Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1056847	02/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Urogynecology, Ltd	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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: A) Based on review of laboratory policies and procedures, laboratory records, and interview with general supervisor (GS) #1; the laboratory failed to ensure positive and negative quality control (QC) materials for every target tested were performed each day of Urinary Tract Infection - Antibiotic Resistance (UTI-ABR) Polymerase Chain Reaction (PCR) molecular panel testing for six of six patient testing dates reviewed in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Seqonce Quadruplex UTI-ABR", which stated, under: i. "Quality Control", "A Negative [Non-Template Control] (NTC) and a Positive Control must be included in each assay run to detect potential failure in specimen processing, amplification, or detection steps." ii. "Table 1", the following pathogen targets tested on the UTI (Lioness) PCR Panel: Pathogen Targets: Acinetobacter baumannii Escherichia coli Enterococcus faecalis Klebsiella oxytoca Klebsiella pneumoniae Enterobacter cloacae Citrobacter freundii Proteus mirabilis Morganella morganii Klebsiella aerogenes Enterococcus faecium Ureaplasma urealyticum Streptococcus agalactiae Staphylococcus saprophyticus Serratia marcesens Candida albicans Candida parapsilosis Candida tropicalis Candida glabrata

Staphylococcus aureus Pseudomonas aeruginosa Mycoplasma hominis Providencia stuartii Proteus vulgaris iii. "Table 2", the following antibiotic resistant targets tested on the ABR (Pongo) PCR Panel: ABR Targets: Erythromycin ribosome methyltransferase A (ErmA) Erythromycin ribosome methyltransferase B (ErmB) Methicillin-resistant Staphylococcus aureus (MRSA) gene (mecA) Tetracycline resistance determinant (Tet (A)) Beta-lactamase, Imipenemase (bla-IMP, IMP-7) Quinolone resistance gene A (qnrA) Quinolone resistance gene B (qnrB) Sulphydryl variable gene (SHV) Quinolone resistance gene S (qnrS) New Delhi Metallo-beta-Lactamase 1 (NDM-1) Oxacillinase-48 (OXA-48, bla-OXA) Klebsiella pneumoniae carbapenemase (KPC, bla-KPC) Verona integron-encoded metallo-beta-lactamase (VIM, bla-VIM) Cephamycin resistance gene (FOX) Ampicillin resistance gene (ampC) Azithromycin resistance gene (ACT) Cefotaximase-Munich group 9 (CTX-M group 9) Cefotaximase-Munich group 1 (CTX-M group 1) Temoniera beta-Lactamase (TEM) Cefotaximase-Munich group 2 (CTM-M group 2) Vancomycin resistance gene A1 and A2 (vanA1_vanA2) Sulphonamine resistance gene 2 (SUL2) Sulphonamine resistance gene 1 (SUL1) Vancomycin resistance gene B (vanB) iv. "Table 3", the following targets included in each of the subsequent positive control materials: UTI-CP (Control Positive)-1: Staphylococcus saprophyticus Streptococcus agalactiae Citrobacter freundii Proteus mirabilis Morganella morganii Proteus vulgaris Acinetobacter baumannii Staphylococcus aureus Enterococcus faecalis Escherichia coli UTI-CP-2: Klebsiella aerogenes Enterococcus faecium Mycoplasma hominis Ureaplasma urealyticum Enterobacter cloacae Klebsiella oxytoca Klebsiella pneumoniae Pseudomonas aeruginosa Providencia stuartii Serratia marcesens UTI-CP-3: Candida albicans Candida parapsilosis Candida tropicalis Candida glabrata ABR Control 1: ACT mecA qnrA qnrB qnrS vanA1_vanA2 vanB SUL1 SUL2 ABR Control 2: NDM-1 OXA-48, bla-OXA VIM, bla-VIM bla-IMP, IMP-7 CTX-M Group 1 CTX-M Group 2 CTX-M Group 9 TEM ABR Control 3: ampC ErmA ErmB FOX KPC, bla-KPC SHV Tet (A) 3. Review of laboratory records revealed positive QC material was not performed for every target tested each day of UTI-ABR PCR molecular panel testing for six of six patient testing dates reviewed. Date of Testing: Patient: Positive QC Performed: 02/23/2024 NSU12347027 UTI-CP-2 & ABR Control 2 only 05/29/2024 NSU12347301 UTI-CP-1 & ABR Control 1 only 10/09 /2024 NSU12347585 UTI-CP-1 & ABR Control 1 only 01/29/2025 NSU12347752 UTI-CP-3 & ABR Control 3 only 06/12/2025 NSU12347856 UTI-CP-1 & ABR Control 1 only 12/03/2025 NSU12348041 UTI-CP-3 & ABR Control 3 only 4. Interview with GS #1 on 02/24/2026, at 12:50 pm, confirmed the laboratory rotated the positive QC materials performed each day of testing and failed to ensure positive and negative QC materials for every target tested were performed each day of UTI-ABR PCR molecular panel testing for six of six patient testing dates reviewed in the specialty of microbiology. B) Based on review of laboratory policies and procedures, laboratory records, and interview with GS #1; the laboratory failed to ensure positive and negative QC materials for every target tested were performed each day of Women's Health (WH) PCR molecular panel testing for five of five patient testing dates reviewed in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Seqonce Quadruplex Women's Health (Amur) Panel", which stated, under: i. "Quality Control", "A Negative [Non-Template Control] (NTC) and a Positive Control must be included in each assay run to detect potential failure in specimen processing, amplification, or detection steps." ii. "Table 1", the following pathogen and antibiotic resistance targets tested on the WH PCR Panel: Pathogen/ABR Targets: Herpes Simplex Virus 1 (HSV1) Herpes Simplex Virus 2 (HSV2) Treponema pallidum Gardnerella vaginalis Neisseria gonorrhoeae Chlamydia trachomatis Trichomonas vaginalis Haemophilus ducreyi Mycoplasma genitalium Ureaplasma urealyticum

	Atopobium vaginae Streptococcus agalactiae Escherichia coli Enterococcus faecalis Prevotella bivia Staphylococcus aureus Bacteroides fragilis Mycoplasma hominis Bacterial Vaginosis-Associated Bacterium 2 (BVAB2) Lactobacillus crispatus Lactobacillus jensenii Lactobacillus iners Lactobacillus gasseri Megasphera 1 Megasphera 2 Mobiluncus curtisii Mobiluncus mulleris Candida krusei Candida tropicalis Candida galabrata Candida parapsilosis Candida albicans Candida Lusitania Candida auris Vancomycin resistance gene A (VanA) Vancomycin resistance gene B (VanB) Methicillin-resistant Staphylococcus aureus (MRSA) gene (mecA) iii. "Table 2", the following targets included in each of the subsequent positive control materials: STI (Sexually Transmitted Infection)-CP-1: HSV1 Treponema pallidum Chlamydia trachomatis Trichomonas vaginalis Mycoplasma genitalium Ureaplasma urealyticum STI-CP-2: HSV2 Neisseria gonorrhoeae Haemophilus ducreyi Gardnerella vaginalis Atopobium vaginae WH-CP-1: Streptococcus agalactiae Escherichia coli Enterococcus faecalis Prevotella bivia Staphylococcus aureus Bacteroides fragilis Mycoplasma hominis BVAB2 Lactobacillus crispatus Lactobacillus jensenii Lactobacillus iners Lactobacillus gasseri Megasphera 1 Megasphera 2 Mobiluncus curtisii Mobiluncus mulleris VanA VanB mecA UTI-CP3: Candida krusei Candida tropicalis Candida galabrata Candida parapsilosis Candida albicans Candida Lusitania Candida auris 3. Review of laboratory records revealed positive QC material was not performed for every target tested each day of WH PCR molecular panel testing for five of five patient testing dates reviewed. Date of Testing: Patient: Positive QC Performed: 02/23/2026 NSU12347028 STI-CP-1 only 05/29/2024 NSU12347302 WH-CP-1 only 10/09/2024 NSU12347581 WH-CP-1 only 01/29/2025 NSU12347753 WH-CP-1 only 06/12/2025 NSU12347857 STI-CP-2 only 4. Interview with GS #1 on 02/24/2026, at 12:50 pm, confirmed the laboratory rotated the positive QC materials performed each day of testing and failed to ensure positive and negative QC materials for every target tested were performed each day of WH PCR molecular panel testing for five of five patient testing dates reviewed in the specialty of microbiology.