Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0665970	**(X3) Date Survey Completed** 02/04/2020
Name of Provider or Supplier Gynecology & Obstetrics Of Dekalb Pc	**Street Address, City, State** 2801 N Decatur Rd Ste 190, Decatur, 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 Provider Performed Microscopy (PPM) Clinical Laboratory Improvement Amendments (CLIA) survey was completed on February 4, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) logs, observation during the laboratory tour, review of laboratory test package inserts, and staff interview, the laboratory failed to follow current manufacturer's instructions for all waived tests performed by the laboratory as required. Findings include: 1. Review of waived test package inserts and observation during the laboratory tour on 2/04/2020 at approximately 11:45 a.m. revealed there were no required QC logs available at the time of survey for the following waived tests: Hemoglobin (Hemocue Hb 201),Urine Human Chorionic Gonadotropin (Consult Diagnostics), and FIT test (Fecal Occult Blood) for 2019 and 2020 thus far. 2. An interview with the CLMA in a doctor's office on 2/4/2020 at approximately 12:30 p.m. confirmed the lack of QC documents for the aforementioned waived tests for 2019 and 2020 thus far.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves

	a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review, lack of Provider Performed Microscopy (PPM) testing personnel (TP) competency documents, lack of biannual peer review documents, and subsequent staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for each specialty and subspecialty of testing performed as required. Findings include: For details refer to D5203, D5209, D5217, and D5219
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a laboratory policy and procedure manual (SOP) review and staff interview, the laboratory did not have a policy and procedure for positive identification and optimum integrity of a patient's specimen throughout all phases of testing as required.. Findings include: 1. SOP review revealed there was no specimen identification policy and procedure available at the time of survey. 2. An interview with the Clinical Lead Medical Assistant (CLMA) in a doctor's office on 2/4/2020 at approximately 10:30 a. m. confirmed the lack of a positive specimen identification policy and procedure for the laboratory.
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 laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow a policy and procedure to assess (TP) competency as required. Findings include: 1. SOP review revealed there was no policy and procedure to assess (TP) competency available at the time of survey. 2. Lack of TP competency documents revealed there was no annual competencies performed for the following TP(CMS 209) for 2018, 2019, and 2020 thus far: Staff #2, Staff #3, Staff #4, Staff #5, Staff #6, and Staff #7. 3. An interview with the CLMA in a doctor's office on 2/4/2020 at approximately 10:30 a.m. confirmed the lack of a TP competency policy and procedure at the time of survey. During the same interview, the CLMA confirmed there were no competency documents available at the time of survey for the aforementioned staff for 2018, 2019, and 2020 thus far.

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 testing personnel (TP) document review and staff interview, the laboratory failed to verify at least twice annually the accuracy of any test or procedure performed. Findings include: 1. TP document revealed there were no biannual peer reviews performed on Staff #2 through Staff #7 (CMS 209) for Potassium Hydroxide (KOH) testing and Fern testing in 2018, 2019, and 2020 thus far. 2. An interview with the CLMA in a doctor's office on 2/4/2020 at approximately 11:00 a.m. confirmed the lack of KOH and Fern test peer reviews for the aforementioned testing personnel for 2018, 2019, and 2020 thus far.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory failed to verify at least twice annually the accuracy of any test or procedure performed. Findings include: 1. TP document revealed there were no biannual peer reviews performed for Parasitology (Wet Preparation) testing for Staff.#2 through Staff #7 (CMS 209) in 2018, 2019, and 2020 thus far. 2. An interview with the CLMA in a doctor's office on 2/4/2020 at approximately 11:00 a.m. confirmed the lack of Parasitology (Wet Preparation) peer reviews for the aforementioned testing personnel in 2018, 2019, and 2020 thus far.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), lack of microscopic qualitative quality control (QC) documents, and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required. Findings include: For details refer to D5401 and D5449

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on (SOP) review and staff interview, the laboratory director (LD) failed to ensure an approved SOP was available as required. Findings include: 1. SOP review revealed the LD did not approve the SOP for 2019 and 2020 thus far. 2. An interview with the CLMA in a doctor's office on 2/4/2020 at approximately 11:00 a.m. confirmed the lack of the LD's approval of the laboratory SOP for the aforementioned dates.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of equipment maintenance documents and subsequent staff inteview, the laboratory failed to perform and document equipment maintenance activities as required. Findings include: 1. Laboratory document review revealed there were no routine maintenance documents available at the time of survey for the Clinical Pathology Laboratory centrifuge and the Nikon microscope for 2018, 2019, and 2020 thus far. 2. An interview with the CLMA in the laboratory on 2/4/2020 in his office at approximately 11:45 a.m. confirmed the lack of routine maintenance for the laboratory microscope and centrifuge for the aforementioned dates..
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by:

	Based on observation and staff interview, the laboratory failed to perform and document equipment function checks as required. Findings include: 1. Observation during the laboratory tour on 2/04/2020 at approximately 11:45 a.m. revealed the Clinical Pathology Laboratory centrifuge was last calibrated on 10/6/2017. 2. An interview with the CLMA on 2/04/2020 at approximately 11:45 a.m. in the laboratory confirmed the lack of annual calibration for the laboratory microscope.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documents and staff interview, the laboratory failed to perform required quality controls (QC) for qualitative microscopic laboratory testing. Findings include: 1. Lack of quality control documents for Potassium Hydroxide (KOH), Wet Preparation (Parasitology), and Fern test revealed there were no qualitative microscopic QC documents available at the time of survey for 2018, 2019, and 2020 thus far. 2. An interview with the CLMA in the laboratory at approximately 12:00 p.m. on 2/4/2020 confirmed the lack of QC documentation for the aforementioned qualitative microscopic tests for 2018, 2019, and 2020 thus far.
D5980	PPM LABORATORY DIRECTOR CFR(s): 493.1355 The laboratory must have a director who meets the qualification requirements of 493. 1357 and provides overall management and direction in accordance with 493.1359. This CONDITION is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), lack of testing personnel (TP) peer review, lack of TP competency documents, lack of quality control (QC) documents review, and subsequent staff interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory as required. Findings incllude: For details refer to: D5203, D5209, D5217, D5219, D5401, D5433, D5435, D5449, and D1001
D5983	PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359 The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review, lack of testing personnel (TP) peer review documents, lack of TP competency documents, quality control (QC) document review, and staff interview, the laboratory director (LD) failed

	to provide oversight and management over the laboratory as required. Findings include: 1. SOP review revealed the LD failed to approve and sign the SOP annually for 2018, 2019, and 2020 as required. 2. Lack of. testing personnel (TP) annual competency documents revealed there were no TP competencies available at the time of survey for 2018, 2019, and 2020 thus far. 3 Lack of TP biannual peer review documents revealed there were no Potassium Hydroxide (KOH), Wet Preparation (Parasitology), or Fern test TP peer review documents available at the time of survey for 2018, 2019, and 2020 thus far. The following TP lacked biannual peer reviews: (CMS 209) Staff #2 through Staff #7. 4. Lack of waived test QC documents revealed there were no QC logs available at the time of survey for the following waived tests for 2018, 2019, and 2020 thus far: Hemoglobin (Hemocue Hb 201), Urine Human Chorionic Gonadotropin (Consult), and FIT (Fecal occult blood). 5. An interview with the CLMA in a doctor's office on 2/4/2020 at approximately 12:45 p.m. confirmed the aforementioned findings.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on lack of quality control (QC) documents and subsequent staff interview, the laboratory failed to meet the specific requirements for its certificate type. Findings include: For details refer to D8201
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on lack of waived test quality control (QC) documents and subsequent staff interview, the laboratory failed to follow manufacturer's instructions for waived testing as required. Findings include: 1. Lack of waived QC documents revealed there were no QC logs available at the time of survey for the following waived tests for 2018, 2019, and 2020 thus far: Hemoglobin (Hemocue Hb 201), Urine Human Chorionic Gonadotropin (Consult), and FIT (Fecal occult blood). 2. An interview with the CLMA in a doctor's office on 2/4/2020 at approximately 12:45 p.m. confirmed the lack of required QC documents for the aforementioned tests for 2018, 2019, and 2020 thus far.