

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0970666	(X3) Date Survey Completed 02/19/2024
Name of Provider or Supplier Atrium Health Navicent Women's Care Fertility	Street Address, City, State 4075 Elnora Drive Suite A, Macon, 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 February 19, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. 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>

	<p>This CONDITION is not met as evidenced by: Based on review of the Proficiency Testing (PT) documents provided by American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE), the laboratory failed to obtain successful scores for the event 2 of 2022 and event 1 of 2023 for the Specialty of Hematology, sub specialty of Sperm Morphology. This is a condition level deficiency. Condition: D-2106 Successful Participation (Condition) 493.893 (a)(b)(c) Reference: D 2130 Hematology</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing (PT) documents provided by American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE), the laboratory failed to obtain successful scores for the event 2 of 2022 and event 1 of 2023 for the Specialty of Hematology, sub specialty of Sperm Morphology. Findings: 1. A review of the AAB/MLE PT documents confirmed the laboratory failed to receive successful scores for event 2 of 2022 and event 1 of 2023 for the specialty of Hematology and sub specialty of Sperm Morphology. There are two events a year for this sub specialty. 2. Interview with the Laboratory Director and the Technical Consultant, on 2/19/2024, at approximately 4:30pm, in the conference room, confirmed the aforementioned statement.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Proficiency Testing (PT) documents provided by American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE), the laboratory failed to obtain successful scores for the event 2 of 2022 and event 1 of 2023 for the Specialty of Hematology, sub specialty of Sperm Morphology. The Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart. This is a condition level deficiency. REFERENCE: D 6018 Laboratory Director Responsibilities 493.1407 (e)(4)(iii)</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to</p>

identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the Proficiency Testing (PT) documents provided by American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE), the laboratory failed to obtain successful scores for the event 2 of 2022 and event 1 of 2023 for the Specialty of Hematology, sub specialty of Sperm Morphology. The Laboratory Director(LD) failed to provide overall management and direction.

Findings: 1. Review of the AAB/MLE PT documents, the laboratory failed to receive successful scores for event 2 of 2022 and event 1 of 2023 for the specialty of Hematology and sub specialty of Sperm Morphology. There are two events provided by the PT provider each year for this sub specialty. The LD failed to follow up with additional testing to verify the accuracy of performing testing for sperm morphology
2. Interview with the Laboratory Director and the Technical Consultant, on 2/19/2024 at approximately 4:30pm in the conference room, confirmed the aforementioned statement.