

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0880750	(X3) Date Survey Completed 10/19/2018
Name of Provider or Supplier Northwest Professional Obstetrics & Gynecology Ltd	Street Address, City, State 121 S Wilke Rd #515, Arlington Heights, IL	
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
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Clinical Laboratory Improvement Amendments application (CMS 116), manuals, records, and an interview with the testing personnel (TP) and office staff, the laboratory failed to ensure the information entered into a record system is transcribed or entered accurately, affecting 7 out of 9 patients. Findings: 1. Review of the patients' test log and their respective charts in the laboratory's electronic medical record (EMR) system revealed the following: a). The collection times of 7 out of 9 patients' recorded were incorrect. 2. The laboratory's manual does not include an ongoing mechanism to ensure the accuracy of manual entries by personnel entering information into its EMR system. 3. On a Recertification survey conducted on 10/19/2018 at 12:30 PM, the TP and office staff confirmed the above findings.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p>

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's Clinical Laboratory Improvement Amendments application (CMS 116), manuals, records, and an interview with the testing personnel (TP) and office staff, the laboratory failed to ensure the record system it uses provided the all required information, affecting 349 patients. Findings: 1. Review of the patients' test log and their respective charts in the laboratory's electronic medical record (EMR) system revealed the following: a). The records and dates of all specimen testing, including the identity of the personnel who performed the tests were not recorded for 9 out 9 patients. 2. The laboratory's manual does not instruct the laboratory personal to record the dates of all patients tested and who performed the test into the EMR system. 3. The CMS 116 signed by the laboratory director attests that the laboratory has tested 349 patients during the year of 2018. 4. On a Recertification survey conducted on 10/19/2018 at 12:30 PM, the TP and office staff confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's manual, final report, the Clinical Laboratory Improvement Amendments (CLIA) application (CMS 116), and an interview with the testing personnel (TP) and office staff, the laboratory failed to ensure test reports include all information as specified in 493.1291(c)(1)- (c)(6), affecting 349 patients. Findings: 1. The laboratory's manual does not instruct the laboratory personal to record the name and address of the laboratory location where the test was performed when testing is performed in-house. 2. The "final report" of 9 out of 9 patients reviewed fails to include the name and location of the Microbiology tests performed in the laboratory. 3. On the CMS 116, the LD documents that 349 patients are tested annually. 4. On a Recertification survey conducted on 10/19/2018 at 12:15 PM, the TP and office staff confirmed the above findings.