

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2172258	(X3) Date Survey Completed 10/20/2022
Name of Provider or Supplier Golden Isles Healthcare, Llc	Street Address, City, State 144 East Oak Street, Mcrae, 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 October 20, 2022. 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:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on competency documents review and staff interview, the Laboratory Director (LD) failed to review and sign off on the Testing Personnel(TP) competencies. Findings include: 1. Competency document review revealed the Laboratory Director (LD) did not review or sign off on the Testing Personnel (TP) competencies for 2020, 2021, and 2022. 2. During an interview with Testing Personnel #1 (CMS-209) on October 20, 2022 at approximately 2:30 PM in the waiting room area, confirmed that the Laboratory Director(LD) did not review or sign off on competencies for Testing Personnel for years 2020, 2021, or 2022.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for</p>

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on competency records and staff interview, the Laboratory Director failed to assure that the competency records were reviewed and signed off for the Testing Personnel(TP). The Finding include: 1. Competency records revealed that the Laboratory Director did not review or sign off on the competency records for the Testing Personnel for 2020, 2021, and 2022. 2. During an interview with the Testing Personnel#1 (CMS-209) on October 20, 2022 at approximately 2:40 PM, in the waiting area, confirmed that the Laboratory Director did not review or sign off on the competency records for the Testing Personnel.