Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0256000	01/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dekalb-Gwinnett Ob/Gyn Pc	4045 Wetherburn Way, Norcross, 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 January 23, 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 observation during the laboratory tour 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. Observation during the laboratory tour on 1/23/2020 at approximately 1:30 p.m. revealed there were no manufacturer's instructions available at the time of survey for the following waived tests: Macroscopic Urinalysis (Siemens Multistix), Blood Glucose (Accu Chek), and Urine Human Chorionic Gonadotropin (hCG). 2. Observation during the laboratory tour on 1 /23/2020 at approximately 1:30 p.m. revealed there were no required quality control (QC) documents available at the time of survey for the aforementioned waived tests for 2020 thus far. . 3. An interview with the laboratory director (LD) in the laboratory at approximately 1:30 p.m. on 1/23/2020 confirmed the lack of manufacturer's instructions for the aforementioned waived tests available at the time of survey. 4. An interview with the LD in his office on 1/23/2020 at approximately 1:45 p.m. confirmed the lack of required QC documents for 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 lack of a laboratory policy and procedure manual (SOP), lack of testing personnel (TP) 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, 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 lack of a laboratory policy and procedure manual (SOP) and subsequent staff interview, the laboratory failed to establish and follow written policies and procedures to ensure positive identification and optimum integrity of patient specimens as required. Findings include: 1. Lack of a laboratory SOP revealed there was not a policy and procedure available at the time of survey for positive patient specimen identification. 2. An interview with the laboratory director in his office on 1 /23/2020 at approximately 11:00 a.m. confirmed the lack of a patient specimen identification policy and procedure.
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 a laboratory policy and procedure manual (SOP), lack of testing personnel (TP) documents, and subsequent staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency as required. Findings include: 1. Lack of TP documents and an SOP revealed there was not a policy and procedure available at the time of survey to assess employee competency for Staff #2 (CMS 209) or Staff #2 (CMS 209) . 2. An interview with the laboratory director in his office on 1/23/2020 at approximately 11:15 a.m. confirmed the lack of an employee competency policy and procedure and, during the same. interview, the LD confirmed the lack of competencies for the aforementioned TP.

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 lack of testing personnel documents and a subsequent staff interview, the laboratory failed to verify at least twice annually the accuracy of any test or procedure performed. Findings include: 1. The lack of TP documents revealed twice annual peer reviews were not performed for Potassium Hydroxide (KOH) testing in 2018, 2019, and 2020 thus far. 2. An interview with the laboratory director in his office on 1/23 /2020 at approximately 11:30 a.m. confirmed the lack of KOH peer reviews for the aforementioned dates.
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 lack of testing personnel (TP) documents and subsequent staff interview, the laboratory failed to verify at least twice annually the accuracy of any test or procedure performed. Findings include: 1. Lack of TP documents revealed there were no twice annual peer reviews performed for Parasitology (Wet Preparation) testing in 2018, 2019, and 2020 thus far. 2. An interview with the laboratory director in his office on 1 /23/2020 at approximately 11:30 a.m. confirmed the lack of Parasitology (Wet Preparation) peer reviews for the aforementioned dates.
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 lack of a laboratory policy and procedure manual (SOP) and subsequent staff interview, the laboratory director (LD) did not ensure an approved policy and procedure manual (SOP) was available as required. Findings include: 1. The lack of a laboratory SOP revealed there was no laboratory SOP available at the time of survey. 2. An interview with the LD in his office on 1/23/ 2020 at approximately 10:30 a.m. confirmed there was not a laboratory SOP available at the time of survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure reagents and solutions not be used after their expiration date as required. Findings include: 1. Observation during the laboratory tour on 1/23/2020 at approximately 1:30 p.m. revealed a bottle of Potassium Hydroxide (KOH) 10 percent reagent on the laboratory counter near the microscope which had expired on 6/28/2017. . Observation during the same tour at 1:30 p.m. on 1/23/2020 revealed there was no replacement available at the time of survey. 2. An interview with the laboratory director in the laboratory on 1/23/2020 at approximately 1:30 p.m. confirmed the KOH solution in use had expired and there was no replacement available at the time of survey.
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 the lack of laboratory maintenance documents and subsequent staff interview, the laboratory failed to perform and document equipment maintenance activities as required. Findings include: 1. Lack of laboratory maintenance documents revealed there were no routine maintenance documents available at the time of survey for the Conphar microscope or the Horizon miniE centrifuge for 2018, 2019, and 2020 thus far. 2. An interview with the laboratory director on 1/23/2020 in his office at approximately 1:00 p.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 1/23/2020 at approximately 1:30 p.m. revealed the Conphar microscope had not been calibrated since July, 2004. 2. Observation during the laboratory tour on 1/23/2020 at approximately 1:30 p.m. revealed the Horizon miniE centrifuge had not been calibrated since September 10, 2008. 3. An interview with the laboratory director on 1/23/2020 at approximately 2:00 p.m. confirmed the lack of calibration for the laboratory microscope and centrifuge.
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 review of patient records and staff interview, the laboratory failed to perform and document required quality controls (QC) for qualitative testing. Findings include: 1. Patient record review revealed the laboratory failed to provide QC documentation at the time of survey for Microscopic Urinalysis, Potassium Hydroxide (KOH), Parasitology (Wet Preparation), and Qualitative Semen Analysis patient testing for 2018, 2019, and 2020 thus far.. 2. An interview with the laboratory director in his office on 1/23/2020 at approximately 1:30 p.m. confirmed the lack of QC for aforementioned qualitative laboratory tests for 2018, 2019, and 2020 thus far.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on laboratory document review and staff interview, the laboratory failed to establish a policy and procedure for monitoring and correcting problems with test reporting as required. Findings include: 1. Laboratory document review revealed there was not a policy and procedure for corrective action available at the time of survey. 2. An interview with the laboratory director in his office on 1/23/2020 at approximately 2:00 p.m. confirmed the lack of a corrective action policy and procedure available at the time of survey.
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 lack of a laboratory policy and procedure manual, lack of quality control documents, lack of peer review documents, lack of testing personnel competency documents, lack of equipment maintenance documents, and performance of laboratory tests beyond the scope of their certificate, the laboratory director failed to provide overall management and direction of the laboratory as required. Findings: For details refer to D1001,D5203, D5209, D5217, D5219, D5401, D5433, D5435, D5449, and D8201
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 the lack of a policy and procedure manual (SOP), the lack of testing personnel (TP) competency documents, the lack of twice-annual peer review documents, and the lack of quality control (QC) documents, the laboratory director (LD) failed to provide adequate oversight over the laboratory as required. Findings include: 1. Based on the lack of a policy and procedure manual (SOP), the lack of testing personnel (TP) competency documents, the lack of twice-annual peer review documents, and the lack of quality control (QC) documents, the laboratory director (LD) failed to provide adequate oversight over the laboratory as required. 2. At interview iwth the LD in his office on 1/23/2020 at approximately 2:30 pm. confirmed the lack of the aforementioned documents.
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 patient document review and staff interview, the laboratory failed to meet the specific requirements for its certificate type and failed to follow manufacturer's instructions for waived testing.. 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 observation during the laboratory tour, patient record review, and staff interview, the laboratory performed laboratory test beyond the scope of the certificate held by the laboratory and failed to follow manufacturer's instructions for waived testing. Findings include: 1. Patient record review revealed a Quick Vue Plus serum pregnancy test was performed on 1/7/2020 which is a moderate complexity test. 2. An interview with the laboratory director in his office on 1/23/2020 at approximately 1:45 p.m. confirmed the performance of the aforementioned moderate complexity serum pregnancy test on 1/07/2020. 3. Observation during the laboratory tour on 1/23/2020 at approximately 1:30 p.m. revealed there were no manufacturer's instructions available at the time of survey for the following waived tests: Macroscopic Urinalysis (Siemens Multistix), Blood Glucose (Accu Chek), and Urine Human Chorionic Gonadotropin (hCG). 4. Observation during the laboratory tour on 1/23/2020 at approximately 1:30 p.m. revealed there were no required quality control (QC) documents available at the time of survey for the aforementioned waived tests for 2020 thus far. . 5. An interview with the laboratory director (LD) in the laboratory at approximately 1:30 p.m. on 1/23/2020 confirmed the lack of manufacturer's instructions for the aforementioned waived tests available at the time of survey. 6. An interview with the LD in his office on 1/23/2020 at approximately 1:45 p.m. confirmed the lack of required QC documents for the aforementioned tests for 2020 thus far. 6. An interview with the laboratory director in his office on 1/23/2020 at approximately 1:45 p.m. confirmed the performance of the aforementioned moderate complexity serum pregnancy test on 1/07/2020.