

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0679874	<b>(X3) Date Survey Completed</b>  08/18/2021
<b>Name of Provider or Supplier</b>  Ob/Gyn Associates Of Erie	<b>Street Address, City, State</b>  100 Peach Street, Suite 202, Erie, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the technical Supervisor (TS), the laboratory failed to perform maintenance on 3 of 3 Fisher Scientific Thermometers from 08/18 /2019 to the day of survey. Findings include: 1. On the day of survey, 08/18/2021, observation of the laboratory revealed, 3 of 3 Fisher Scientific Thermometers were due for maintenance on 10/18/2014: - Room temperature thermometer - s/n: 122594842. - Refrigerator temperature thermometer - s/n: 122594688. - Freezer temperature thermometer - s/n: 122594710. 2. The laboratory could not provide a thermometer maintenance procedure policy . 3. The TS confirmed the findings about on 08/18/2021 around 3:00 pm.</p>
<b>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's validation records and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure performance specification procedures used are adequate to determine the accuracy and precision</p>

for the SARS - CoV-2 testing performed on the Cepheid GeneXpert System and the Architect ci 4100 before reporting patient test results in 2021. Findings Include: 1. On the days of survey 08/18/2021, a review of the Cepheid GeneXpert System and the Architect ci 4100 validation records revealed the following was not assessed before reporting patient test results in 2021: The Cepheid GeneXpert System - SARS - CoV-2 Molecular testing: - did not state performance specifications for accuracy and precision. - Validation was not signed by laboratory director. The Architect ci 4100-SARS - CoV-2 Antibody testing: -Validation was not signed by laboratory director. 2. The TS confirmed the findings above on 08/18/2021 around 2:15 p.m.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory procedure manual, review of personnel competency assessment records and interview with the technical supervisor (TS), the TS failed to perform competency assessment for 4 of 4 TP performing urine sedimentation and semen analysis microscopic examinations in 2020 and 2021. Findings Include: 1. On the day of survey, 08/18/2021, a review of TP competency assessment records revealed, 4 of 4 TP performing the following tests were not assessed for competency in 2020 and 2021: - Semen analysis microscopic examinations. - Urine sedimentation microscopic examinations. 2. The TS confirmed the findings above on 08/18/2021 around 1:50 pm.

**D6125**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel (TP) competency assessment records and interview with the technical supervisor (TS), the TS failed to assess the test performance for 2 of 4 TP through external proficiency testing samples or internal blind testing samples for all tests performed in the departments of Chemistry, Hematology, Immunology, Microbiology, Immunochemistry and Urinalysis in 2019 and 2020. Findings Include: 1. On the day of survey, 08/18/2021, review of TP competency assessment records revealed, 2 of 4 TP were not assessed for test performance through external proficiency testing samples or internal blind testing samples for all testing performed in the departments of Chemistry, Hematology, Immunology, Microbiology, Immunochemistry and Urinalysis in 2019 and 2020. 2. The TS confirmed the finding above on 08/18/2021 around 2:00 pm.