Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2126465	08/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Fmccp North Hills Health Center	W129 N7055 Northfield Drive, 1st Floor, Rm 1064, Menomonee Falls, 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
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 surveyor review of verification records for the CHEM8+ and CG4+ cartridges for the i-STAT analyzer and interview with a technical consultant (Staff A), the laboratory did not evaluate precision for two of the two cartridge types before using the cartridges for patient testing starting on December 6, 2024. Findings include: 1. Review of the document, "North Hills iSTAT (365246) 12-2013 Validation Summary", for the i-STAT analyzer, serial number SN365246, showed no evidence of evaluation of precision of the analyzer for either the CHEM8+ or CG4+ cartridges. The Laboratory Director approved the summary and the use of the CHEM8+ and CG4+ cartridges for patient testing on November 22, 2024. 2. Interview with Staff A on August 8, 2025, at 11:30 AM confirmed the verification studies for the i-STAT analyzer did not include evaluation of precision for the CHEM8+ or the CG4+ cartridges and confirmed the laboratory did not evaluate precision prior to the start of patient testing with the two cartridge types on December 6, 2024.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)

	(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor review of documented humidity readings in the laboratory and interview with the General Supervisor (Staff B), the Laboratory Director did not ensure the humidity in the laboratory was appropriate for the testing performed in December 2024 and January 2025, two of two winter months reviewed. Findings include: 1. Review of documented humidity readings in the laboratory from December 2024 and January 2025 showed the acceptable relative humidity range was 18 - 80% and showed personnel documented humidity readings less than 18% on 60 of the 62 days in the two months. The records showed personnel documented corrective actions as "unable to adjust, QC okay". 2. Interview with Staff B on August 8, 2025, at 11:30 AM confirmed the laboratory humidity was not within the defined range during December 2024 and January 2025 and confirmed the director did not ensure the laboratory could maintain the appropriate humidity levels as defined by the laboratory.