Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405335	05/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Westbrook Medical Center	920 Bell Ave, Westbrook, MN	

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
D0000	The Sanford Westbrook Medical Center laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the initial survey completed on May 14, 2026. The following standard-level deficiencies were cited: 493.1253 Establishment and verification of performance specifications 493.1291 Test report .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to complete all required Performance Verification (PV) activities prior to reporting patient test results for one of three Chemistry analytes implemented in 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General supervisor during a tour of the laboratory at 12:12 p.m. on 5/13/26. 2. A Siemens Dimension EXL 200 was observed as present and available for use during the tour. The laboratory implemented procalcitonin, urine microalbumin, and urine creatinine testing using the Dimension in December 2024. 3. The laboratory was required to establish and verify a reference range for all new test methods as defined in the Validation Data for Siemens Dimension EXL 200 Summary and plan for implementation provided by the laboratory on the date of survey. 4. Urine microalbumin PV documentation was approved by the laboratory director on 12/4/24

	and included accuracy, precision, and reportable range verification. A reference range was not established for urine microalbumin. 5. The GS indicated 234 patients received urine microalbumin testing on the Dimension analyzer between test implementation and the date of survey. 6. In an interview at 2:10 p.m. on 5/13/26, the GS confirmed the above findings. .
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of two pertinent Chemistry reference intervals were included on a patient test report in 2025. Findings are as follows: 1. The laboratory performed urine creatinine and urine microalbumin testing on patient samples under the Chemistry specialty as confirmed by the General Supervisor (GS) during a tour of the laboratory at 12:12 p.m. on 5/13/26. 2. A Siemens Dimension EXL 200 was observed as present and available for Chemistry testing on patient samples during the tour. 3. A reference interval for urine microalbumin was not present on a patient test report from 5/13/25 reviewed on the date of survey. 4. Performance verification (PV) documentation indicated the laboratory implemented urine microalbumin and urine creatinine testing in December 2024. A reference range for urine microalbumin was not established during the PV activities. See D5421. 5. In an interview at 9:44 a.m. on 5/14/26, the GS confirmed the above findings and indicated 234 urine microalbumin tests had been performed on patient samples between implementation and the date of survey. .