Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1019216	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Islands Family Medical Center	101 Blue Fin Circle, Suite 7, Savannah, 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 September 12, 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:
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 review of laboratory freezer temperature charts and staff interview, the laboratory failed to take corrective action when the temperature of the freezer used to store patient specimens fell outside the acceptable range. Findings include: 1. Review of temperature charts for the laboratory freezer used to store specimens required to be kept frozen prior to testing revealed the temperature was outside the acceptable range of negative 5 to negative 15 degrees centigrade on 80 of 89 days between June 31, 2018 and September 12, 2018 and 47 of 58 days between November 3, 2016 and January 30, 20017. No documentation of corrective action is available. 2. Interview with testing personnel #1 (see CMS 209) on September 12, 2018 at 12 pm in the laboratory director's office confirmed the temperature was outside the acceptable range and no documentation of corrective action is available.
D5429	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by the surveyor during a tour of the laboratory and staff interview, the laboratory failed to perform maintenance and function checks on the LabCorp Horizon Mini E centrifuge used to prepare specimens for testing. Findings include: 1. Observation by the surveyor during a tour of the laboratory revealed a sticker on the centrifuge showing rotations per minute (RPM) check on the centrifuge was last performed on 7/3/2012.. 2. Interview with testing personnel # 1 on September 12, 2018 at 12 pm in the laboratory confirmed there is no documentation of centrifuge maintenance and RPM check after 7/3/12 and maintenance is not performed yearly as required.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient reports and staff interview, the laboratory failed to include patient reference ranges for white blood cell count (WBC) on patient reports. Findings include: 1. Review of 2 of 2 patient reports for WBC testing performed by the laboratory revealed reference ranges are not include on reports. 2. Interview with testing personnel # 1 (see CMS 209) on September 12, 2018 at 1 pm in the laboratory director's office confirmed reference ranges are not included on patient reports.