Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0219882	01/12/2018
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation and interview with the laboratory director (LD), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 1/12/18 at 12:30 PM, the LD confirmed that the eye wash station was not located in the room where laboratory testing is performed.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory did not ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from 2016 and 2017 showed that signed attestation statements were not available at the time of the survey for the 2nd and 3rd PT events of 2017 in bacteriology; and 2. A copy of the PT results and scores from 3rd event, 2016 in bacteriology was not available at the time of the survey. 3. During an interview on 1/12/18 at 12:30 PM, the LD confirmed that the laboratory did

	not maintain all PT documents for a minimum of two years from the date of the PT testing event.
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 director (LD), 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 2nd event of 2017. 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 1/12 /18 at 12:30 PM, the LD confirmed that unsatisfactory PT scores had not been investigated.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory director (LD), the laboratory did not provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the BD Affirm Microbial Identification System. Findings: 1. A review of the SOPM showed that there were no written procedures for patient preparation; specimen collection, labeling, storage, preservation, processing, and referral; criteria for specimen acceptability and rejection; control procedures; and the laboratory's system for entering results in the patient record and reporting patient results. 2. A review of the SOPM showed a one page "Affirm Procedure" which included instructions for testing samples on the Affirm, but it did not include the procedures

	mentioned above. 3. Document review showed that there was no instrument operator's manual available at the time of the survey. 4. During an interview on 1/12/18 at 12:30 PM, the LD confirmed that the SOPM did not contain written preanalytical, analytical, and post analytical policies and procedures for testing with the BD Affirm.
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 quality control (QC) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the lot numbers and expiration dates of all reagents in the BD Affirm Microbial Identification Test kit were documented. Findings: 1. The laboratory documents the lot number and expiration date that's printed on the outside of the BD Affirm testing kit on their patient log. 2. A review of patient logs from January to December, 2016 showed that the documentation did not include lot numbers and expiration dates for the reagent cassettes and other reagents used in the kit, each of which have a unique lot number and expiration date. 3. During an interview on 1/12/18 at 12:30 PM, the LD confirmed that there were no lot numbers or expiration dates documented for each of the reagents included in the BD Affirm Microbial Identification Test kit.
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 standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the laboratory director (LD), the laboratory did not run 2 levels of QC each day of patient testing and failed to establish an Individual Quality Control Plan (IQCP) for performing testing on the BD Affirm Microbial Identification System. Findings: 1. During an interview at 10:00 AM, laboratory staff stated that positive and negative QC is performed on the first box opened of each new lot number of kits for the BD Affirm Microbial Identification System. Laboratory staff stated that they did not have an IQCP in place to reduce the amount of QC required when performing testing on the BD Affirm. 2. During an interview on 1/12 /18 at 12:30 PM, the LD confirmed that an IQCP had not been performed for testing on the BD Affirm Microbial Identification System.
D5481	CONTROL PROCEDURES

	CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) and patient log record review and interview with the laboratory director (LD), the laboratory did not ensure that QC was run and acceptable on each new lot number of BD Affirm Microbial Identification kit before being used to run patient specimens. Findings: 1. During an interview at 10:00 AM, the laboratory staff stated that the lab orders two boxes of cartridges for the BD Affirm at a time. The 2 kits have the same lot number and expiration date. The laboratory runs QC on the first box opened of the new lot number. 2. A review of QC records from 2016 showed that for at least 90% of the time, patient specimens were logged and tested before QC was performed on a new lot number of kit. 3. During an interview on 1/12/18 at 12:30 PM, the LD confirmed that QC was not performed on new lot numbers of BD Affirm kits prior to patient testing.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with the laboratory director (LD), the laboratory failed to document corrective action when refrigerator temperatures were out of range. Findings: 1. The temperature range for the laboratory refrigerator is 35 - 46 degrees Fahrenheit; and 2. From July, 2017 to December, 2017 the refrigerator temperatures were out of range 48 out of 126 times recorded. 3. There were no corrective actions documented for these dates. 4. During an interview on 1/12 /18 at 12:30 PM, the laboratory staff confirmed that there were no corrective actions documented for the days that the refrigerator temperatures were out of range.
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 director (LD), the 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 1/12/18 at 12:30 PM, the LD confirmed that there was no list of duties and responsibilities for the LD, clinical consultant, technical consultant, and testing personnel in the SOPM.