

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219882	(X3) Date Survey Completed 01/16/2020
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing personnel, the laboratory's approved standard operating procedure manual (SOPM) did not include an interpretation of the abbreviations used when documenting information on the patient log and written instructions for how to complete the "Affirm Log Sheet." Findings: 1. Review of the documentation on the patient logs showed that the section labeled "Reagents" had three different reagents being documented with the lot number and expiration dates and the abbreviations "L", "B", and "S." 2. The information listed on the "Affirm Log Sheet" did not include instructions for documenting the three</p>

reagents on the log as well as the identity of the abbreviations being used. 3. The "Affirm Log Sheet" procedure was written and attached to the patient log clip board. These instructions were not approved, and dated by the laboratory director and included in the approved SOPM used by the laboratory staff. 4. During the survey on 01/16/2020 at 11:15 AM the testing personnel confirmed that the SOPM did not include the identity of the abbreviation used and the approved instruction listed on the "Affirm Log Sheet."

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on review of the validation procedure, validation records for the new Affirm VPIII (microbial identification system) and interview with the testing person, the laboratory director did not ensure that the verification records were found to be acceptable ensuring that the information was accurate and reliable prior to testing patient samples. Findings: 1. The validation procedure for the Affirm VPIII shows that it was signed and approved on 5/2018. The laboratory followed the validation procedure and tested quality control materials during May and June 2018 on the new analyzer and tested patients on the old and new analyzer on 6/11/18. 2. When interviewed the testing person confirmed that there was no written summary /conclusion documentation stating that the data collected met the manufacturers requirements and the new analyzer was accurate and reliable prior to testing patient samples. 3. During the survey on 01/16/2020 at 11:15 AM the testing person confirmed that there was no written conclusion stating that the validation was found to be acceptable prior to testing and reporting patient test results.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on review of the microbiology patient results on the patient log sheet, the patient results in the computer and interview with the testing person, the testing personnel did not ensure that patient results were entered into the computer system as required by the laboratory's standard operating procedure manual (SOPM). Findings: 1. Review of four patient computer records showed that one of the four patients did not have their results entered into the computer system for review by the physician who ordered the test. The patient log showed that several patients were tested on 07/24 /2019 and the results were recorded on the patient log but one of the patients did not

have their results entered into the computer system as required by the SOPM. 2. During the exit interview on 01/16/2020 at 11:15 AM the testing person confirmed that the computer system did not have the required patient test results from 07/24/2019.