

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219882	(X3) Date Survey Completed 02/28/2024
Name of Provider or Supplier Women Ob/Gyn	Street Address, City, State 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 09/27/2022 for not rotating proficiency testing 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 the office manager (OM), the laboratory did not ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has four TP listed on the "Laboratory Personnel Report" (CMS-209). 2. A review of microbiology PT attestation worksheets from 2022 through 2024 showed that PT was performed by one of the four TP for three out of five events. The surveyor was unable to find out which TP performed the PT for the 3rd event of 2022 because the laboratory failed to maintain the attestation statement. 3. During an interview on 02/21/2024 at 1:00 PM, the OM confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the individual testing or examining the samples signed the PT attestation statements, attesting that PT specimens were run in the same manner as patient samples. Findings: 1. A review of microbiology PT records from 2022 through 2024 showed that in three of five events, the attestation statements were not signed by the LD or the testing person (TP) who performed the PT. The attestation statements for two of five PT events was missing. 2. Upon request, the laboratory provided electronic printouts of the attestation statements for four of five PT events which listed the name of the LD and the TP. One of five attestation statements was still missing. 3. During an interview at 11:00 AM, the LD stated that they sign the attestation statement online when entering the PT results and that they enter the name of the TP who performed the PT. 4. The attestation statement which comes with each PT event states, "Electronic signatures must have evidence that only the authorized person can utilize the signature." The LD confirmed that the TP did not have their own log-in credentials to sign the attestation statement themselves online and that the TP did not sign the attestation statements.

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 office manager (OM), the laboratory did not ensure that a self-evaluation of unsatisfactory PT scores was performed as part of the corrective action taken. Findings: 1. The laboratory received a score of 60% on microbiology PT performed during the 3rd event of 2023. 2. A review of PT records showed that upon investigation, the laboratory determined that two of the PT specimens were switched due to poor labeling of the test cartridges. 3. The corrective actions documented on the "Performance Review and Corrective Action" form provided with the PT scores did not include a self-evaluation of the laboratory's PT results to determine whether the laboratory passed the PT. 4. During an interview on 02/21/2024 at 10:25 AM, the OM confirmed that the laboratory did not perform a self-evaluation of unsatisfactory PT scores.

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 office manager (OM), 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. Upon request, the laboratory staff found the instrument operator's manual in an office not attached to the lab. Laboratory staff were not aware of the location of the operator's instrument manual. 3. During an interview on 02/21/2024 at 1:00 PM, the OM confirmed that the SOPM did not contain written preanalytical, analytical, and post analytical policies and procedures for testing with the BD Affirm.

D5413

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)**

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on standard operating procedure manual (SOPM), instrument manual, and temperature log record review, and interview with the office manager (OM), the laboratory failed to accurately define, monitor, and document laboratory room temperature and room humidity to ensure proper reagent storage and reliable test system operation for testing with the BD Affirm Microbial Identification System. Findings: 1. The laboratory performs microbiology testing on the BD Affirm Microbial Identification System. 2. A review of the "BD MicroProbe Processor Instrument User's Manual" showed that the acceptable room temperature for instrument operation is "22 - 28 C" (71.6 - 82.4 F) and that the acceptable ambient humidity is "10 - 85%." 3. A review of the "Room/Refrigerator Temperatures" log showed that the laboratory's acceptable room temperature was listed as "68 - 90" (F) which did not match the temperature range dictated by the manufacturer. 4. The laboratory did not measure or document room humidity levels. 5. A review of room temperature logs from 01/02/2024 to 01/30/2024 showed that the laboratory's room temperature was outside the manufacturer's acceptable range six out of 21 days recorded. 6. During an interview on 02/21/2024 at 1:00 PM the OM confirmed that

the laboratory failed to ensure reliable test system operation by defining acceptable room temperature and humidity ranges and documenting room temperatures and humidity in the laboratory.

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) and patient log record review and interview with the office manager (OM) and testing personnel (TP), the laboratory did not run 2 levels of QC each day of patient testing and failed to establish an Individualized Quality Control Plan (IQCP) for performing testing on the BD Affirm Microbial Identification System. Findings: 1. During an interview at 9:15 AM, TP #1 stated that positive and negative QC is performed on each box/kit opened for the BD Affirm Microbial Identification System. 2. SOPM review showed that the laboratory had performed the Risk Assessment portion of the IQCP, but did not have a completed, approved IQCP in place to reduce the amount of QC required when performing testing on the BD Affirm. An IQCP must include a Risk Assessment, Quality Control Plan, and a Quality Assessment and be signed by the laboratory director. 3. The laboratory documents external QC results on the top two rows of the "Affirm Log Sheet." Results of patient testing are documented on the 22 rows remaining on each page. A review of QC records and patient logs from 08/29 /2023 through 01/25/2024 showed that QC was performed 14 times in 21 weeks of testing, with a total of 308 patients being tested. 4. During an interview on 02/21/2024 at 1:00 PM, the OM confirmed that the laboratory did not run 2 levels of QC each day of patient testing and that a complete and approved IQCP was not available at the time of the survey for testing on the BD Affirm Microbial Identification System.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview with the office manager (OM), the laboratory director acting as the technical consultant (TC) failed to perform and document the competency reviews on all testing personnel (TP), assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings: 1. The laboratory currently has four TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). 2. A review of competency

assessment records from 2023 showed that one out of four competency assessments was signed by a laboratory staff member (TP #1) who is not qualified as a TC (Bachelor of Science with two years' experience). 3. During an interview on 02/21/2024 at 1:00 PM, the OM confirmed that the person who performed the annual competency assessment on TP #2 was not qualified with a Bachelor of Science degree and 2 years' experience in laboratory testing [493.1411(b)(4)(i & ii)] to evaluate the competency of the TP.