Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2168592	11/08/2022
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with the technical consultant, the laboratory failed to review proficiency testing and evaluate the laboratory's results for two of sixteen events reviewed. The findings include: 1. Review of the laboratory's CAP proficiency testing results revealed the following events had not reviewed: Hematology 2021 event three Cardiac Markers 2021 event three 2. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the laboratory failed to review and evaluate proficiency testing results for two of sixteen events reviewed from 2021 and 2022.
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 review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the technical consultant, the laboratory failed to evaluate the accuracy of non-graded proficiency testing scores in

	2021 and 2022 for six of ten surveys that included non-graded PT scores. The findings include: 1. Review of the laboratory's proficiency testing records revealed the following events with non-graded scores that had not been evaluated for accuracy: 2021 event three--Hematology 2022 event one--Hematology 2022 event two--Hematology 2021 event three--Cardiac Markers 2022 event one---Cardiac Markers 2022 event three--Cardiac Markers 2. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the laboratory failed to evaluate the accuracy of non-graded PT scores in 2021 and 2022 for six of ten events with non-graded scores.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with the technical consultant, the laboratory's corrective actions were ineffective in correcting problems with the laboratory's testing personnel not following the PT program's instructions. The samples were analyzed in the incorrect mode for the hematology survey for three of three events in 2021. The findings include: 1. Review of the laboratory's proficiency testing records revealed the following: 2021 event one: White Blood Cell (WBC) automated differential score = 0% for a failure to submit results. Corrective action included documentation that the tech failed to run the PT samples in the QC mode as required by the PT program. 2021 event two: Multiple parameters for the WBC automated differential scored as unacceptable. Corrective action documentation included that the PT samples were not run in QC mode as required by the PT program. There was no evidence the error had been reviewed with the tech who made the error. 2021 event three: Unacceptable results for multiple parameters including the WBC differential. Review of instrument printouts revealed the samples had not been run in QC mode as required by the PT program. The PT event had not been reviewed or evaluated (Refer to D5211). 2. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the laboratory's corrective actions were ineffective in correcting problems with the laboratory's testing personnel following the PT program's requirements for sample analysis for the hematology PT samples, resulting in three of three events in 2021 with failing scores for the WBC automated differential.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 review of the laboratory procedure manual and interview with the technical consultant, the laboratory's procedure for the PathFast instrument did not include calibration verification requirements/procedures. The findings include: 1. Review of the procedure for the PathFast instrument used for performing patient testing for creatine kinase-MB (CK-MB), Troponin I, N-terminal-pro B-type Natriuretic Peptide (NT-proBNP) and fibrin degradation product (D-Dimer) revealed calibration verification requirements/procedure was not included as part of the procedure. 2. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the procedure for the PathFast instrument did not include calibration verification requirements /procedures.
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 procedure for the PathFast instrument and interview with the technical consultant, the laboratory failed to ensure the procedure for the PathFast instrument was approved by the lab director before use. The findings include: 1. Observation of the laboratory on 11/08/22 at 11 am revealed the PathFast instrument in use for patient testing for creatine kinase MB, Troponin I, fibrin degradation product (D-Dimer), and N-terminal-pro B-type Natriuretic Peptide (NT-proBNP). 2. Review of the laboratory procedure for the PathFast instrument revealed it had not been approved, signed or dated by the laboratory director. 3. Interview with the technical consultant on 11/08/22 at 6pm confirmed the laboratory failed to ensure the procedure for the PathFast instrument had been reviewed and approved by the laboratory director before use.
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 manufacturers' environmental operating specifications, and interview with the technical consultant, the laboratory failed to monitor the humidity in the area where the Sysmex XN 430 complete blood count (CBC) instrument and the PathFast chemistry/hematology instrument were located in 2022. The findings include: 1. Observation of the laboratory on 11/05/22 at 11 am revealed the Sysmex XN 430 CBC instrument and the PathFast chemistry /hematology instrument in use for performing patient testing. No device for monitoring of humidity was noted in the laboratory area where the instruments were located. 2. Review of the manufacturer environmental operating conditions revealed an operating humidity of 20-85% for the Sysmex XN 430 and 20-80% for the PathFast instrument. 3. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the laboratory failed to monitor the humidity in the laboratory area where the Sysmex XN 430 CBC instrument and the PathFast chemistry/hematology instrument were in use on the date of the survey (11/08/22).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 observation of the laboratory, lack of documentation, and interview with the technical consultant, the laboratory failed to verify the manufacturer normal range for the creatine kinase MB (CK-MB), Troponin I, cross-linked fibrin degradation products (D-Dimer), N-terminal-pro B-type Natriuretic Peptide (NT-proBNP) and myoglobin in 2021. The findings include: 1. Observation of the laboratory on 11/08/22 at 11 am revealed the PathFast instrument in use for patient cardiac testing to include CK-MB, Troponin, D-Dimer and NT-proBNP, new since the last survey date. 2. Review of patient accession #22053789 revealed patient testing reported for CK-MB, Troponin I, Myoglobin, D-Dimer and NT- proBNP on 04/22/22. 3. Review of validations that were approved on 09/29/21 revealed no documentation that the manufacturer patient normal range for the PathFast instrument for the CK-MB, Troponin, Myoglobin, D-Dimer, and NT-ProBNP analytes was verified. 4. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the laboratory did not verify the manufacturer normal range for the PathFast instrument in 2021.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the PathFast manufacturer package inserts, laboratory records and interview with the technical consultant, the laboratory failed to perform six month calibration verification in March 2022 for the Creatine Kinase-MB (CK-MB), Troponin I, Myoglobin, cross-linked fibrin degradation products (D-Dimer), N-terminal-pro B-type Natriuretic Peptide (NT-proBNP) analytes. The findings include: 1. Observation of the laboratory on 11/08/22 at 11 am revealed the PathFast instrument in use for patient testing for CK-MB, Troponin I, D-Dimer and NT-proBNP. 2. Review of the manufacturer package inserts for CK-MB. Troponin I, Myoglobin, D-Dimer and NT-proBNP revealed all five analytes are calibrated using two calibrator levels. 3. Review of laboratory records revealed that calibration verification was performed during install on 09/29/21. There was no documentation that the calibration verification due March 2022 was performed. 4. Review of patient accession #22053789 revealed patient testing for all five analytes on 04/22/22. 4. Interview with the technical consultant on 11/08/22 at 6pm confirmed the calibration verification due March 2022 for the PathFast instrument for the CK-MB, Troponin I, Myoglobin, D-Dimer and NT-proBNP analytes was not performed when due.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the technical consultant, the laboratory failed to ensure reference material was available to testing personnel for white blood cell (WBC) differential and slide review/cell morphology in 2022. The findings include: 1. Observation of the laboratory on 11/08/22 at 11 am revealed a microscope on the counter in use for patient testing for white blood cell manual differential and slide review/cell morphology. No reference material was observed in

	the laboratory. 2. Review of patient accession #22117474 revealed a manual differential reported on 09/12/22. 3. Interview with the technical consultant on 11/08 /22 at 6 pm confirmed the laboratory failed to ensure reference material for WBC manual differential and slide review/cell morphology was available to testing personnel on the date of the survey (11/08/22).
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 review of the laboratory procedure manual, review of laboratory records, interview with the technical consultant and email communication with the technical consultant, the laboratory failed to follow the procedure for review of complete blood count (CBC) quality control (QC) in 2021 and 2022. The findings include: 1. Review of the laboratory procedure for the Sysmex XN 430 revealed that the following quality control reports would be reviewed monthly: Insight IQAP Exception Report Summary Report Continuous Calibration Verification Detailed Daily Verification 2. Review of laboratory records for QC lot number 2154 revealed no documentation that the required reports for this lot number had been reviewed. 3. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the laboratory failed to follow its' own procedures for review of Sysmex CBC quality control. He further stated he was not sure when the review was last performed, but probably sometime in late 2021. 4. Email communication from the technical consultant on 11/15/22 at 4:07 pm revealed lot 2154 was in use from 06/21/22 until 09/12/22.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of a final patient test report for manual differential and interview with the technical consultant, the laboratory failed to have an adequate system in place to ensure the accuracy of final patient test reports resulting in incorrect result fields included in the final patient test report for manual differential for patient accession #22117474 in 2022. The findings include: 1. Review of the final patient test report for manual differential on lab accession #22117474, reported on 09/12/22, revealed progesterone included as a result field on the manual differential report. 2. Interview with the technical consultant on 11/08/22 at 6 pm confirmed the laboratory failed to

	have an adequate system in place to ensure the accuracy of final patient test reports resulting in the manual differential report having incorrect result fields as part of the final patient result.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of previous survey notes, personnel records and interview with the technical consultant, the technical consultant failed to perform testing personnel competency assessment for the use of the new PathFast instrument prior to patient testing. The findings include: 1. Observation of the laboratory on 11/08/22 at 11 am revealed the PathFast instrument in use for patient testing for CK-MB, Troponin I, NT-proBNP, and D-Dimer. 2. Review of previous survey notes from 02/13/20 revealed the laboratory had previously performed these tests on the Alere Triage instrument. 3. Review of personnel records revealed no documentation that the technical consultant had evaluated testing personnel competency for the use of the new instrument platform prior to patient testing. 4. Interview with the technical consultant on 11/08/22 at 6 pm confirmed there was no documentation that competency assessment for the use of the PathFast instrument platform had been performed prior to patient testing.