, KOH hair, skin and nail examination for fungal elements, fecal white blood cell examination, and manual differential, a Polymedco PathFast used for performing fibrin degradation products (D-Dimer), N-terminal pro B-type natriuretic peptide (NT-proBNP) and high sensitivity cardiac Troponin I (hs-TnI), and an Alcor MiniiSED used for performing erythrocyte sedimentation rate (ESR). Supplies and tubes for performing venipuncture and capillary blood collection were noted during the observation. 2. A review of the laboratory procedure manual revealed no procedures for venipuncture and capillary blood collection, or specimen labeling requirements. 3. Technical consultant one (as listed on FORM CMS-209) confirmed the survey findings during an interview on 05/13/26 at 1:50 p.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, a review of the laboratory's 2025 and 2026 calibration verification documents, a review of a patient test report, a review of a patient activity report, and staff interview, the laboratory failed to follow the procedure for six-month calibration verification for the D-Dimer analyte (one of three analytes) performed on the Polymedco Pathfast instrument, with approximately 54 patient D-Dimer results reported during the gap in calibration verification from 03/04/25 until 09/06/25. The findings include: 1. Laboratory observation on 05/13/26 at approximately 8:10 a.m. revealed the Polymedco PathFast used for performing D-Dimer, NT-proBNP, and hs-TnI. 2. A review of the laboratory procedure titled "Polymedco Pathfast Cardiac Biomarker Immunoassay" revealed that calibration verification would be performed every six months for the three analytes performed on the Polymedco PathFast instrument. 3. A review of the laboratory's calibration verification documents revealed that the calibration verification for D-Dimer that was due on 03/04/25 was not performed until 09/06/25 (one of three calibration verifications for the D-Dimer analyte). 4. A review of a patient test report revealed patient sample number 925226264 reported on 08/14 /25 during the gap in calibration verification for the D-Dimer analyte. 5. A review of a

	patient activity report revealed that approximately 54 patient D-Dimer results were reported during the gap in calibration verification for the D-Dimer analyte. 6. Technical consultant one confirmed the survey findings during interview on 05/13/26 at approximately 4:45 p.m.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of test validation records, a review of the procedure manual, and staff interview, the laboratory director failed to approve the new Alcor MiniiSED ESR procedure prior to patient testing that began on 03/13/2026. The findings include: 1. A review of test validation records revealed that the Alcor MiniiSED ESR instrument was put into use on 03/13/26. 2. A review of the Alcor MiniiSED procedure revealed that the procedure had not been approved by the laboratory director. 3. Technical consultant one confirmed the survey findings during an interview on 05/13/26 at approximately 4:45 p.m.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the control manufacturer's instructions for use, and staff interview, the laboratory failed to ensure that one of three hematology controls was not used past the expiration date on the date of the survey. The findings include: 1. Laboratory observation on 05/13/26 at approximately 8:10 a. m. revealed a Sysmex KX-21N instrument that was used for performing patient testing for CBC w/Diff. Three levels of EightCheck 3WP CBC controls were observed, labeled with open date and corrected expiration dates. One of the three (lot 60760712) was labeled as opened on 04/26/26, with a corrected expiration date of 05 /17/26 (21 days). 2. A review of the manufacturer's instructions for use revealed that the controls were stable for 14 days after opening. Based on the manufacturer's instructions, the labeled control open expiration date should have been 05/10/26, resulting in the use of the control three days past the open expiration date. 3. Technical consultant one confirmed the survey findings during an interview on 05/13 /26 at approximately 4:45 p.m.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test

	performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of a final patient test report for Potassium Hydroxide (KOH), and staff interview, the final patient test report failed to include the units of measure for KOH (one of twenty) analytes reviewed. 1. A review of a final patient test report for KOH revealed no units of measure (patient medical record number 2976207, reported on 03/05/26). 2. Technical consultant one confirmed the survey findings during interview on 05/13/26 at approximately 4:45 p.m.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209) and the Aspen Web 116 database, a review of the laboratory director job description, lack of documentation, and staff interview, on the survey date, the laboratory director listed on the FORM CMS-209 failed to qualify as director due to a lack of documentation of either one year directing moderately complex testing, or the required 20 Continuing Medical Education (CME) credits. Refer to D6003.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16

semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry /MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:
Based on a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209) and the Aspen Web 116 database, a review of the laboratory director job description, lack of documentation, and staff interview, on the survey date, the laboratory director listed on the FORM CMS-209 failed to qualify as director due to a lack of documentation of either one year directing moderately complex testing, or the required 20 CME credits. The findings include: 1. A review of the Form CMS-116 and FORM CMS-209 survey

	forms, and the Aspen Web 116 database, revealed the name of a laboratory director that did not match the name of the laboratory director listed in the ASPEN Web 116 database. 2. A review of job descriptions revealed that the laboratory director listed on the CMS survey forms signed a laboratory director job description on 05/04/26. 3. A review of the laboratory director's qualifications revealed no documentation that qualified the director to direct moderately complex patient testing. 4. Technical Consultant One (as listed on the FORM CMS-209) confirmed the survey findings during an interview on 05/13/26 at approximately 4:45 p.m.