Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2310477	(X3) Date Survey Completed 09/04/2025
Name of Provider or Supplier Obgyn Associates Of Montgomery Pc	**Street Address, City, State** 495 Taylor Road, Suite A, Montgomery, AL	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the General Supervisor/Testing Personnel 1 (GS /TP1), the laboratory failed to implement a mechanism to verify the accuracy of the two non-regulated analytes, Human Papilloma Virus (HPV) Genotyping and the HPV test. The surveyor noted PT failures in two consecutive events for 2025. The findings include: 1. A review of the 2025 API PT records revealed the HPV Genotyping and HPV test performance evaluation scores, as follows: A) 2025 Microbiology (Virology) First Event: HPV Genotyping and the HPV test with scores of 60% each B) 2025 Microbiology (Virology) Second Event: HPV Genotyping with a score of 40%, and the HPV test with a score of 60% 2. The GS/TP1 confirmed the above findings during the exit conference on 09-04-2025 at 3:58 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on reviews of the laboratory's Daily Incubator and Heat Block Temperatures logs, the electronic patient testing history data and an interview with the General Supervisor/Testing Personnel 1 (GS/TP1), the laboratory failed to ensure Incubator and Heat Block Temperatures were recorded each day of patient testing. The surveyor noted no Incubator and Heat Block Temperatures were recorded for 50 of the 58 testing days from October-December 2024. The findings include: 1) A review of the Daily Incubator and Heat Block Temperatures logs revealed no documentation of the Incubator and Heat Block Temperatures from 10-07-2024 through 12-17-2024 when patient testing was performed. 2. A further review of the laboratory's Daily Incubator and Heat Block Temperatures logs indicated the following specified laboratory ranges. A) Incubator temperature range of 35-42 degrees Celsius B) Heat Block temperature range of 93-97 degrees Celsius 3. A review of the electronic patient testing history data from 10-07-2024 through 12-17-2024 revealed 946 patients were performed when the Incubator and Heat Block Temperatures were not monitored and recorded. 4) The GS/TP1 confirmed the above findings during the exit conference on 09-04-2025 at 3:58 PM.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) 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; (b)(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 a review of Testing Personnel (TP) competency records and an interview with the General Supervisor/Testing Personnel 1 (GS/TP1), the Technical Supervisor (TS) failed to assess and document the semi-annual competency of TP1 listed on the CMS 209 (Laboratory Personnel Report) form, performing high complexity testing. The surveyor noted one of the two TP had the semi-annual competency evaluation completed approximately 10 months after the initial training. The findings include: 1. A review of the 2025 competency records revealed TP1 was trained on 10-21-2024, however the semi-annual evaluation was not performed until 08-06-2025 (approximately 10 months after the initial training). 2. The GS/TP1 confirmed the above findings during the exit conference on 09-04-2025 at 3:58 PM.