Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0671419	(X3) Date Survey Completed 01/29/2019
Name of Provider or Supplier Aurora Health Center-Elkhorn	**Street Address, City, State** 201 E Morrissey Dr, Elkhorn, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of reagents in the laboratory and interview with the technical consultant, the Sedistain available for use at the microscope expired on April 29, 2018. Findings include: 1. Observation of reagents available by the microscope in the laboratory on January 29, 2019 at 3:45 PM revealed a bottle of Sedistain, lot 1605 006. The expiration date listed on the bottle was April 29, 2018. 2. Interview with the technical consultant on January 29, 2019 at 3:45 PM confirmed the Sedistain was past its expiration date and was available for use for urinalysis microscopic testing.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on surveyor review of calibration records for the Poch 100i hematology analyzer and interview with the technical consultant, the laboratory did not calibrate the analyzer every six months in 2017 as required in their procedures. Findings include: 1. Review of calibration records for the Poch 100i analyzer showed no record of calibrations between July 2016 and September 2017. 2. Interview with the technical consultant on January 29, 2019 at 3:15 PM confirmed calibration is required every six months and the laboratory did not perform calibration of the Poch 100i analyzer between July 2016 and September 2017.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control procedures and records, and patient test result logs, and interview with the technical consultant, testing personnel performed serum human chorionic gonadotropin (hCG) testing on four days in September and October 2018 without testing serum quality control material as required in the laboratory's Individualized Quality Control Plan (IQCP). Findings include: 1. Review of the IQCP for serum hCG testing showed testing of Quidel low positive and negative serum control material on the first Monday of the month and with each new lot number of the test kit is required. 2. Review of the 2018 quality control log for the QuickVue+ hCG test showed no record of serum quality control testing on lot number 704249 between September 24 when the laboratory first used the new lot of reagent for serum hCG patient testing and October 6, 2018. 3. Review of the "hCG Time of Testing QuickVue+: One Step hCG Combo" log for patient test results from September and October 2018 showed serum testing was performed with lot 704249 on patient samples on September 24, September 28, October 1 and October 4, 2018. 4. Interview with the technical consultant on January 29, 2019 at 3:15 PM confirmed testing personnel did not follow the laboratory's quality control procedures when they did not test serum controls with the lot number used to perform patient serum hCG tests on four days in September and October 2018.