

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1056847	(X3) Date Survey Completed 03/08/2018
Name of Provider or Supplier North Shore Urogynecology, Ltd	Street Address, City, State 351 S Greenleaf - Ste E, Park City, 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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</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 office staff; the laboratory failed to ensure the specimen requisitions solicit the required information as define in 493.1241(c)(1)-(c)(8), affecting 300 tests performed. Findings: 1. Review of specimen submission documents revealed that the laboratory's requisitions does not include the following information: (8). Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. The name and address of the laboratory that patients' tissue surgery specimens are referred to for Histology slide processing is not provided on 6 out of 6 specimen requisitions printed for review. 2. The laboratory's manual does not include a test requisition form for specimen submissions. 3. The CMS 116 signed by the laboratory director attests that</p>

the laboratory has performed 300 tests. 4. On a Recertification survey conducted on 03 /08/2018 at 12:30 PM, the laboratory director confirmed the above findings.