Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2126465	(X3) Date Survey Completed 09/03/2019
Name of Provider or Supplier Fmccp North Hills Health Center	**Street Address, City, State** 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs, observation of freezer storage and interview with the general supervisor, the laboratory has not defined storage conditions that are consistent with the manufacturer's instructions for pediatric bilirubin controls. Findings include: 1. Review of temperature logs showed the laboratory's acceptable freezer temperature range is less than or equal to negative 15 degrees Celsius (C). 2. Observation of the freezer on September 3, 2019 at 1:00 PM revealed Bio-Rad Pediatric Controls stored in the freezer. The manufacturer's packaging showed the acceptable storage range was negative 20 to negative 70 degrees C. 3. Interview with the general supervisor on September 3, 2019 at 1:15 PM confirmed the laboratory defined acceptable storage temperature range is not consistent with the manufacturer's instructions.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	annually, after the first year. This STANDARD is not met as evidenced by: Based on review of competency evaluation records and interview with the general supervisor, the technical consultant did not document the required annual competency evaluation for chemistry and microscopic testing in 2018 for one of two testing personnel. Findings include: 1. Review of competency evaluation records for staff A showed no evidence of evaluation of competency for the Piccolo chemistry analyzer or microscopic testing in 2018. 2. Interview with the general supervisor on September 3, 2019 at 10:50 AM confirmed the competency records for staff A were not complete for 2018.