Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0388904	11/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Watertown Regional Medical Center,	132 Hospital Dr, Watertown, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Insitute (API) proficiency testing (PT) records and interview with the testing personnel, staff A, the laboratory director or designee did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for two of three hematology events in 2021 and two of two hematology events in 2022. Findings include: 1. Review of API PT records from 2021 and 2022 showed the laboratory director or designee did not sign the attestation form for the hematology events two and three in 2021 and events one and two in 2022. 2. Interview with staff A on November 10, 2022, at 10:20 AM confirmed the laboratory director or designee did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for two of three hematology events in 2021 and two of two hematology events in 2022.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of proficiency testing and laboratory records and interview with testing personnel, staff A, the laboratory did not verify the accuracy of

	microscopic urinalysis testing twice annually in 2021 and 2022. Findings include: 1. Review of proficiency testing records showed no evaluation of accuracy of microscopic urinalysis testing in 2021 and 2022. 2. Review of laboratory records showed no evidence of twice annual accuracy checks of microscopic urinalysis testing in 2021 and 2022. 3. Interview with staff A on November 10, 2022, at 10:25 AM confirm providers performed microscopic urinalysis testing in 2021 and 2022 and confirmed the laboratory had not verified the accuracy of the test twice annually in 2021 and 2022. Item 2: Based on surveyor review of proficiency testing and laboratory testing records and interview with testing personnel, staff A, the laboratory did not verify the accuracy of potassium hydroxide (KOH) and vaginal wet mount testing twice annually in 2021 and 2022. Findings include: 1. Review of proficiency testing records showed no evaluation of accuracy of KOH and vaginal wet mount testing in 2021 and 2022. 2. review of laboratory records showed no evidence of twice annual accuracy checks for KOH and vaginal wet mount testing in 2021 and 2022. 3. Interview with staff A on November 10, 2022, at 10:25 AM confirm providers performed KOH and vaginal wet mount testing in 2021 and 2022 and confirmed the laboratory had not verified the accuracy of the tests twice annually in 2021 and 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of calibration verification records and interview with testing personnel, staff A, the laboratory did not perform calibration verification every six months on the Sysmex poch-100i hematology analyzer in 2021 and 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Sysmex poch-100i analyzer on October 22, 2022. Further review showed no evidence of additional calibration verification performed on the analyzer in 2021 and 2022. 2. Interview with the staff A on November 10, 2022, at 11:10 AM confirmed the laboratory did not perform calibration verification every six months on the Sysmex poch-100i analyzer in 2021 and 2022.