Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2168592	11/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic, Pa Convenient Care Medina, The	101 Garrett Dr, Medina, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. 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 the laboratory's College of American Pathologists (CAP) and American Proficiency Institute (API) proficiency testing (PT) records, and staff interview the laboratory failed to ensure proficiency testing samples were performed by personnel who routinely perform patient testing when Testing Person Two performed 14 of 17 PT events in 2024 and 2025. The findings include: 1. Laboratory observation on 11/17/25 at 8:10 a.m. revealed the following non-waived test systems used for patient testing: The Sysmex XN430 Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff). A microscope used for performing urine microscopy and vaginal wet prep and potassium hydroxide (KOH) testing. The Polymedco Pathfast for high-sensitivity Troponin I (hs-TnI), Fibrin Degradation Product (D-Dimer), and N-Terminal-pro B-type Natriuretic Peptide (NT-proBNP). 2. A review of the Form CMS-209 revealed three personnel who performed patient testing. 3. A review of the laboratory's CAP PT records revealed that Testing Person Two had performed 14 of 17 PT events. 4. Technical Consultant Two confirmed the survey findings during an interview on 11/17/25 at 5:00 p.m.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency

	testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's CAP and API PT records and staff interviews, one of seventeen PT Performance Evaluation reports was not retained (2025 Event One API Chemistry Core). The findings include: 1. A review of the laboratory's PT records revealed that the Performance Evaluation report was not retained for the API Chemistry Core Event One. 2. Technical Consultant Two confirmed the survey findings during an interview on 11/17/25 at 5:00 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 laboratory's testing personnel competency assessment policy, a review of testing personnel competency assessment records and staff interview, the laboratory failed to follow it's own policies and procedures for assessing testing personnel competency in 2024 and 2025. The findings include: 1. Laboratory observation on 11/17/25 at 8:10 a.m. revealed the following non-waived test systems used for patient testing: The Sysmex XN430 Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff). A microscope used for performing urine microscopy, vaginal wet prep, and potassium hydroxide (KOH) testing. The Polymedco Pathfast for high-sensitivity Troponin I (hs-TnI), Fibrin Degradation Product (D-Dimer), and N-Terminal-pro B-type Natriuretic Peptide (NT-proBNP). 2. A review of the laboratory policy for assessing testing personnel competency 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. Thereafter, competency assessment will be performed at least annually. The following six procedures will be performed for testing personnel for each test that the individual is approved to perform. 1. Directly observe test performance, including patient preparation, if applicable, specimen handling, processing and testing. 2. Monitor the recording and reporting of test results. 3. Review worksheets, QC records, PT results and preventive maintenance records. 4. Directly observe performance of instrument maintenance and function checks. 5. Assess test performance using previously analyzed testing samples. 6. Assessment of problem solving skills. Note: Technical Consultants, Technical Supervisors, and General Supervisors who are performing testing on patient specimens are also required to have competency assessment including the six procedures." 3. A review of testing personnel competency assessment records revealed that: The 2024 Annual Competency Assessment was not performed for Established Testing Person One /Technical Consultant One for any test system. The 2024 Annual Competency

	Assessment was not performed for Established Testing Personnel Two for any test system. The 2025 Annual Competency Assessment, completed on 11/11/25 for Testing Person One/Technical Consultant One, did not include evaluation of test performance using blind testing or proficiency testing for the Sysmex XN430 CBC w /Diff instrument or the Polymedco Pathfast Cardiac Testing instrument. The 2025 Annual Competency Assessment, completed on 11/14/25 for Testing Person Two, did not include an evaluation of test performance using blind testing or proficiency testing for the CBC w/Diff performed on the Sysmex XN 430 or the Polymedco Pathfast Cardiac Testing instrument. The Six-Month Competency Assessment, completed on 09/12/25 for Testing Person Three, did not include an evaluation of test performance using blind testing or proficiency testing for any test system. The 2025 Annual Competency Assessment, completed on 11/15/25 for Testing Person Three, did not include evaluation of test performance using blind testing or proficiency testing for the Sysmex XN 430 CBC w/Diff or the Polymedco Pathfast Cardiac Testing instrument. 4. Technical Consultant Two confirmed the survey findings during an interview on 11/17/25 at 5:00 p.m.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and staff interview, the laboratory failed to evaluate PT results that were not graded by the PT program for four of ten PT events with ungraded scores from 2024 and 2025. The findings include: 1. A review of the laboratory's CAP PT records revealed the following ungraded scores that were not evaluated to determine the accuracy of the laboratory's performance: 2025 Event One-Hematology with Automated White Blood Cell Differential (FH(-A)-Educational Challenge for Immature Granulocyte percent and Immature Granulocyte absolute count for sample numbers FH9-01, FH9-02, FH9-03, FH9-04, and FH9-05. 2025 Event Two-Hematology with Automated White Blood Cell Differential (FH9-B)-Educational Challenge for Immature Granulocyte percent and Immature Granulocyte absolute count for sample numbers FH9-06, FH9-07, FH9-08, FH9-09, and FH9-10. 2025 Event One-Blood Cell Identification-(BCP-A)-Educational Challenges for sample numbers BCP-06, BCP-07, BCP-08, BCP-09, BCP-10 2025 Event Two-Blood Cell Identification-(BCP-B)Educational Challenges for sample numbers BCP-16, BCP-17, BCP-18, BCP-19, BCP-20. 2. Technical Consultant Two confirmed the survey findings during an interview on 11/17/25 at 5:00 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: CITATION ONE: Based on laboratory observation, a review of the laboratory procedure manual, lack of documentation, and staff interview, the laboratory failed to follow the procedure for performing biannual centrifuge checks for the centrifuge timer and Revolutions Per Minute (RPMs) in 2024 and 2025. The findings include: 1. Laboratory observation on 11/17/25 at 8:10 a.m. revealed a centrifuge used to spin down urine samples to prepare for microscopic examination. 2. A review of the laboratory procedure titled "MISCELLANEOUS LAB MAINTENANCE" revealed that the centrifuge timer and RPMs were to be checked biannually. 3. There was no documentation that the function checks had been completed biannually in 2024 or 2025. 4. The Regional Quality Assurance Manager confirmed the survey findings during an interview on 11/17/25 at 1:10 p.m. CITATION TWO: Based on laboratory observation, a review of the laboratory procedure manual, a review of the available calibration verification documents and staff interview, the laboratory failed to perform six-month calibration verification for analytes performed on the Polymedco Pathfast instrument when due in 2024 and 2025. The findings include: 1. Laboratory observation on 11/17/25 at 8:10 a.m. revealed the Polymedco Pathfast used for high-sensitivity Troponin I (hs-TnI), Fibrin Degradation Product (D-Dimer), and N-Terminal-pro B-type Natriuretic Peptide (NT-proBNP). 2. A review of the laboratory procedure for the Polymedco Pathfast revealed that calibration verification for the analytes would be performed every six months. 3. A review of calibration verification documents revealed that calibration verification was not performed when due in October 2024, and no calibration verification was performed in 2025 for the previous Troponin I assay, D-Dimer, or NT-pro-BNP assays. 4. The Regional Quality Assurance manager confirmed the survey findings during an interview on 11/17/25 at 1:30 p.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	Based on a review of test validation records, the laboratory procedure manual, patient test reports, and staff interview, the laboratory failed to update the Polymedco Pathfast procedure to include the correct reference range and reportable range for the high-sensitivity Troponin I (hs-TnI) assay prior to patient testing that began on 11/13/25. The findings include: 1. A review of test validation records revealed that the laboratory validated the high-sensitivity Troponin I (hs-TnI) on the Polymedco Pathfast instrument on 11/10/25. 2. A review of the laboratory procedure for the Polymedco Pathfast instrument revealed that the procedure had not been updated to reflect the correct reference range and reportable range. 3. A review of patient test reports revealed that the first patient for hs-TnI was reported on 11/13/25 for patient 1657014. 4. Technical Consultant Two confirmed the survey findings during an interview on 11/17/25 at 5:00 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 the laboratory procedure manual and staff interview, the laboratory failed to ensure that the laboratory director had approved recently revised procedures prior to implementation in 2025. The findings include: 1. A review of the laboratory procedure manual revealed the following recently revised procedures that had not been approved for use by the laboratory director. Sysmex XN 450/XN430 Automated Hematology Analyzer Manual Differential Procedure Manual Stain for Peripheral Blood Smear Smear Review and Manual Differential Criteria Preparation of Blood Smear Examination of Urine Sediment Wet Prep Polymedco Pathfast Cardiac Biomarker 2. Technical Consultant Two confirmed the survey findings during interview on 11/17/25 at 5:00 p.m.
D5791	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. This STANDARD is not met as evidenced by: CITATION ONE: Based on a review of the laboratory records and staff interview, the daily background counts performed for the Sysmex XN 430 CBC w/Diff instrument had not been reviewed for eight of the seventeen months reviewed; the temperature and humidity records for August, September, and October 2025 had not been reviewed. The findings include: 1. A review of laboratory records revealed no documentation that the daily background counts performed for the Sysmex XN 430 CBC w/Diff instrument had been for reviewed for 09/2024, 11/2024, 12/2024, 01 /2025, 02/2025, 04/2025, 09/2025, and 10/2025. 2. A review of laboratory environmental records revealed that the August, September, and October 2025 temperature and humidity records had not been reviewed. 3. Technical Consultant Two confirmed the survey findings during interview on 11/17/25 at 5:00 p.m. CITATION TWO: Based on a review of the laboratory procedure for the Sysmex XN

	430 CBC w/Diff, lack of documentation, and staff interview, the laboratory failed to follow the policy for review of designated reports for the Sysmex XN 430 CBC instrument for two of seven lots reviewed. The findings include: 1. A review of the laboratory procedure for the Sysmex XN 430 CBC w/Diff instrument revealed a requirement for monthly review of the Sysmex Insight report, exception report, summary report, and daily detail verification monthly. The policy stated the Continuous Calibration Verification report would be review with each Lot number and /or monthly. 2. A review of the laboratory's CBC w/Diff quality assessment review records revealed the following: No documented review of the daily detail verification report, the continuous calibration verification report, or the Insight report for Lot number 4349 used from 01/02/25 to 03/25/25. No documented review of the continuous calibration verification report for lot number 5067 used from 03/26/25 to 06/17/25. 3. Technical Consultant Two confirmed the survey findings during an interview on 11/17/25 at 5:00 p.m.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on a lack of documentation and staff interview, the laboratory director failed to document onsite laboratory visits at least once every six months in 2025. 1. On the survey date, there was no documentation that the laboratory director performed onsite visits at least once every six months. 2. Technical Consultant Two confirmed the survey findings during an interview on 11/17/25 at 5:00 p.m.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on a review of the Form CMS-209, a lack of documentation, and a staff interview, Technical Consultant One did not have documentation of training on the quality assessment activities of the laboratory. The findings include: 1. A review of the Form CMS-209 revealed a technical consultant listed that was new since the last survey date (Technical Consultant One). 2. There was no documentation that Technical Consultant One had received training on the laboratory's quality assessment activities, competency assessment policies, and proficiency testing review activities. 3. Technical Consultant Two confirmed the survey findings during interview on 11/25 /25 at 5:00 p.m.