Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2310087	04/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
The Jackson Clinic, Pa-Midtown	619 Skyline Dr, 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
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. This STANDARD is not met as evidenced by: Based on direct observation, a review of quality controls (QC) files, the laboratory procedure manual, and staff interview, the laboratory's QC procedure for the Polymedco Pathfast instrument did not match the QC protocol that the laboratory followed. The findings include: 1. Laboratory observation on 04/04/25 at 10:30 a.m. revealed the following control vials used for performing QC on the Polymedco Pathfast instrument for Troponin I, NTproBNP and D-Dimer assays: Biorad Liquichek Cardiac Marker Level 1 (Lot number 1003121), Level 1C (Lot number 1003116), and Level 3 (Lot number 1003123). Biorad Liquichek D-Dimer Level 1 (Lot number 74441) and Level L (Lot 74444). 2. A review of QC files in the Orchard LIS revealed that the control files for Troponin I were Levels 1C and Level 3, the control files for NTproBNP were Level 1 and Level 3, and the control files for D-Dimer were Level 1 and Level L. 3. A review of the laboratory's Pathfast procedure revealed that controls used for Troponin I were Level 1 and Level 1C, NTproBNP controls were Level 1 and Level 3, and D-Dimer controls were Level 1 and Level 2. 4. The laboratory director confirmed by phone interview on 04/09/25 at 1:45 p.m. that the laboratory's QC procedure for the Pathfast instrument was inconsistent with the

	control protocol used in the laboratory as recommended by the manufacturer. Word Key: D-Dimer = Fibrin degradation product NTproBNP=N-terminal pro hormone B-type natriuretic peptide (NTproBNP) LIS=Laboratory Information System
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on direct observation, review of Biorad Quality Control (QC) package inserts, lack of QC ranges, review of laboratory QC records, review of manufacturer control data assay sheets, review of a patient activity log, and staff interview, the laboratory failed to verify the QC ranges and QC lot numbers used for the Troponin I and N-terminal pro hormone B-type natriuretic peptide (NTproBNP) assays when QC lot numbers and reagent box lot numbers changed. The findings include: 1. Laboratory observation on 04/04/25 at 10:30 a.m. revealed the following control vials used for performing QC on the Polymedco Pathfast instrument for Troponin I, NTproBNP and D-Dimer assays: Biorad Liquichek Cardiac Marker Level 1 (Lot number 1003121), Level 1C (Lot number 1003116), and Level 3 (Lot number 1003123). Biorad Liquichek D-Dimer Level 1 (Lot number 74441) and Level L (Lot 74444). 2. A review of the Biorad Cardiac Marker LT package inserts revealed the following: Level 3 (Lot 1003123) for Troponin I revealed no QC ranges. The comment code stated "The reagent kit manufacturer requests that you refer to LSI MEDIENCE PATHFAST reagent kit's CONTROL DATA SHEETS for assignment of values." Level 1 (Lot 1003121) for NTproBNP revealed no QC ranges. The comment code stated "The reagent kit manufacturer requests that you refer to LSI MEDIENCE PATHFAST reagent kit's CONTROL DATA SHEETS for assignment of values." Level 3 (Lot 1003123) for NTproBNP revealed no QC ranges. The comment code stated "The reagent kit manufacturer requests that you refer to LSI MEDIENCE PATHFAST reagent kit's CONTROL DATA SHEETS for assignment of values." 3. A review of the Pathfast Control Data Sheets on the survey date (04/04/25) revealed analyte QC ranges were not provided for the following: Troponin reagent lot 1102602800 for the Cardiac Marker Level 3 - lot number 1003123. NTproBNP reagent lot 1062602771 for the Cardiac Marker Level 1 (lot number 1003121) or Level 3 (lot number 1003123). 4. A review of the laboratory records revealed the following: The NTproBNP Level 1 lot number was set up as 1003111 in the Orchard LIS; the observed lot number was 1003121 (see finding one). The Level 1 QC lot number 1003121 was potentially put into use on 03/05/25. The NTproBNP and Troponin I Level 3 QC lot number was set up as 1003113 in the Orchard LIS; the observed lot number was 1003123 (see finding one). The Level 3 QC lot 1003123 was potentially put into use on 03/03/25 for both assays. 5. The laboratory requested the control data sheets for the affected reagent lots on the survey date. A review of the manufacturer control data sheets obtained on the survey date and the QC ranges used

	by the laboratory revealed the laboratory used ranges that were not consistent with the manufacturer's ranges as follows: Troponin I Level 3-The QC range for Level 3 (lot number 1003123) was 10.1 - 18.7 ng/mL. The QC range in the Orchard LIS was 13.4 - 24.9 ng/mL. NTproBNP Level 1-The QC range for Level 1 (Lot 1003121) was 143-265 pg/mL. The QC range in the Orchard LIS was 140 - 260 pg/mL. NTproBNP Level 3-The QC range for Level 3 (Lot 1003123) was 5278 - 9802 pg/mL. The QC range in the Orchard LIS was 5159 - 9581 pg/mL. 6. A review of a patient activity log covering the period from the last onsite survey on 02/11/25 to 04/09/25 (date of revisit) revealed that the laboratory had not tested any patients. 7. The lead testing person and technical consultant confirmed during an interview on 04/04/25 at 12:30 p. m. that the laboratory failed to manage QC lot number changes and changes in QC ranges when reagent box lot numbers changed. They also confirmed that with each box lot of reagent, the control ranges for both Troponin I and NTproBNP changed, and the laboratory had not acquired the correct control datasheet from the manufacturer to ensure the correct QC ranges were used for the evaluation of QC data. Word Key: LIS=Laboratory Information System pg/mL=picograms/milliliter ng /mL=nanograms/milliliter