

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0388485	<b>(X3) Date Survey Completed</b>  09/19/2019
<b>Name of Provider or Supplier</b>  Fmccp- Town Hall Health Center	<b>Street Address, City, State</b>  W180 N8000 Town Hall Road, Menomonee Falls, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records from events one and two in 2019 and interview with the general supervisor, the laboratory did not verify the accuracy of ungraded proficiency testing results for Chloride, Direct LDL (low density lipoprotein) and TIBC (total iron binding capacity). Findings include: 1. Review of Wisconsin State Laboratory of Hygiene proficiency testing records from 2019 show the following tests were ungraded due to insufficient peer groups and the results showed no evidence of evaluation by the laboratory: Event one: Chloride, Direct LDL, and TIBC Event two: Direct LDL and TIBC 2. Interview with the general supervisor on September 18, 2019 at 9:45 AM confirmed the laboratory had not evaluated the ungraded scores to verify accuracy of the tests.</p>
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory water system records and interview with the general supervisor, the laboratory did not ensure function checks were within established limits. Findings include: 1. Review of the "Laboratory Central Water System" log from August 2019 showed the laboratory monitors function checks for the water system. The log includes the following three function checks and established acceptable ranges: Pump discharge pressure 40-60 Inlet final filter pressure 25-50 psi Outlet final pressure 25-50 psi The August 2019 log shows the laboratory documented function checks for twenty-six days. The laboratory documented pump discharge pressures between 66 and 70, no entries were in the acceptable range. The laboratory documented three acceptable inlet final filter pressures, all others were above the established range. The laboratory documented fourteen acceptable outlet final pressures, all others were above the established range. 2. Interview with the general supervisor on September 18, 2019 at 2:30 PM confirmed recorded function checks were not within established acceptable ranges.