Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0219882	09/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Women Ob/Gyn	2003 Medical Parkway, Suite 250, Annapolis, 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
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 review of proficiency testing (PT) records, the PT standard operating procedure (SOP), and patient testing logs and interview with the laboratory director (LD), the laboratory failed to ensure that PT results were documented in the same manner as patient results and PT samples were tested by the testing personnel (TP) who routinely performed patient testing. Findings: 1. Records for six PT events were reviewed for the Microbiology 2020 3rd event through the 2022 2nd event. 2. The laboratory used the Affirm VPIII Microbial Identification Test system which required the TP to visually read the test results from the Probe Analysis Card. The only records of the test results were what was manually documented by the TP. 3. The TP documented patient results on the Affirm Log Sheet which captured the date of testing, patient name, test results and the initials of the TP who performed the testing. 4. The laboratory's PT SOP stated to "[d]ocument testing numbers (VP-01, VP-02, etc) onto Affirm log sheet." 5. The PT results were not recorded on the Affirm Log Sheet in three of the six PT events (2022 2nd event, 2021 3rd event, and 2021 1st event). 6. The PT SOP stated "[r]emove cards from processor, lay them on a paper towel for Lab Director to review and validate results." The LD did not review and validate results for routine patient testing. 7. The laboratory personnel report (CMS-209) listed four TP. 8. Review of the attestation statements showed that TP 1 performed testing for five of the six PT events, TP 2 performed testing for one of the six PT events, and TP 3 performed none of the six PT events (TP 4 was recently hired). Review of the Affirm Log Sheets from 08/18/2020 - 08/23/2022 showed that TP 1 did not perform routine patient testing, only testing of PT samples. 9. During the

	survey on 08/25/2022 at 12:00 PM, the LD confirmed that PT sample results were not consistently documented with routine patient results and were not tested by the TP who routinely performed patient testing.
D2026	BACTERIOLOGY CFR(s): 493.823(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to document an investigation into the unsatisfactory results received during the 2021 Microbiology 2nd PT event. Findings: 1. The laboratory used the Affirm VPIII Microbial Identification Test system to identify Candida species, Gardnerella vaginalis, and Trichomonas vaginalis in patient specimens. 2. The laboratory received a score of 60 percent for Gardnerella vaginalis in the 2021 Microbiology 2nd PT event. 3. In the section titled "Corrective action taken (if indicated)" on the performance evaluation it was written that "10/15/21 controls were ran x 2 & all were correct." 4. The PT records did not include documentation of an investigation into the root cause of the unacceptable PT score, including corrective actions taken for patient results that may have been affected by the same issues affecting the PT samples. 5. During the survey on 08/25/2022 at 12:00 PM, the LD confirmed that there was no documentation of an investigation into the root cause of the unacceptable PT score and whether patient results were potentially affected.
D2044	MYCOLOGY CFR(s): 493.827(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to document an investigation into the unsatisfactory results received during the 2021 Microbiology 2nd PT event. Findings: 1. The laboratory used the Affirm VPIII Microbial Identification Test system to identify Candida species, Gardnerella vaginalis, and Trichomonas vaginalis in patient specimens. 2. The laboratory received a score of 60 percent for Candida species in the 2021 Microbiology 2nd PT event. 3. In the section titled "Corrective action taken (if indicated)" on the performance evaluation it is written that "10/15/21 controls were ran x 2 & all were correct." 4. The PT records did not include documentation of an

	investigation into the root cause of the unacceptable PT score, including corrective actions taken for patient results that may have been affected by the same issues affecting the PT samples. 5. During the survey on 08/25/2022 at 12:00 PM, the LD confirmed that there was no documentation of an investigation into the root cause of the unacceptable PT score and whether patient results were potentially affected.
D2053	PARASITOLOGY CFR(s): 492.829(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to document an investigation into the unsatisfactory results received during the 2021 Microbiology 2nd PT event. Findings: 1. The laboratory used the Affirm VPIII Microbial Identification Test system to identify Candida species, Gardnerella vaginalis, and Trichomonas vaginalis in patient specimens. 2. The laboratory received a score of 60 percent for Trichomonas vaginalis in the 2021 Microbiology 2nd PT event. 3. In the section titled "Corrective action taken (if indicated)" on the performance evaluation it is written that "10/15/21 controls were ran x 2 & all were correct." 4. The PT records did not include documentation of an investigation into the root cause of the unacceptable PT score, including corrective actions taken for patient results that may have been affected by the same issues affecting the PT samples. 5. During the survey on 08/25/2022 at 12:00 PM, the LD confirmed that there was no documentation of an investigation into the root cause of the unacceptable PT score and whether patient results were potentially affected.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's product insert (PI), the quality control (QC) standard operating procedure (SOP), and patient testing logs and interview with the laboratory director (LD), the laboratory failed to consistently document the performance of external QC on new reagent lot numbers prior to patient testing using the Becton Dickinson (BD) Affirm VPIII Microbial Identification Test system. Findings: 1. The manufacturer's PI, 670160JAA(04) 2019-06, stated that "[e]ach reagent lot must be tested for adequate sample lysis and release of target nucleic acid."

	2. The laboratory's SOP titled "Quality Control Testing" stated that external controls need "to be done when a new box of Affirm BD VPIII, is opened. BEFORE PATIENT TESTING and/or Monthly." 3. The laboratory documented patient results on the Affirm Log Sheet (log) that included a section at the top of the log for the BD Affirm VPIII reagent kit lot number (#). The top two rows of each page of the log contained cells to record the date of testing, lot #, and results of external QC testing for that reagent kit lot # followed by rows for patient test results (22 per page). 4. Logs were reviewed for patient test and external QC results from 08/18/2021 through 08/23/2022 which included 40 different reagent kit lot #s. 5. Seven of the 40 reagent kit lot #s did not have external QC results documented prior to patient testing: a. Kit lot # 2060333, 18 patients tested from 06/16/2022 b. Kit lot # 1321459, 22 patients tested from 04/20/2022-05/03/2022 c. Kit lot # 1298171, 22 patients tested from 02/15 /2022-03/03/2022 d. Kit lot # 1293147, 22 patients tested from 02/04/2022-02/15 /2022 e. Kit lot # 1265933, 22 patients tested from 01/10/2022-01/18/2022 f. Kit lot # 1007994, 22 patients tested from 04/14/2021-04/29/2021 g. Kit lot # 0273197, 22 patients tested from 12/14/2020-12/28/2020 6. In addition, three kit lot #s did not include documentation of the date QC testing was performed (1096966, 1057753, and 1029847) and four kit lot #s did not include documentation of the external QC lot # used (1096966, 1029847, 0330731, and 0248720). 7. During the survey on 08/25 /2022 at 12:00 PM, the LD confirmed that results of external QC performed on new BD Affirm VPIII reagent kit lot #s were not consistently documented prior to patient testing.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that there was a documented investigation into the root cause of unacceptable proficiency testing scores and corrective actions were taken for any potentially affected patient samples. Cross-refer to tags D2026, D2044, and D2053 for more details.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) credentials and interview with the practice manager (PM), the laboratory director failed to ensure all TP had documentation of credentials required to perform moderate complexity testing. Findings: 1. The laboratory personnel report (CMS-209) listed four TP. 2. The PM confirmed that documentation of educational requirements (diplomas or transcripts) for all four TP was not available on-site during the survey. 3. The credentials were requested via email on 08/31/2022 at 3:16 PM and 09/13/2022 at 4:17 PM and were received via email on 9/19/2022 at 8:54 AM. 4. Documentation received for TP 3 did not include a school diploma or transcript. 5. As of 09/27/2022, no diploma or school transcript was received for TP 3 to verify whether TP 3 was qualified to perform moderate complexity testing.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: The testing personnel failed to ensure that results from external quality control testing on new lot numbers of Affirm VPIII Microbial Identification Test reagent kits were documented prior to performing patient testing. Cross-refer to tag D5461 for more details.