Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0966153	03/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Regional Medical Group Obstetrics & Gynecology	260 Congress Parkway, Ste A, Crystal Lake, IL	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the surveyor's review of the proficiency testing (PT) documents, manual, records, and an interview with the laboratory director (LD) and staff; the laboratory failed to test PT samples with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory using the laboratory's routine methods. Findings: 1. The laboratory is enrolled in a PT program for testing Candida species (Yeast), Gardnerella vaginalis and Trichomonas vaginalis using the BD Affirm test system. 2. The PT records show that the laboratory participated in 6 out of 6 PT events during the years of 2016 and 2017. 3. The patient test log showed that the PT samples for 0 out of 6 PT events, were not recorded in the laboratory's test log along with the patients. 4. On a Recertification survey conducted on 03/29/2018 at 12: 00 PM, the LD and staff confirmed the above findings.
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 the surveyor's review of the Laboratory Personnel Report (CMS 209), the

	policies, procedures, employee records and an interview with the laboratory director (LD) and staff; the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing moderately complex testing, affecting 5 out of 5 testing personnel (TP). Findings: 1. The CMS 209 lists 5 TP performing tests for Candida species (Yeast), Gardnerella vaginalis and Trichomonas vaginalis using the BD Affirm test system (a moderately complex test) in the laboratory. 2. The personnel files presented revealed that 5 out of 5 TP testing assessments did not indicate whether the TP were competent to perform the various tests conducted in the laboratory. 3. The competency procedure used to evaluate TP is a check list of observations. There is no written indication on the 5 out of 5 competencies reviewed that the TP assessed had performed with "Satisfactory" or "Unsatisfactory" performances; or whether supervision or non-supervision is required for the assessed employee. 4. The laboratory's competency policy and step-by-step procedure also does not include the following: ** The assessment of test performance through testing previously analyzed specimens or internal blind testing samples, when external proficiency testing samples are unavailable.** 5. On a Recertification survey conducted on 03/29/2018 at 12:00PM, the LD and staff confirmed the above findings.
D5419	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the laboratory test volume worksheet, records, manual, and an interview with the laboratory staff; the laboratory failed to ensure that the components of reagent kits of different lot numbers are not interchanged, affecting 3000 tests. Findings: 1. On 03/29/2018 at 11:00 AM during a tour of the laboratory, the surveyor observed the following concerning the BD Affirm test kits: 1). The testing personnel (TP) stores the reagent packs and BD Affirm test cards that will be used for the day in the laboratory, while the kit remains in the refrigerator located in another room. 2). The reagent packs and BD Affirm test cards does not have the lot number of the kit from which it was retrieved, written on it. 3). In the refrigerator where the BD Affirm kits are stored, multiple kit lots were opened and components removed for use. 4). No documentation was as provided evidence to show kit components were not interchanged. 2. The laboratory's quality control logs and worksheet revealed that multiple kit lots were in-use during the same period of time. 3. The laboratory's manual does not include a policy or procedure to address and prevent the interchanging of BD Affirm kits with different lot numbers. 4. The laboratory's test volume worksheet states that the laboratory performed 3000 tests during the year of 2017 and 2018. 5. On a Recertification survey conducted on 03/29 /2018 at 12:00PM, the LD and staff confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, manuals, and an interview with the laboratory director (LD) and staff; the laboratory failed to document a complete Individual Quality Control Plan (IQCP) for testing performed in the specialty of Microbiology, affecting 3000 tests. Findings: 1. A review of the IQCP documentation showed that the laboratory's plan does not include a quality control (QC) plan which defines the reduced QC procedure established for the BD Affirm test system for identifying Trichomonas (Tri), Gardnerella Vaginosis (GV) and Candida sp (Y for Yeast) from vaginal source specimens. 2. The qualit control (QC) logs and worksheets show that the laboratory performs external QCs every 7 days. 3. The laboratory's test volume worksheet states that the laboratory performed 3000 tests during the year of 2017 and 2018. 4. On a Recertification survey conducted on 03/29 /2018 at 12:00PM, the LD and staff confirmed the above findings.