| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>33D0865147 | (X3) Date Survey Completed<br>02/28/2018 |
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| **Name of Provider or Supplier**<br>Long Island Womens Health Care Group | **Street Address, City, State**<br>173 Mineola Boulevard, Suite 200, Mineola, NY | |

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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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor review of procedure manual and interview with the testing person, the laboratory failed to establish written procedures for: 1) Transportation of Affirm specimens from the Syosset office to the Mineola office for the testing; and, 2) Describing the laboratory's turnaround time for Affirm testing from sample collection, processing and entering test results into the patients' permanent record. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c) |

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| | The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor review of five random patient test reports for Affirm testing and confirmed in an interview with the testing person at 10:00 AM on the day of survey, the laboratory failed to include the report date on the final test reports for five of five patient test reports. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor's review of competency assessment records and confirmed in an interview with the testing person, the laboratory director, acting as the technical consultant, failed to ensure that competency assessment for the testing person was performed in calendar year 2017. |