Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264373	(X3) Date Survey Completed 07/19/2018
Name of Provider or Supplier Atrium Health Navicent Urgent Care North	**Street Address, City, State** 3400 Riverside Dr, Macon, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 19, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the Procedure Manual for the laboratory and staff interview, the laboratory failed to address the procedure for handling laboratory specific complaints. Findings: 1. Review of the Procedure Manual for the laboratory, a procedure for handling facility complaints pertaining to the laboratory, was not address. 2. Interview with staff #2, and staff #3 (CMS 209 form), and a conference call with the Quality Management Department of the Medical Center, on July 19, 2018, at approximately 5: 40 pm, in the meeting/vending room, confirmed that the laboratory did not have a procedure addressing the directions for handling complaints specifically for the laboratory.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on the review of the Testing Personnel Competency documents, and staff interview, the laboratory failed to assess testing personnel on the six minimal regulatory requrements. Findings: 1. Reveiw of the Competency Assessment documents for the testing personnel, the laboratory failed to assess each employee of problem solving skills. 2. Interview with staff #2 , and #3 (CMS 209 form) on July 19, 2018, at approximately 4:30 pm, in the meeting/vending room, confirmed that the personnel were not assessed on their problem solving skills.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the Urine Microscopic procedure, and staff interview, the laboratory failed to address the use of posted pictures of microscopic findings, as well as available books, for the review of testing personnel performing urine microscopic examinations. Findings: 1. Review of the Urine Microscopic procedure failed to address the use of posted pictures or available books in the department for the review of testing personnel performing urine microscopic examinations for comparison if questions arise. The procedure states to leave a slide for the pathologist to review, but the facility does not have a pathologist. 2. Interview with staff #2, and #3 , on July 19, 2018, at approximately 5:30 pm in the meeting/vending room confirmed that the facility did not have posted pictures for comparison, and the availability of books in the department for comparison, if questions arise during a urine microscopic examination.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the Quality Control (QC) documents and the Quality Control Procedure(QCP) for the iSTAT Troponin , the laboratory failed to perform two levels of controls each day of patient testing, Findings: 1. Review of the QC documents, showed that the laboratory was performing QC for the iSTAT Troponin as described in the manufacturers' instructions, but not following the regulatory requirements. The laboratory failed to provide an acceptable Individualized Quality Control Plan.

	(IQCP). An acceptable IQCP is composed of three parts: A Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. The IQCP must be approved by the Laboratory Director (LD). 2. Interview with staff #2, and staff #3 (CMS 209 form), on July 19, 2018, at approximately 5:45 pm the meeting/vending room, confirmed that the laboratory was only performing QC as described in the manufacturers' instructions, and did not have an acceptable IQCP plan.