Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2310087	02/11/2025
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
D0000	During an initial certification survey on 02/11/25, the laboratory was found out of compliance with the following conditions: 493.1250 Condition: Analytic systems. 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.
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 laboratory observation, a review of laboratory procedures, lack of documentation, a review of a patient activity log and patient test reports, and staff interview, the laboratory failed to ensure the procedure for the Polymedco Pathfast instrument included the normal range for each test performed, the reportable range for the N-terminal-pro B-type Natriuretic Peptide (NT-proBNP) assay, and calibration procedures for each test performed (Refer to D5403), failed to verify the manufacturer performance specifications for three of four non-waived Food and Drug Administration (FDA) approved test systems (Refer to D5421), and failed to establish performance specifications for two of two textbook procedures (Refer to D5423).
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 laboratory observation, a review of the laboratory procedure manual, a patient activity report and patient test report, and a staff interview, the laboratory procedure for the Polymedco Pathfast instrument lacked the required procedure manual elements of normal range for all three analytes performed, reportable range for the NT-proBNP analyte, and calibration procedures for all three analytes with 13 patient NT-proBNP results released since the first patient was tested on 12/19/24. The findings include: 1. Laboratory observation on 02/11/25 at 11:50 a.m. revealed the Polymedco Pathfast instrument (serial number 1807-03219) used for performing NT-proBNP, cardiac Troponin I (cTNI) and cross-linked fibrin degradation products (D-Dimer). 2. A review of the laboratory procedure for the Pathfast instrument revealed that the procedure lacked normal ranges for all three analytes, reportable range for the NT-proBNP, and calibration procedures for all three analytes. 3. A review of a patient activity report and a patient test report revealed that 13 patient NT-proBNPs had been reported since the first patient was reported on 12/19/24 for accession number MT24354010. No cTNI or D-Dimer patient testing had occurred. 4. A phone interview with the laboratory director on 02/18/25 at 2:30 p.m. confirmed the survey findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, review of a patient activity report and patient test records, and staff interview, the laboratory failed to verify the

	manufacturer performance specifications for three of four non-waived FDA approved test systems before patient testing which began in December 2024. Verification of manufacturer performance specifications were not performed for the Siemens Clinitek Advantus urine dipstick instrument, the three tests performed on the Polymedco Pathfast instrument, and the expected normal value for the McKesson Consult Mononucleosis test kit. The findings include: 1. Laboratory observation on 02/11/25 at 11:50 am revealed the following non-waived test systems used for performing patient testing: Siemens Clinitek Advantus instrument (serial number KP576002428) used for dipstick urinalysis. Sysmex XN 430 instrument (serial number 12065) used for Complete Blood Count with automated White Blood Cell Differential (CBC w /diff). Polymedco Pathfast instrument (serial number 1807-03219) used for performing NT-proBNP, cTNI, and D-Dimer. A microscope was used to perform wet prep and urine microscopic examinations. A McKesson Consult Mononucleosis test kit was used to perform serum mono testing. 2. On the survey date (02/11/25), there was no documentation that the laboratory verified the manufacturer's performance specifications for the Clinitek Advantus urine dipstick, the Polymedco Pathfast NT-proBNP, cTNI, and D-Dimer tests or the expected normal value for the McKesson Consult Mononucleosis test. 3. Review of a patient activity report and patient test reports revealed the following: For the Clinitek Advantus urinalysis instrument: Since the first dipstick urinalysis test for patient accessioning number MT24352023 was reported on 12/17/24, approximately 159 patient tests were performed. For the Polymedco Pathfast instrument: No patients were reported for the cTNI. No patients were reported for the D-Dimer. Since the first patient's NT-proBNP result, for patient laboratory accessioning number MT24354010, was reported on 12/19/24, 13 patient NT-proBNP results were reported. The patient's expected normal range was not verified for the McKesson Consult mononucleosis test. A total of two patients had been reported, with the first reported on 12/20/24 for patient MT24355034. 4. The laboratory director confirmed the survey findings during an interview on 02/11/25 at 6: 30 pm. She stated that she took over as laboratory director after the laboratory began testing and that the previous director had not ensured the verifications were completed.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, review of a patient activity report and patient test results, and staff interview, the laboratory failed to establish performance specifications for the urine microscopy and wet prep microscopic procedures before patient testing (two of two textbook procedures). Approximately 68 urine microscopy tests were reported since the first patient urine microscopy test was

	reported on 12/19/24. 1. Laboratory observation on 02/11/25 at 11:50 am revealed the following non-waived test systems used for performing patient testing: Siemens Clinitek Advantus instrument (serial number KP576002428) used for dipstick urinalysis. Sysmex XN 430 instrument (serial number 12065) used for Complete Blood Count with automated White Blood Cell Differential (CBC w/diff). Polymedco Pathfast instrument (serial number 1807-03219) used for performing NT-proBNP, cTNI, and D-Dimer. A microscope was used to perform wet prep and urine microscopic examinations. A McKesson Consult Mononucleosis test kit was used to perform serum mono testing. 2. On the survey date (02/11/25), there was no documentation that the laboratory had established performance specifications for the urine microscopy and vaginal wet prep textbook procedures. 3. A review of a patient activity report and patient test results revealed that approximately 68 patient urine microscopy results had been reported since the first patient urine microscopy test was performed on 12/19/24 for patient accessioning number MT24354023. No vaginal wet preps had been performed. 4. The laboratory director confirmed the survey findings during an interview on 02/11/25 at 6:30 pm. She stated that she took over as laboratory director after the clinic began testing and that the previous director had not ensured the validations were completed before testing.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (FORM CMS 209), review of laboratory records, and staff interview, the laboratory failed to ensure the required position of Clinical Consultant was filled. (Refer to D6057).
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on a review of the FORM CMS-209, a review of laboratory personnel records, and a staff interview, the laboratory failed to ensure the position of Clinical Consultant was filled to provide consultation concerning the diagnosis, treatment, and management of patient care. 1. A review of the FORM CMS-209 revealed the position of Clinical Consultant was not marked. 2. A review of laboratory personnel records revealed no documentation that the required position of Clinical Consultant

	was filled; the laboratory director did not qualify as a Clinical Consultant. 3. The laboratory director confirmed the survey findings during an interview on 02/11/25 at 6: 45 p.m.