Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2168592	04/15/2024
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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of reagent and quality control (QC) records, lack of records, patient test records, and staff interviews, the laboratory failed to monitor QC for accuracy and precision over time for the Troponin I and N-terminal-pro-B-type natriuretic peptide (NT-proBNP) tests performed on the Polymedco Pathfast instrument (Refer to D5441) and failed to maintain records of QC ranges and statistical parameters for the Troponin I and NT-proBNP (Refer to D5469).
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, lack of documentation, review of reagent and quality control records, patient test records, and staff interviews, the laboratory failed to monitor complete blood count with automated white blood cell differential (CBC w/diff) quality control (QC) for accuracy and precision over time (Refer to D5441 Citation One), failed to monitor QC for accuracy and precision over time for the cross-linked fibrin degradation product

	(D-Dimer) performed on the Polymedco Pathfast instrument (Refer to D5441, Citation Two), failed to maintain records of QC ranges and statistical parameters for the D-Dimer assay (Refer to D5469), and failed to follow the quality assessment plan for the CBC w/diff testing performed on the Sysmex XN 430 (Refer to D5791).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: CITATION NUMBER ONE: Based on observation of the laboratory, review of quality control records, lack of documentation, and staff interview, the laboratory failed to monitor CBC w/Diff quality control for accuracy and precision over time in 2023 and 2024. The findings include: 1. Observation of the laboratory on 04/15/24 at 8:25 a.m. revealed the Sysmex XN 430 (serial number 11245) used for performing patient testing for CBC w/diff. 2. The laboratory failed to provide documentation of QC records and reviews that included monitoring for accuracy and precision over time for three of three months reviewed - March 2023 (lot 3041), September 2023 (lot 3209), and February 2024 (lot 4012). 3. The technical consultant confirmed the survey findings during the interview on 04/15/24 at 4:30 p.m. He further confirmed the laboratory failed to document review of reports that monitored shifts and trends from February 2023 to the survey date on 04/15/24. CITATION NUMBER TWO: Based on observation of the laboratory, review of quality control records, lack of records, and staff interview, the laboratory failed to monitor quality control for accuracy and precision over time for the tests performed on the Polymedco Pathfast instrument in 2023 and 2024. 1. Observation of the laboratory on 04/15/24 at 8:25 a.m. revealed the Polymedco Pathfast instrument (serial number 161002851) used for performing patient testing for D-Dimer, Troponin I, and NT-proBNP. 2. The laboratory failed to provide documentation that QC data was monitored for accuracy and precision over time for any of the three tests. The months reviewed included April 2023, November 2023, and January 2024. 3. The technical consultant confirmed the survey findings during an interview on 04/15/24 at 4:30 p.m. He further stated the laboratory had not printed any reports in 2023 or 2024 that included monitoring of QC over time.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control

materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, staff interview, review of reagent and quality control (QC) records, lack of documentation, patient test records, interview with the technical consultant, and staff interview via phone, the laboratory failed to maintain records of the mean and standard deviation (statistical parameters) entered in the Polymedco Pathfast instrument for the D-Dimer, Troponin I and NT-proBNP analytes in 2023 and 2024, with approximately 61 D-Dimer tests, 250 Troponin I, and 220 NT-proBNP tests performed annually. The findings include: 1. Observation of the laboratory on 04/15/24 at 8:25 a.m. revealed the Polymedco Pathfast instrument used for performing patient testing for D-Dimer, Troponin I, and. NT proBNP. The observed lot number on the box of Troponin I reagent was B374; the lot number of the reagent inside the box and the MC entry card (used to scan the reagent lot number into the instrument) was 1102504744. 2. During an interview on 04/15/24 at 3 p.m. the lead testing person and the technical consultant described the following: Each box of reagent for D-Dimer, Troponin I and NT proBNP has a four-digit "Box" lot number. The reagent cartridges contained within the box have a different lot number from the box lot number. Each box also has an MC Entry Card with the reagent lot number. When the lab starts using the reagent lot, the information from the MC entry card is scanned into the instrument. It does not include the box lot number. Each Troponin I and NT Pro-BNP reagent box includes a control package insert that lists lot numbers of Biorad controls and the corresponding control ranges. The control ranges are specific to the 'box' lot number. The reagent lot number is not included on the control datasheet. The laboratory keeps a reagent log that only includes the 'box' lot number. The corresponding 'reagent' lot number is not included in the records. The box lot number does not print on the instrument printout for either patients or QC. The QC ranges used by the laboratory are maintained in the Polymedco Pathfast instrument. 3. Review of reagent and QC records for the Troponin I and NT-ProBNP reagent revealed the following: QC printouts from 04/10/23, 11/07/23, and 01/22/24 did not include the Box lot number. The QC printouts from 04/10/23 did not include the QC lot number for either of the two levels of Biorad controls. The "MC Entry Card" included the reagent lot, but not the four-digit 'Box lot.' The laboratory's reagent log included the box lot but not the reagent lot. The QC printouts did not include the four-digit lot number from the reagent box and could not be matched to the appropriate QC ranges. 4. The laboratory failed to provide records of the quality control ranges including the mean and standard deviation (statistical parameters) used for each 'Box' lot and corresponding 'Reagent' lot of Troponin I and NT-ProBNP box/reagent. Records of the QC lot numbers and QC ranges entered in the Pathfast instrument were not maintained for D-Dimer, NT-proBNP, and Troponin I QC performed on 04/10/23. Records of QC ranges entered into the Pathfast instrument were not maintained for D-Dimer, N-proBNP and Troponin I QC performed on 11/07/23 or 01/22/24. 5. Review of patient records revealed testing for D-Dimer, Troponin I, and NT-proBNP performed on 04/10/23 for lab accession # 23046576, on 11/7/23 for lab accession number 23141212 and on 01/22/24 for lab accession # 24008093. 6. The technical consultant confirmed the survey findings during interview on 04/15/24 at 4:30 p.m. 7.

	The laboratory liaison stated during interview on 04/25/24 at 4:45 p.m. that the laboratory performed an average of 61 D-Dimer tests, 250 Troponin I tests and 220 NT-proBNP testing annually.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, lack of documentation, and staff interview, the laboratory failed to follow the quality assessment (QA) plan for the Sysmex XN 430 CBC w/Diff when it did not review the required monthly reports beginning February 2023 to the date of the survey on 04/15 /24. This was previously cited on the survey conducted on 11/08/22, and compliance was not maintained. The findings include: 1. Observation of the laboratory on 04/15 /24 at 8:25 a.m. revealed the Sysmex XN 430 (serial number 11245) used for performing patient testing for CBC w/diff. 2. Review of the laboratory procedure for the Sysmex XN 430 revealed that the following QA reports were to be reviewed monthly: Insight IQAP, Exception Report, Summary Report, Continuous Calibration Verification Certificate, and Detailed Daily Verification Report. 3. The laboratory failed to provide documentation of monthly review for the Exception Report, Summary Report, Continuous Calibration Verification Certificate, or Detailed Daily Verification from February 2023 to the survey date on 04/15/24. 4. During an interview on 04/15/24 at 4:30 p.m., the technical consultant confirmed that the laboratory failed to follow the QA plan for reviewing the required monthly reports from February 2023 to the survey date on 04/15/24. He further confirmed the laboratory failed to maintain compliance with the previous plan of correction. WORD KEY: IQAP=Inter-laboratory Quality Assurance Program