Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0689044	04/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Adult Pediatric Urology & Urogynecology	2735 North Clarkson Street, Fremont, NE	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's procedure, surveyor observation of control slides, and interview with the laboratory director the laboratory failed to label control slides following the laboratory's procedure manual on two out of two control slides. The findings include: 1. The laboratory's procedure "New Lot Verification Protocol Benchmark ULTRA Plus" states "Label the control slide using the Ventana software with the appropriate antibody, including the new lot number in the space where the case number would normally go. Example: NEW LOT#E12345". 2. Surveyor observation of two control slides revealed the slides were labeled as the following: Slide 1 - "Control QC New Lot UHP 12/1/2025". Slide 2 - "New Lot BCC Control UHP 1/19/2026" 3. Interview with the laboratory director on 4/21/2026, at 10: 50 AM, confirmed the laboratory did not label the control slides as indicated on the procedure.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)

	(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director the laboratory failed to verify precision on the Ventana Benchmark Ultra Plus prior to reporting patient test results. The findings include: 1. The surveyor requested the performance specification verification documents for the Ventana Benchmark Ultra Plus analyzer. 2. Interview with the laboratory director on 4/21/2026, at 10:29 AM, confirmed the laboratory failed to perform precision on the Ventana Benchmark Ultra Plus analyzer prior to reporting patient test results. 3. The laboratory reported 835 tests using the Ventana Benchmark Ultra Plus from 12/1/2025 - 4/21/2026.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, review of laboratory's lot verification documentation, and interview with the laboratory director the laboratory failed to document all control procedures performed on three out of three lot verification changes. The findings include: 1. The laboratory's procedure "New Lot Verification Protocol Benchmark ULTRA Plus" states "After review of the slides, the Pathologist with return both the slides and the Antibody New Lot Verification form. Look at the Antibody New Lot Verification form to verify that the lot has been checked. 1) If the comment section is marked "yes" by the Pathologist. The new lot is now ready for use." 2. Review of the laboratory's lot verification documentation of three lot verification changes did not show the comment section marked yes by the pathologist. 3. Interview with the laboratory director on 4/21/2026, at 10:57 AM, confirmed the pathologist did not mark the comment section as yes, not documenting all control procedures for the three lot verification changes.