

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0942947	(X3) Date Survey Completed 08/20/2018
Name of Provider or Supplier Northern Obstetrics & Gynecology	Street Address, City, State 3111 New Hyde Park Road, New Hyde Park, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of waived testing supplies and an interview with the office manager, the laboratory failed to keep records and documentation for the waived pregnancy test and for the Multistix 10 SG urinalysis strips. Findings: At approximately 10 AM on August 20, 2018 it was confirmed by the office manager that the laboratory did not have the following records for the waived testing performed in the laboratory: 1. There was no package inserts available for the urine pregnancy test therefore it was impossible to determine if any QC was required by the manufacturer and to determine the proper steps the laboratory is required to follow to perform the pregnancy test properly. 2. The laboratory had no pregnancy testing record logs, to include the lot numbers and expiration dates. 3. There was no package inserts available for the Clarity Urocheck 10 SG urinalysis strips and there were no documentation of lot numbers and expiration dates. 4. For Fecal Occult Blood the laboratory had no documentation of lot numbers and expiration dates.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on lack of Quality Assurance (QA) records and an interview with the office manager, the laboratory failed to verify the accuracy of interpretation of the KOH, wet mount and fern tests at least twice per year for calendar year 2017 and up to survey date. FINDINGS: 1. The office manager confirmed on August 20, 2018 at approximately 9:30 AM that the accuracy of interpretation of the KOH, wet mount and fern testing was not performed at least twice yearly in calendar year 2017 and up to survey date. 2. Approximately 200 patients' KOH, wet mount and fern slides were interpreted and reported in calendar year 2017 and up to survey date.

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 lack of policies and procedures and an interview with the office manager at the time of this survey, the laboratory failed to have a complete written procedure manual to include the following procedures: 1. Patient preparation, specimen collection, labeling of the specimen to include patient's name and unique identifier and when appropriate specimen source, storage/temperature and preservation, and criteria for specimen acceptability and rejection; 2. Procedures for KOH, wet mount and fern testing; 3. Verification accuracy at least twice annually for KOH, wet mount and fern testing; and, 4. Procedures for the preventive maintenance of the microscope.

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 a surveyor's observation of the laboratory testing area and an interview with the office manager, the laboratory failed to discontinue the use of the expired testing material. FINDINGS: 1. On August 20, 2018 at approximately 9:30 AM the office

manager confirmed surveyor's findings that the laboratory used a bottle of 500 ml Potassium Hydroxide (KOH) lot # 1514013 expiration date May 2017, from June 2017 through the survey date. 2. Approximately 50 patients were tested and reported for KOH using the expired KOH reagent during the above time frame.

D5980

PPM LABORATORY DIRECTOR
CFR(s): 493.1355

The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359.

This **CONDITION** is not met as evidenced by:

Based on surveyor interview with the office manager, the laboratory failed to have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359. Findings: The laboratory issued a certificate of Provider Performed Microscopy Procedures (PPMP) is required to notify Centers for Medicare & Medicaid Services (CMS) within 30 days of change in laboratory director. At approximately 9:30 AM on August 20, 2018, the office manager confirmed that the previous laboratory director resigned on February 27, 2018 and the laboratory failed to notify CMS from February 27, 2017 through August 22, 2018.

D5981

PPM LABORATORY DIRECTOR QUALIFICATIONS
CFR(s): 493.1357

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in 493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required. (b) The laboratory director must meet one of the following requirements: (b) (1) Be a physician, as defined in 493.2. (b)(2) Be a midlevel practitioner, as defined in 493.2, authorized by a State to practice independently in the State in which the laboratory is located. (b)(3) Be a dentist, as defined in 493.2.

This **STANDARD** is not met as evidenced by:

Based on surveyor interview with the office manager, the CMS Form 209 and the CMS Form 116 submitted on August 22, 2018, the laboratory did not have a qualified Director from February 27, 2018 through August 21, 2018. Findings: At approximately 9:30 AM on August 20, 2018, the office manager confirmed that the laboratory director resigned on February 27, 2018 and the laboratory currently does not have a director.