Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2025887	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic, Pa - Innovation Park, The	145 Innovation Drive, 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	A recertification survey was conducted on 04/13/23. The facility was found NOT to be in compliance with the following 42 CFR PART 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed. 42 CFR 493. 1250, Analytic systems ==========
D2004	ENROLLMENT CFR(s): 493.801(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's Casper Report 155 and proficiency testing reports (PT), and staff interviews, the laboratory failed to ensure participation in one PT program for the year 2022 before switching to a different PT program for 2022 events two and three for testing performed on the Polymedco PathFast instrument. The findings include: 1. Observation of the laboratory on 04/13/23 at 8:30 am revealed the Polymedco PathFast instrument in use for performing patient testing for Troponin I, B-Type Natriuretic Peptide (NT-ProBNP), Creatine Kinase MB (CK-MB), and Fibrin Degradation Products (D-Dimer). 2. Review of the laboratory's Casper Report 155 and PT evaluation reports revealed PT participation with the College of American Pathologists (CAP) for 2022 event one, and American Proficiency Institute (API) for 2022 events two and three for the Polymedco PathFast chemistry instrument. 3. Interview with the lab director and technical consultant #2 on 04/13/23 at 6:00 pm confirmed the laboratory failed to ensure participation with one PT program before switching to a new PT program for testing performed on the Polymedco PathFast chemistry instrument in 2022. ==========

D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (Form CMS-209), review of the laboratory's proficiency testing (PT) records, and interview with technical consultant #2, the laboratory failed to ensure persons who perform patient testing on the Polymedco PathFast instrument used for performing cardiac testing participated in performance of proficiency testing in 2021, 2022, and 2023. The findings include: 1. Review of the Form CMS-209 revealed four personnel who perform patient testing in the laboratory in suite 300. 2. Review of the laboratory's proficiency testing attestation statements revealed the proficiency testing for the Polymedco PathFast instrument used for performing cardiac testing (CK-MB, Troponin I, NT-ProBNP and D-Dimer) was performed by testing person number two for six of seven PT events from 2021, 2022, and 2023. 3. Interview with technical consultant #2 on 04/13/23 at 6 pm confirmed the laboratory failed to ensure proficiency testing was performed by personnel who perform patient testing when testing person number two performed six of seven PT events for cardiac tests performed on the Polymedco PathFast instrument in 2021, 2022, and 2023. ==========
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Citation Number One Based on review of coagulation quality control (QC) records for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (PTT), lack of records, patient test reports and staff interview, the laboratory failed to retain quality control printouts for the PT and PTT for a period of two years for QC performed on 01/12/23. The findings include: 1. Review PT and PTT QC records revealed the QC is manually recorded on a log. 2. Request was made on 04/13/23 at 5 pm to the technical consultant #2 for instrument printouts for the PT and PTT QC recorded as the 2nd run (PM) performed on 01/12/23. No instrument printouts were maintained, no record was available. 3. Review of patient MRN 99734175 revealed PT and PTT reported on 01/12/23 at 4:52 PM. 3. Interview with the lab director and technical consultant #2 on 04/13/23 at 6 pm confirmed the laboratory failed to maintain instrument printouts for a period of two years for the PM QC performed for PT and PTT on 01/12/23. ========== Citation Number Two Based on observation of the laboratory, task demonstration, document request, and staff interviews, the laboratory failed to maintain quality control (QC) package inserts that come in each box of reagent for the Polymedco PathFast instrument for a period of two years. 1. Observation of the laboratory on 04/13/23 at 8:30 am revealed the Polymedco PathFast instrument in use for performing patient testing for Troponin I, B-

	Type Natriuretic Peptide (NT-ProBNP), Creatine Kinase MB (CK-MB), and Fibrin Degradation Products (D-Dimer). The Biorad QC lot numbers in use for the D-Dimer assay were 74421 and 74424. 2. The lead testing person for chemistry was asked to demonstrate the method for entering the QC ranges in the PathFast instrument on 04 /13/23 at 5pm. She stated that each box of reagent for the PathFast instrument comes with a card with a unique reagent lot that is scanned into the PathFast when reagent lots are started. A package insert is also included that lists specific lot numbers of Biorad controls and the appropriate ranges that are specific to the reagent lot. The QC ranges are manually entered from the card into the PathFast instrument for each new lot of reagent that is received. 3. Request on 04/13/23 at 5pm for the QC package insert for the current reagent lot for the D-Dimer assay revealed the package insert was not available. 4. During an interview with the chemistry lead on 04/13/23 at 5:00 pm, the chemistry lead stated that the QC package insert for the D-Dimer assay had been discarded. She further stated that she tries to keep all the package inserts, but they may not all be kept. 5. Interview with the lab director and technical consultant #2 on 04/13/23 at 6 pm confirmed the laboratory failed to retain the QC package insert for the D-Dimer current reagent lot number. ==========
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of laboratory procedures, patient test records, environmental records, manufacturer package inserts, quality control records, lack of records, maintenance records and staff interviews, the laboratory failed to have an approved procedure for use of the Streck Diesse Erythrocyte Sedimentation Rate (ESR) instrument (Refer to D5407), failed to monitor the minimum/maximum temperature of the laboratory freezer (Refer to D5413), failed to appropriately label chemistry, urinalysis, hematology and coagulation controls and reagents with open date and corrected expiration date (Refer to D5415), failed to ensure complete blood count (CBC) controls were not used past their expiration date (Refer to D5417), failed to ensure the use of correct quality control ranges for the Troponin I analyte (Refer to D5469), failed to compare results between two urinalysis instruments (Refer to D5775), failed to have an effective quality assessment process in place for detection and correction of errors (Refer to D5793-Citation number one), and failed to have an effective process in place for review of quality control performed on the PathFast instrument (Refer to D5793 citation number two). ==========
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 observation of the laboratory, review of the laboratory procedure manual, patient test records and staff interview, the laboratory failed to have an approved procedure for use of the Streck Diesse Mini Cube Erythrocyte Sedimentation Rate (ESR) instrument since beginning patient testing on 09/01/21 until the date of the survey on 04/13/23. The findings include: 1. Observation of the laboratory on 04/13 /23 at 8:30 am revealed the Streck Diesse Mini Cube instrument in use for performing patient ESR testing. 2. Review of the laboratory procedure manual revealed no approval of the procedure by the laboratory director. 3. Review of patient test reports revealed the first patient was reported on 09/01/21 (MRN 99776319). 4. Interviews with the lab director and technical consultant #2 on 04/13/23 at 6 pm confirmed the laboratory failed to have a procedure that was approved by the laboratory director for use of the Streck Diesse Mini Cube ESR instrument since patient testing began on 09 /01/21 until the date of the survey on 04/13/23. ==========
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 freezer temperature records, and interview with the technical consultant, the laboratory failed to have a process in place for continuous monitoring of the freezer where the chemistry calibrators and controls were stored to ensure correct temperatures were maintained. The findings include: 1. Observation of the laboratory on 04/13/23 at 8:30 am revealed a freezer in use for storage of chemistry calibrators and controls. The label on the inside of the freezer indicated it was "frost proof." 2. Review of freezer temperature records revealed the minimum/maximum freezer temperatures were not recorded/monitored on a daily basis. 3. Interview with technical consultant #2 on 04/13/23 at 6 pm confirmed the freezer used for storage of chemistry reagents and controls goes through defrost cycles and the lab did not have a process in place for continuous monitoring of the freezer temperature to ensure the correct temperatures are maintained. ==========
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package inserts, and staff interview, the laboratory failed to ensure controls and reagents were appropriately labeled with open dates and/or corrected expiration dates on the date of the survey for 14 of 16 controls and reagents observed on the date of the survey (04/13 /23). The findings include: 1. Observation of the laboratory on 04/13/23 at 8:30 am revealed the following: ESR-Chex Plus QC material for use on the Diesse Mini Cube for erythrocyte sedimentation rate (ESR) instrument labeled with an open date of 04 /10/23 but no corrected open expiration date. Performance Verifier 1 and 2 used for performing QC on the Ortho Vitros 350 chemistry instrument (system ID #J27005008) labeled with an open date of 04/10/23, but no corrected open expiration date. Biorad Cardiac Marker and D-Dimer controls used for performing QC on the Polymedco PathFast (serial #1807D-D3219) (for performing D-Dimer, Troponin, CK-MB, and Pro-BNP chemistry tests) labeled with a date 04-10, but no corrected expiration date. Quantimetrix urine dipstick controls used for performing QC on the Siemens Clinitek Advantus Urine Dipstick instrument labeled with an open date of 04 /03/23 and a corrected expiration date of 11/30/23 that exceeded the manufacturer stability range (suite 300 lab only). Citrol controls (levels 1 and 3) used for performing QC on the Sysmex CA--600 instrument for PT and PTT - reconstituted for use with no open date and no corrected expiration date. Innovin used for performing Prothrombin Time (PT) reconstituted for use with no open date or corrected expiration date. 2. Review of control manufacturer package inserts revealed the following: ESR-Chex Plus controls used on the Diesse Mini Cube are good for 7 days after opening. Performance Verifier 1 & 2 used on the Ortho Vitros 350 chemistry instrument - stable for 7 days after reconstitution, except for ALKP, BuBc, Ca, and TBIL which are stable for 3 days after opening. Biorad Cardiac Marker controls are stable after thawing when stored at 2-8C for 20 days for all analytes except for NT-proBNP and Troponin I which are stable for 5 days. Biorad D-Dimer controls are stable for 15 days after opening when stored tightly capped at 2-8C. Quantimetrix Dipper Urinalysis controls are good for 3 months or 20 dips after opening, whichever comes first. Citrol control levels 1 and level 3 are good for 16 hours at 2-8C. Innovin stability after reconstitution when stored at 2-8C is 10 days, but may be shorter if kept onboard. 3. Interview with technical consultant #2 on 04/13/23 at 6 pm confirmed the laboratory failed to label controls and reagents with open dates and corrected expiration dates on the date of the survey (04/13/23). ==========
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation of the laboratory, review of the complete blood count (CBC) manufacturer package insert, and staff interview, the laboratory failed to ensure controls were not used past the expiration date from 03/04/23 to the date of the survey on 04/13/23. The findings include: 1. Observation of the laboratory on 04/13/23 at 8: 30 am revealed the Sysmex XS1000i CBC instrument in use for patient testing. Also observed were three levels of hematology controls being used for performing QC on

	the CBC instrument (Lot numbers 30380804, 30380805, 30380806). The controls were labeled with 02/17. 2. Review of the QC package insert revealed the following statement: "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C. 3. Interview with technical consultant #2 on 04/13/23 at 6:30 pm confirmed the date of 02/17 was the date the vials were opened and the laboratory used the controls past the expiration date from 03/04/23 to the date of the survey on 04/13/23. ==========
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, task demonstration, review of quality control (QC) files for the Polymedco PathFast instrument, and staff interviews, the laboratory failed to have a process in place to verify the correct QC ranges for the Troponin I analyte were used from 03/17/23 to 04/13/23. The findings include: 1. Observation of the laboratory on 04/13/23 at 8:30 am revealed the Polymedco PathFast instrument in use for performing patient testing for Troponin I, NT-ProBNP, CK-MB, and-Dimer. The Biorad QC lot numbers observed in use for Troponin I were 67695 for level 1B and 67693 for level 3. The lot number of reagent observed for Troponin I was E265. 2. The lead testing person for chemistry was asked to describe the method for entering the QC ranges in the instrument on 04/13/23 at 5 pm. She stated that each box of reagent for the PathFast instrument comes with a card with a unique reagent lot that is scanned into the PathFast. A package insert is also included that lists specific lot numbers of Biorad controls and the appropriate ranges that are specific to the reagent lot. The ranges are manually entered from the package insert into the PathFast instrument when each new lot of reagent is started. 3. Review of the laboratory's current QC ranges in use for the Troponin I analyte for reagent lot E265 when compared to the package insert revealed the following: Range in use for level 3 QC lot 67693 = 15.8-29.3 Correct range for level 3 QC lot 67693 = 18.8 - 34.9 4. Staff interviews with the lab director, technical consultant #2 and chemistry lead on 04/13 /23 at 6 pm confirmed the laboratory failed to ensure the use of correct QC ranges for the Polymedco Pathfast instrument for the Troponin I analyte from the time lot E265 started on 03/17/23 until the date of the survey on 04/13/23. ==========
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records and staff interview, the laboratory failed to compare results between two moderately complex urinalysis instruments in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 04/13/23 at 8:30 am revealed two Siemens Clinitek Advantus moderately complex urine instruments in use for performing urine dipstick analysis -- one located in the main laboratory in suite 300 and one located in the urology clinic on the 5th floor. 2. There were no records available for twice a year comparison of results between the two instruments. 3. Interview on 04/13/23 at 6 pm with the lab director confirmed the laboratory did not perform twice a year comparison of results between the two urinalysis instruments in 2021, 2022, and 2023. ==========
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Citation Number 1 Based on review of the laboratory's quality assurance plan, review of laboratory records, and staff interviews, the laboratory failed to have an effective quality assessment process in place, resulting in the lack of printed monthly quality control (QC) for the Polymedco PathFast chemistry instrument and maintenance records that were missing documentation with no documentation of corrective action in January, February, and March 2023. The findings include: 1. Review of the laboratory's quality assurance plan revealed the laboratory would effectively monitor and assess all phases of testing, evaluate the effectiveness of written policies and procedures, revise policies and procedures when necessary, identify problems and apply corrective action. Quality control and maintenance records are reviewed monthly. 2. Review of laboratory records revealed the following: The QC records for the Polymedco PathFast instrument used for performing Troponin I, NT-Pro BNP, CK-MB and D-Dimer had not been printed or reviewed for January, February or March 2023. No corrective action was documented for the lack of printed QC and reviews. The maintenance log for the Sysmex XS-1000i Complete Blood Count instrument had no documentation of weekly maintenance for the month of February 2023. The form was reviewed by the lab director with no documentation of corrective action. The PathFast maintenance log for the months of January, February and March 2023 did not have documentation of weekly or monthly maintenance with no corrective action documented. The forms had been reviewed by the lab director. 3. Interview with the lab director and technical consultant #2 on 04/13/23 at 6 pm confirmed the laboratory's quality assessment process was ineffective in detecting and

	correcting problems with monthly review of QC and documentation of instrument maintenance in 2023. ========== Citation Number 2 Based on observation of the laboratory, review of QC records, interview with the chemistry lead, patient test reports, and interview with the lab director and technical consultant #2, the laboratory failed to have an effective review process in place when QC records used for reviewing for the Polymedco PathFast instrument QC did not reflect the laboratory's ranges used at the time of testing. The findings include: 1. Observation of the laboratory on 04/13/23 at 8:30 am revealed the Polymedco PathFast instrument in use for performing patient testing for Troponin I, NT-ProBNP, CK-MB, and D-Dimer. The QC lot numbers observed in the refrigerator in use for Troponin I were 67695 for level 1B and 67693 for level 3. The reagent lot number in use was E265. 2. Review of the cumulative monthly QC records printed during the survey for the Troponin I performed on the PathFast instrument for the months of January, February, and March 2023 revealed multiple shifts and trends on the Levy Jennings graphs. Many of the values were outside the acceptable range of the QC limits. 3. Interview with the chemistry lead on 04/13/23 at 5:30 pm revealed the following: The QC had not been printed for review on a monthly basis for January, February, and March 2023. The reagent lot numbers and QC ranges change periodically. Previous QC is not printed for review when reagent or QC lot numbers change. What is printed and submitted for review may or may not represent the laboratory's correct QC ranges for the period of review. 4. Review of patient test records revealed patient reporting for Troponin I, NT-ProBNP, CK-MB, and D-Dimer during the period when QC reports were not printed (02/14/23-patient MRN 3444668). 5. Interview with the lab director and technical consultant #2 on 04/13/23 at 6 pm confirmed the laboratory's process for management and review of QC files for the PathFast instrument was not effective review since the QC reports printed did not represent the correct QC ranges that corresponded with reagent and QC lot number use.