

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0860463	(X3) Date Survey Completed 07/12/2022
Name of Provider or Supplier Glynn Immediate Care Pc	Street Address, City, State 3400 Parkwood Dr, Brunswick, 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 12, 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:
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Control(QC) for the Chemistry analyzer, Abbott iSTAT, and staff interview, the laboratory failed to perform Chemistry controls, every day of patient testing, for the years 2020, 2021, and 2022. Findings: 1. Review of the QC for the Abbott iSTAT Basic Chemistry Profile, for the years 2020, 2021, and 2022, the laboratory was only performing QC when a new lot number of testing cartridges was opened. 2. Interview with staff #2(CMS 209 form), on July 12, 2022, at approximately 1pm in the office, confirmed the above aforementioned statement.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on review of the Quality Control(QC) for the Chemistry analyzer, Abbott iSTAT, and staff interview, the Laboratory Director(LD) failed to provide overall operation and administration of the laboratory. The laboratory failed to perform Chemistry controls, every day of patient testing, for the years 2020, 2021, and 2022. Findings: 1. Review of the QC for the Abbott iSTAT Basic Chemistry Profile, for the years 2020, 2021, and 2022, the laboratory was only performing QC when a new lot number of testing cartridges was opened. 2. Interview with staff #2(CMS 209 form), on July 12, 2022, at approximately 1pm in the office, confirmed the above aforementioned statement.