Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1019216	(X3) Date Survey Completed 11/04/2020
Name of Provider or Supplier Islands Family Medical Center	**Street Address, City, State** 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 November 4, 2020. 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all records for a minimum of two years as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the lack of PT log sheets available at the time of survey for the following Hematology PT events: 2019 and 2020 -- Events A, B, and C. 2. An interview with Staff #2 (CMS 209) on 11/4/2020 in the conference room at approximately 11:45 a.m. confirmed the lack of PT event log sheets available at the time of survey for the aforementioned dates.
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 laboratory policy and procedure manual (SOP), testing personnel (TP) document review, and staff interview, the laboratory failed to follow policies and procedures as required. Findings include: 1. Review of the laboratory SOP and TP document review revealed the lack of TP initial training documentation in 2019 and six-month competency documentation in 2020 as required by the policy and procedure for TP competency performance. 2. An interview with Staff #2 (CMS 209) in the conference room on 11/4/2020 at approximately 11:00 a.m. confirmed the SOP competency policy and procedure was not followed for TP evaluation of performance in 2019 and 2020.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure all PT reports received were reviewed by the appropriate staff as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD did not review the following Hematology PT events: 2020 -- Events A and B. 2. An interview with Staff #2 (CMS 209) in the conference room on 11/4/2020 at approximately 1 p.m. confirmed the LD did not review the aforementioned 2020 AAFP PT events.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview the laboratory director/technical consultant (LD/TC) failed to ensure TP receive appropriate training, prior to testing patient specimens, for the type and complexity of the services offered as required. Findings include: 1. TP document review revealed the lack of 2019 initial training documentation available at the time of survey for Staff #2 (CMS 209). 2. An interview with Staff #2 (CMS 209) in the conference room on 11/4/2020 at approximately 10:45 a.m. confirmed an initial training was not performed for her in 2019.
D6053	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 at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens as required. Findings include: 1. TP document review revealed the lack of 2020 six-month competency documentation available at the time of survey for Staff #2 (CMS 209). 2. An interview with Staff #2 (CMS 209) in the conference room on 11/4/2020 at approximately 10:45 a.m. confirmed a six-month competency was not performed for her in 2020.