Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1070129	01/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Gynecology Center	2401 Brandermill Blvd Suite 200, Gambrills, MD	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) and patient log record review and interview with the laboratory staff, the laboratory staff did not test PT samples in the same manner as patient samples. Findings: 1. The laboratory uses a BD Affirm Microbial Identification System to test for Candida, Gardnerella, and Trichomonas. Patient specimens are recorded on a patient log prior to testing. 2. A review of patient logs from 2016 to 2017 showed that PT specimens were not recorded on the patient log in 4 of 6 Bacteriology PT events. 3. During an interview on 1/22/18 at 11:00 AM, the laboratory staff confirmed that PT specimens were not being logged on to the patient log in the same manner as patients.
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 1/18/2016 for not rotating PT among all staff performing patient testing. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with laboratory staff, the laboratory did not ensure that all the testing personnel that tested patient samples performed the PT. Findings: 1. The laboratory currently has 3 testing personnel performing bacteriology testing as listed on the "Laboratory Personnel Report (CMS-209)." 2. A review of bacteriology PT attestation worksheets from 2016 and 2017 showed that for 5 of 6 events, PT was performed by the same testing person. 3. During an interview on 1/22 /17 at 11:00 AM, the laboratory staff confirmed that PT samples were not tested each year by all the staff that perform patient testing to ensure accurate and reliable patient test results.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory did not ensure that unsatisfactory PT scores were investigated and corrective action taken for 1 of 6 PT events from 2016 to 2017. Findings: 1. The laboratory received a score of 80% on bacteriology PT performed during the 1st event of 2016. 2. A review of PT records showed that there was no documentation of an investigation by the laboratory as to the cause of the unsatisfactory score, or of corrective action performed. 3. During an interview on 1/22/18 at 11:00 AM, the laboratory staff confirmed that unsatisfactory PT scores had not been investigated.
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 quality control (QC) record review and interview with laboratory staff, the laboratory did not ensure that both a positive and a negative control were run each time external QC was run on the BD Affirm Microbial Identification System. Findings: 1. A review of QC records from 2016 to 2017 showed that the laboratory was running a positive tri-valent control on the BD Affirm but no negative external control. 2. During an interview, laboratory staff stated that they did not run a negative external control when running the positive control on the kit and that they were not aware that it was required. 3. Record review showed that the laboratory does have an IQCP in place to reduce the amount of QC required when performing testing on the

	BD Affirm. 4. During an interview on 1/22/18 at 11:00 AM, the laboratory staff confirmed that a negative external control was not being performed on the BD Affirm Microbial Identification System.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) plan and interview with the laboratory staff, the laboratory director (LD) failed to ensure that the QA plan was maintained to identify failures and corrective actions taken when failures are identified. Findings: 1. The "Monthly Quality Assurance Checklist" lists the QA tasks that the LD performs as part of the QA review each month. A check mark under the column "Yes/No" indicates if the task was performed. 2. From January, 2016 to December, 2017 the "Yes" column was checked for every task listed; and 3. Document review showed that the laboratory had unsigned copies of the checklist which were pre-checked and identical in appearance to those which were signed by the LD over the prior 2 years. 4. The checklist states, "Proficiency Tests were handled in the same manner as patient specimens." The LD's QA review failed to ensure that PT samples are recorded like patients in the testing records. See D2006. 5. The LD's QA review failed to ensure that PT samples were run by all testing personnel performing laboratory testing. See D2007. 6. The checklist states, "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." The LD failed to take and monitor corrective action after the PT failed. See D5221. 7. During an interview on 1/22/18 at 11:00 AM, the laboratory staff confirmed that the laboratory's QA plan was not maintained to identify failures in quality as they occur.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory director (LD) did not specify in writing the duties and responsibilities of each person involved

	in the performance of preanalytic, analytic, and postanalytic phases of testing. Findings: 1. A review of the standard operating procedure manual (SOPM) showed that there were no descriptions of duties and responsibilities for the LD, clinical consultant, technical consultant, and testing personnel. 2. During an interview on 1/22 /18 at 11:00 AM, the laboratory staff confirmed that there was no list of duties and responsibilities for the LD, clinical consultant, technical consultant, and testing personnel in the SOPM.