Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0679874	06/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ob/Gyn Associates Of Erie	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA Recertification survey was conducted at OB/GYN Associates of Erie on 6/15/2023 by the Pennsylvania Department of Health (PA DOH). The laboratory was surveyed under 42 CFR Part 493 CLIA Requirements. Specific deficiencies cites are as follows: 1. On the date of the survey, 06/15/2023 at 12:14 PM, interview with the Technical Supervisor (TS) revealed the laboratory failed to meet the following conditions for multiple laboratories operating at the same location with different CLIA certificates and using the same personnel and equipment from 8 /18/2021 to the date of the survey: -Quality control (QC) was not ran independently for each CLIA certificate and failed to show that each laboratory is operating independently. QC records indicate that QC was only performed to asses testing for 1 CLIA certificate for the following: - 1 of 1 Abbott Alinity i - 1 of 1 Sysmex XP-300 - 1 of 1 Cepheid GeneXpert - 1 of 1 DiaSorin XL 2. The TS confirmed these findings on 6/15/23 around 2:00 PM
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on lack of documention and interview with the Technical Supervisor (TS), the laboratory failed to establish a procedure for competency assessments for 5 of 5 testing personnel (TP) who performed testing on the Cepheid GeneXpert. Findings include: 1. On the day of the survey, 06/15/2023 at 8:58 PM, the laboratory could not provide competency assessment for 5 of 5 TP for each category of tests performed on the Cepheid GeneXpert from 8/18/2021 to the date of the survey. 2. The TS confirmed the findings above on 06/15/2023 around 02:00 PM.

D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy for 1 of 3 Hematology PT results in 2022, 1 of 3 Special Immunology PT results in 2022, 1 of 3 Urinalysis and Microscopy PT results in 2022, and 1 of 1 Special Immunology PT results in 2023. Findings Include: 1. On the day of survey, 06/15/2023 at 10:45 AM, review of 2022 CAP proficiency testing records revealed that the laboratory did not verify the accuracy for the following analyte that was given an unacceptable grade: - CAP 2022 Hematology 1st event - MPV (FH-13) was unacceptable 2. On the day of survey, 06/15/2023 at 10:45 AM, review of 2022 CAP proficiency testing records revealed that the laboratory did not verify the accuracy for the following analytes that was not graded by the proficiency testing agency: - CAP 2022 Special Immunology 2st event - Anti-thyroglobulin and Anti-thyroid (S2-10) was not graded - CAP 2022 Urinalysis and Microscopy 2nd event - Specific Gravity (CHEM 02 and CHEM 03) was not graded - CAP 2023 Special Immunology 1st event - Anti-thyroglobulin and Anti-thyroid (S2-03) was not graded 3. The TS confirmed the findings above on 06/15/23 around 2:00 PM.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Technical Supervisor (TS), the laboratory failed to evaluate, twice a year, the relationship between test results for 3 of 3 Affirm VP analyzers from 08/18/2021 to the day of the survey. Findings include: 1. On the day of the survey, 06/15/2023 at 12:03 am, the laboratory could not provide documentation of the biannual comparison of test results between 3 of 3 Affirm VP analyzers for Candida species, Gardnerella Vaginosis, and Trichomonas Vaginosis performed from 8/18/2021 to the date of the survey. 2. The laboratory performed 938 Candida species, Gardnerella Vaginosis, and Trichomonas Vaginosis tests in 2022. 3. TP #1 confirmed the finding above on 6/15/2023 at 3:00 PM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of Patient Test Report and interview with Technical Supervisor (TS), the laboratory failed to include on test reports the Emergency Use Authorizations (EUA) disclaimer regarding COVID-19 testing from 8/18/2021 to the date of survey. Finding Include: 1. On the day of survey, 06/15/23, a review of some test reports (1 of 1) revealed the test reports did not include the disclaimer regarding the Emergency Use Authorizations (EUA) for COVD-19 testing. 2. The TS confirmed the findings above on 06/15/2023 around 2:00 PM.