Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0388938	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Watertown Family Practice Associates Sc	127 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT), American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, and interview with testing personnel, the laboratory failed to successfully participate in PT for the Sodium and Chloride analytes in the Subspecialty of Routine Chemistry for events 2018-1, 2018-2 and 2018-3. See D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT), American Association of Bioanalysts (AAB) PT records, and interview with testing personnel, the laboratory failed to have successful performance in PT for the Sodium and Chloride analytes in the Subspecialty of Routine Chemistry for events 2018-1, 2018-2 and 2018-3. Findings include: 1. Review of PT records in the federal CASPER reporting system shows that the laboratory failed two consecutive PT events for Sodium in the Subspecialty of Routine Chemistry - Event 2018-1, score 40% and Event 2018-2, score 60%. 2. Review of PT records in the federal CASPER reporting system shows that the laboratory failed two consecutive PT events for Chloride in the Subspecialty of Routine Chemistry - Event 2018-2, score 20% and Event 2018-3, score 60%. 3. Surveyor review of the AAB PT evaluation reports and interview with testing personnel, Staff A, on November 1, 2018 at 11:30 AM confirmed the failed PT scores. This results in a failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events for each analyte which is unsuccessful PT performance.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on surveyor review of microscopy proficiency testing (PT) records and interview with testing personnel, the laboratory has not documented evaluation of not scored or not graded microscopy results for event two in 2017. Findings include: 1. Review of American Academy of Family Physicians (AAFP) PT records for urine microscopy and wet prep microscopy for 2017 show no documented review of "Not graded-lack of referee consensus" samples for event 2017-B. 2. Interview with testing personnel, Staff A, on November 1, 2018 at 11:00 AM confirms the laboratory did not document evaluation of not scored and not graded samples.
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: Based on surveyor review of proficiency testing (PT) records and interview with testing personnel, the laboratory has not verified the accuracy of urine microscopy testing twice annually. Findings include: 1. Review of 2018 PT records showed no

	evidence of evaluation of accuracy of urine microscopy testing. 2. Interview with testing personnel, Staff A, on November 1, 2018 at 11:30 AM confirmed the laboratory did not verify the accuracy of urine microscopy testing twice annually. This is a repeat deficiency previously cited January 13, 2017.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the procedure manual and interview with testing personnel, the laboratory procedure manual does not have a procedure that provides step by step instructions for performing urine microalbumin testing on the Afinion ACR (albumin creatinine ratio) analyzer. Findings include: 1. Review of the laboratory procedure manual reveals the laboratory does not have a procedure with step-by-step instructions unique to this lab or specify the quality control (QC) type and frequency, calibration type and frequency, maintenance procedures, patient test reporting, and lab specific reference ranges for microalbumin testing on the Afinion ACR analyzer. 2. Interview with testing personnel, Staff A, on November 1, 2018 at 12:30 PM confirmed the laboratory does not have a procedure for urine microalbumin testing on the Afinion ACR analyzer that specifies the step-by-step instructions specific to this laboratory and along with specifying the QC and calibration type and frequency, maintenance procedures, patient test reporting, and lab specific reference ranges. This is a repeat deficiency previously cited November 5, 2014 and January 13, 2017.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor review of patient test and quality control records and interview with testing personnel, the laboratory has not assayed two control materials of different concentrations at least once each day patient urine microalbumin testing is performed on the Afinion ACR (albumin creatinine ratio) analyzer. Findings include: 1. Review patient test records show that urine microalbumin testing is performed in the lab two days per week. Review of quality control records for the Afinion ACR analyzer in which urine microalbumin patient testing is performed on show that one level of quality control is performed each day of testing. 2. Interview with testing personnel, Staff A, on November 1, 2018 at 1:00 PM confirmed two levels of daily external controls are not assayed each day of patient testing and that an IQCP (Individualized Quality Control Plan) has not been developed for urine microalbumin testing on the Afinion ACR analyzer.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of competency evaluation records and interview with testing personnel, Afinion ACR (albumin creatinine ratio) competency evaluation was not assessed for one of three testing personnel in 2017 and 2018. Findings include: 1. Review of competency evaluation records show no evidence of evaluation of urine microalbumin testing for one of three testing personnel (Staff B). Further review shows no documented competency assessment in 2017 or 2018 for the registered nurse (RN) testing personnel, Staff B, on the Afinion ACR analyzer in which urine microalbumin testing is performed. 2. Interview with testing personnel, Staff A, on November 1, 2018 at 10:00 AM confirmed competency assessments had not been performed for RN testing personnel, Staff B, for microalbumin testing on the Afinion ACR analyzer in 2017 or 2018. This is a repeat deficiency previously cited on January 13, 2017.