Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0029144	06/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic, Pa North Convenient Care, The	2859 Highway 45 Bypass, 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
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 review of the validation studies performed for the Alere Triage meter (serial # 00046321) and interview with the technical consultant, the laboratory failed to perform studies for verification of manufacturer's performance specifications for precision and reportable range for the Alere Triage Meter in 2018. The findings include: 1. Review of the validation studies performed in March 2018 for the Alere Triage meter (serial number 00046321) revealed no studies were available for verification of manufacturer's performance specifications for precision and reportable range. 2. Interview with the technical consultant on June 13, 2018 at 1pm confirmed that the validation studies performed for the Alere Triage meter (serial # 00046321) did not include studies for precision and reportable range. The laboratory reports D-dimer, CKMB, myoglobin, and troponin on this instrument and began reporting patients on April 1, 2018 with approximately 50 patients reported since installation of the meter.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure for the Alere Triage meter, the laboratory's procedure manual, the Food and Drug Administration (FDA) database for test complexity, interview with the instrument manufacturer technical services, patient test reports and the laboratory's quality control records for the Triage meter, and interview with the technical consultant the laboratory failed to perform two levels of control each day of patient testing for the CKMB, myoglobin and troponin analytes in 2016, 2017, and 2018. The findings include: 1. Observation of the laboratory on June 13, 2018 at 9:00 am revealed the Alere Triage meter in use for patient testing. 2. Review of the laboratory's procedure for the Alere Triage meter revealed the following: The meter is used for performing CKMB, myoglobin, and troponin. The control frequency is every 30 days and when a new lot number of a kit is opened. 3. Review of the laboratory's procedure manual revealed there was no individualized quality control plan (IQCP) in place for the reduced frequency of quality control for the Alere Triage meter for the CKMB, myoglobin, and troponin analytes. 4. Review of the FDA database for test complexity revealed that the CKMB, myoglobin and troponin analytes performed on the Alere Triage meter are moderately complex tests. 5. Interview via phone on June 15, 2018 at 2:30 pm with the manufacturer's technical services confirmed that the tests for CK-MB, myoglobin and troponin-I performed on the Triage meter are moderately complex. 6. Review of patient number thirteen test report and quality control for the months of June and July 2016 revealed CK-MB, myoglobin and troponin patient testing reported on 07.26.2016 with quality control last performed on 06.23.2016. 7. Review of patient number ten test report and quality control for the months of April and May 2017 revealed patient testing performed on 5.2.17 with quality control last performed on 04.13.17. 8. Interview with the technical consultant on June 13, 2018 at 4:00 pm confirmed the laboratory reports patient testing for CK-MB, myoglobin and troponin using the Alere Triage meter, follows the laboratory's procedure for quality control frequency, does not perform two levels of quality control each day of patient testing, and does not have an IQCP in place for reduced frequency of quality control in 2016, 2017, and 2018.