

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1019216	(X3) Date Survey Completed 09/24/2024
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	<p>A recertification survey was performed on September 24, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVEL: D2016 - Unsuccessful Participation 493.803 (a)(b)(c) NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p>

This CONDITION is not met as evidenced by:
Based on review of the American Association of Bioanalysis (AAB), Proficiency Testing (PT) provider, and staff interview, the laboratory failed to receive an acceptable score for the the 3rd event of 2023 and the 1st event of 2024 for the Specialty Hematology, subspecialty White Blood Cell (WBC). This is a CONDITION level citation. REFERENCE: D-6018 - Laboratory Director Responsibility - 493.1407(e)(4)(iii) D-6019 - Laboratory Director Responsibility - 493.1407(e)(4)(iv)

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 review of the American Association of Bioanalysts (AAB), Proficiency Testing (PT) provider, and staff interview, the laboratory failed to receive an acceptable score for the 3rd event of 2023 and the 1st event of 2024 for the Specialty Hematology, subspecialty White Blood Cell (WBC). There was no documentation to confirm that the evaluation results were reviewed. . Findings: 1. Review of the AAB PT documents, the Laboratory Director failed to ensure the laboratory submitted results for the 3rd event of 2023 and 1st event of 2024 for the Specialty Hematology, subspecialty WBC. There was no documentation of the review by the Laboratory Director of the failed results. 2. Interview with the Laboratory Director (LD) on 09/24 /2024, at approximately 1 pm , in the LD's office, confirmed the above statements.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of the American Association of Bioanalysis (AAB), Proficiency Testing (PT) provider, and staff interview, the Laboratory Director failed to provide corrective action documents for the unsuccessful scores received for the the 3rd event of 2023 and the 1st event of 2024 for the Specialty Hematology, subspecialty White Blood Cell (WBC). Findings: 1. Review of the AAB PT documents confirmed the Laboratory Director failed to provide corrective action for the 3rd event of 2023 and

the 1st event of 2024 for the specialty Hematology, subspecialty WBC. 2. Interview with the Laboratory Director (LD) on 09/24/2024, at approximately 1pm in the LD's office, confirmed the above statement.