

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1056847	(X3) Date Survey Completed 05/08/2024
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
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: Based on review of laboratory policies, bi-annual method accuracy (proficiency testing) records, lack of documentation and interview with the laboratory representative; the laboratory failed to perform method accuracy evaluations for histopathology testing from May of 2022 through the date of survey, 05/08/2024, as required per 493.1236. Findings include: 1. Review of the laboratory test volume records revealed 34 histopathology tests had been performed from May of 2023 to April of 2024. 2. Review of laboratory policies, under "Pathology Quality Assessment Monitoring", under "Procedure", revealed, "Bi-annually 3-5 cases (histopathology slides) are randomly chosen to be sent for quality assessment." 3. Review of laboratory records revealed a lack of bi-annual method accuracy records for histopathology testing in the years of 2022 through date of survey, 05/08/2024. 4. An interview with the laboratory representative at 1:53 pm on 05/08/2024 confirmed the above findings.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory competency records, CMS-209 (Laboratory Personnel Report), and interview with a laboratory representative; the laboratory director (LD) failed to ensure four of four histopathology testing personnel (TP) were competent to conduct histopathology testing in the years of 2022 through the date of survey, 05/08/2024. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report), signed by the LD on 05/03/2024, revealed four TP (TP #1, TP #2, TP #3, and TP #4) qualified to perform histopathology testing on the date of the survey, 05/08/2024. 2. Review of the "Pathology Interpretation Training and Competency" worksheet revealed, "This competency checklist fulfills the requirements for the following delegated responsibilities as performed by the clinical consultant, technical supervisor, general supervisor, and testing personnel for histopathology slide interpretation." 3. Review of "Pathology Interpretation Training and Competency" forms found no competency assessments were documented for four of four histopathology TP (TP #1, TP #2, TP #3, and TP #4) from May of 2022 through the date of survey, 05/08/2024. 4. An interview with the laboratory representative at 1:53 pm on 05/08/2024 confirmed the above findings.