

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0887068	(X3) Date Survey Completed 07/26/2018
Name of Provider or Supplier Mainstreet Clinic	Street Address, City, State 1001 W Main St, Ashland, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with testing personnel, PT samples were not tested by two of three testing personnel who routinely perform patient testing. Findings include: 1. Review of PT records show staff A has performed each of the hematology PT events since 2017. 2. Review of the CMS (Centers for Medicare and Medicaid Services) Form 209, Laboratory Personnel Report (CLIA), signed by the laboratory director on July 20, 2018, showed three testing personnel perform moderate complexity testing in the laboratory. 3. Interview with staff A on July 26, 2018 at 2:00 PM confirmed moderate complexity hematology testing is performed by all three testing personnel and also confirmed PT sample testing has not been rotated through all testing personnel who perform patient testing.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the procedure for competency evaluation of testing personnel and interview with testing personnel, the procedure does not specify how</p>

individuals who conduct non-waived testing will be evaluated, and does not include the six required elements or the requirement for semiannual evaluation during the first year of testing. Findings include: 1. Review of the laboratory procedure for competency evaluation showed the procedure did not identify the six required elements or the timing requirements for the evaluation of staff competency. 2. Interview with staff A on July 26, 2014 at 2:00 PM confirmed the procedure does not provide specific instructions for evaluating competency of testing personnel. This is a repeat deficiency previously cited on June 25, 2014.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on surveyor review of competency records and interview with testing personnel, competency was not evaluated semiannually during the first year new staff tested patient specimens. Findings include: 1. Review of competency records showed no semiannual evaluation for staff A after the initial evaluation in May 2017. 2. Interview with testing personnel, staff A, confirmed competency evaluation was not documented at least semiannually during the first year of patient specimen testing.