Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1068105	(X3) Date Survey Completed 11/30/2023
Name of Provider or Supplier St Marys Health Care System	Street Address, City, State 2470 Daniels Bridge Road Building 300, Athens, 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 proficiency testing desk review was completed on November 30, 2023. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 155 report and review of the College of American Pathologists (CAP) evaluation reports,

	the laboratory failed to sucessfully participate in proficiency testing (PT) for blood gas PH, PO2, and PCO2 for 6 consecutive testing events, resulting in the non- initial unsuccessful participation for blood gas PH, PO2, PCO2. Refer to D2096 and D2097
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CMS 155 report and review of CAP evaluation reports, the laboratory failed to demonstrate satisfactory PT performance for blood gas PH, PO2, PCO2, resulting in the non- initial unsuccessful participation for PH, PO2, PCO2. Findings: 1. A review of Casper Report 155 revealed the laboratory failed blood gas PH on the following: 2021 Event 1 Score 40% 2021 Event 2 Score 0% 2021 Event 3 Score 0% 2022 Event 2 Score 0% 2022 Event 3 Score 0% 2023 Event 1 Score 0% 2023 Event 2 Score 0% 2. A review of Casper Report 155 revealed the laboratory failed blood gas PO2 on the following: 2021 Event 2 Score 0% 2021 Event 3 Score 0% 2022 Event 2 Score 0% 2022 Event 3 Score 0% 2023 Event 1 Score 0% 2023 Event 2 Score 0% 3. A review of Casper Report 155 revealed the laboratory failed blood gas PCO2 on the following: 2021 Event 2 Score 0% 2021 Event 3 Score 0% 2022 Event 2 Score 0% 2022 Event 3 Score 0% 2023 Event 1 Score 0% 2023 Event 2 Score 0% 4. A review of the laboratory's CAP evaluation reports confirmed the laboratory failed blood gas PH, PO2, PCO2 with the aforementioned scores.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the proficiency testing CMS 155 report and CAP evaluation reports for 2021, 2022, and 2023, the laboratory failed to demonstrate satisfactory performance for the overall specialty of routine chemistry in 6 of 6 consecutive testing events. Findings: 1. A review of Casper Report 155 revealed the laboratory failed routine chemistry on the following: 2021 Event 1 Score 25% 2021 Event 2 Score 25% 2022 Event 2 Score 25% 2022 Event 3 Score 25% 2023 Event 1 Score 25% 2023 Event 2 Score 25% 2. A review of the laboratory's CAP evaluation reports confirmed the laboratory failed routine chemistry with the aforementioned scores.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the CMS 155 report and review of CAP PT evaluation reports, the laboratory director failed to provide overall management and direction to successfully participate in proficiency testing. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the CMS 155 and the CAP PT evaluation reports, the laboratory director failed to ensure successful participation for Proficiency Testing. Refer to D2096 and D2097