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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 19D0983864 | (X3) Date Survey Completed 09/19/2019 |
| Name of Provider or Supplier Darrell C Robinson Obgyn | Street Address, City, State 4630 Ambassador Caffery, Suite 214, Lafayette, LA | |
| 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 |
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| D0000 | A Certification Survey was performed on September 1, 2019 at Darrell C Robinson OBGYN, CLIA ID # 19D0983864. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| 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> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation statement for two (2) of four (4) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) proficiency records for 2018 and 2019 revealed the Laboratory Director did not sign the attestation statement for the following events: a) CAP VS-B 2018 b) CAP VS-C 2018 2. In interview on September 19, 2019 at 09:20 am, Personnel 3 stated the laboratory discontinued testing for Candida sp., Bacterial vaginosa, and Trichomonas vaginalis in August 2018. Personnel 3 further stated that the laboratory overlooked getting the Laboratory Director's signature on the above events.</p> |
| 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</p> |

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 record review and interview with personnel, the laboratory failed to establish a policy and procedure manual. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not have a policy to include the following: a) Course of action if test system becomes inoperable 2. In interview on September 19, 2019 at 09:55 am, Personnel 3 confirmed the laboratory did not have a the above policy.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
 Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2009.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5403.