Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393625	08/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Uw Health Northport Family Medical Center	3209 Dryden Dr, Madison, WI	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, the procedure manual, and interview with the laboratory director, for one of one procedure reviewed, the Sysmex XS-1000i analyzer procedure contained conflicting information with regards to the process for handling specimen testing when the humidity reading in the laboratory is out of range. Findings include: 1. Review of the form "UWMF Satellite Temperature and Decontamination Log" revealed the laboratory did not include a range for the laboratory humidity on the form, and instructs testing personnel, "For acceptable

	humidity ranges, see individual procedure manual or letter from manufacturer". 2. Review of the "UWMF Satellites Sysmex XS-1000i Procedure" effective date 07/07 /2025, revealed conflicting information with regards to the process for handling specimen testing when the humidity reading in the laboratory is out of range. In step VI. Maintenance A.6, the procedure instructs, "If readings are outside the recommended range for the analyzer (30-85%), notify your leader. Testing should be sent out until humidity issue is resolved, within acceptable range, and QC is acceptable", while in step IX. Method Limitations, the procedure instructs, "If humidity falls outside of range, it is still acceptable to run patient testing see Sysmex letter. Maintenance will be paged to try and adjust building humidity if problems arise". 3. Interview with the laboratory director on August 27, 2025, at 3:20 PM, confirmed the low end of the acceptable humidity range for the Sysmex was 30%, stated that specimen testing on the Sysmex should cease if humidity in laboratory falls below 30%, and confirmed the finding that the procedure contained conflicting instructions for how testing personnel should handle specimen testing on the Sysmex XS-1000i when the humidity reading in the laboratory is out of range.