Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0887068	09/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mainstreet Clinic	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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on surveyor observation of testing personnel and patient blood samples in the laboratory, review of procedures, and interview with testing personnel, the laboratory did not follow their written policies concerning labeling of patient samples to ensure positive identification for one patient drawn on September 22, 2020. Findings include: 1. Observation of testing personnel on September 22, 2020 at 9:30 AM revealed staff B brought three blood tubes into the laboratory and requested printed patient labels for the tubes. The labels were then applied to the tubes. 2. Observation of the blood sample tubes on September 22, 2020 at 11:00 AM revealed the printed labels on the tubes were for patient 2. Further observation revealed the tubes were not labeled behind the stickers that had been applied in the laboratory. 3. Review of the laboratory's "Specimen Collection and Handling Procedure", showed the following statement in the "Specimen Labeling" section, "Blood tubes must be labeled before leaving the patient". 4. Interview with testing personnel, staff A, on September 22, 2020 at 11:15 AM confirmed testing personnel B did not label the blood tubes before leaving the patient and brought unlabeled tubes to the laboratory.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on surveyor review of hematology proficiency testing (PT) records from event 1 in 2020 and interview with testing personnel, the laboratory did not verify the accuracy of the platelet test when sample AT-3 was not scored by the PT provider. Findings include: 1. Review of PT records from event one in 2020 showed the following results for the platelet test: Sample / reported result / acceptable range AT-1 / 249 / 209 - 349 AT-2 / 56 / 56 - 93 AT-3 / 54 / 57 - 95 Not scored - non-consensus AT-4 / 519 / 405 - 675 AT-5 / 248 / 206 - 344 The records show no evidence of review of the not scored result for sample AT-3. 2. Interview with testing personnel, staff A, on September 22, 2020 at 10:45 AM confirmed the results were not reviewed to verify the accuracy of the platelet results. This is a repeat deficiency previously cited on June 10, 2008 and June 13, 2012.
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 hematology procedures, patient test reports and analyzer printouts, and interview with testing personnel, the procedure manual does not include adult reference intervals (normal values) for each of the individual tests included in the Complete Blood Count (CBC). For the four tests with normal ranges identified in the procedure, the ranges do not match those on patient reports or the analyzer printouts. The reference intervals on the patient test reports do not match the ranges on the analyzer printouts. Findings include: 1. Review of hematology procedures showed the following reference intervals for 21 year olds: Leukocyte Count (White Blood Cell or WBC) 4,500 - 11,000 cells/cmm (cubic millimeter) Segmented Neutrophils % 36 - 66 Band Neutrophils % 5 - 11 Lymphocytes % 24 - 44 2. Review of patient test reports for three adults (Patients 1, 2, and 3) show the following reference intervals: WBC cells/cmm 3,500 - 10,500 RBC (Red Blood Cell) no

	reference interval listed Hemoglobin gr/dL (grams/deciliter) Male: 13.5 - 17.5 Female: 12 - 15.5 Hematocrit % Male: 38.8 - 50 Female: 34.9 - 44.5 MCV (Mean Cell Volume) fL (femtoliters) Male: 80 - 94 Female: 81 - 99 MCH (Mean Corpuscular Hemoglobin) uugm (picogram) 27 - 31 MCHC (Mean Corpuscular Hemoglobin Concentration) gr/dL 32 - 26 RDW (Red Cell Distribution Width) % 11.6 - 14.4 Platelets cells/cmm 150,000 - 450,000 MPV (Mean Platelet Volume) fL 9.1 - 12.4 Neutrophil % 50 - 75 Lymphocyte % 20 - 45 Monocyte % 0-10 3. Review of printouts from Patients 1 and 2 from the Abbott Emerald Hematology analyzer showed the following reference intervals: WBC Male: 4,400 - 10,900 Female: 4,400 - 10,800 RBC (million cells / cmm) Male: 4.7 - 6.1 Female: 5.2 - 5.4 Hemoglobin Male: 14.0 - 18.0 Female: 12.0 - 16.0 Hematocrit Male: 42.0 - 52.0 Female: 37.0 - 47.0 MCV Male: 80.0 - 94.0 Female: 81.0 - 99.0 MCH Male: 27.0 - 32.0 Female: 27.7 - 34.0 MCHC 31.5 - 36.0 RDW Male: 11.5 - 14.5 Female: 11.0 - 14.5 Platelet 130,000 - 400,000 MPV 0.0 - 40.0 Neutrophil % Male: 37.0 - 92.0 Female: 35.0 - 75.0 Lymphocyte % Male: 10.0 - 58.5 Female: 24.0 - 44.0 Mid % 0.1 - 24.0 4. Interview with testing personnel, staff A, on September 22, 2020 at 10:00 AM confirmed the hematology procedures do not include adult reference intervals for the tests included in the CBC. Further interview confirmed reference intervals on the analyzer print out and the test report do not match. This is a repeat deficiency previously cited on June 13, 2012.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory documentation and interview with testing personnel, the laboratory did not have the manufacturer's instructions for the Abbott i-STAT CHEM8+ test cartridges and had not confirmed the laboratory was following the manufacturer's requirements for quality control testing. Findings include: 1. Review of laboratory documentation revealed the laboratory had no manufacturer's instructions for the Abbott i-STAT CHEM8+ test cartridges. 2. Interview with testing personnel, staff A, on September 22, 2020 at 11:45 AM confirmed the laboratory did not have the manufacturer's instructions for the Abbott i-STAT CHEM8+ cartridges and could not confirm the laboratory's quality control procedures met the manufacturer's requirements.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Item 1 Based on surveyor review of laboratory records and interview with testing personnel, the laboratory did not demonstrate it could obtain performance specifications comparable to those established by the manufacturer for testing performed on the Abbott i-STAT CHEM8+ blue cartridge after the manufacturer sent the 'Urgent Product Corrective Action' letter in January 2020. Findings include: 1. Review of laboratory records revealed no records showing the laboratory evaluated performance specifications for the Abbott i-STAT CHEM8+ blue cartridge after receipt of the 'Urgent Product Corrective Action' letter from the manufacturer or after the cartridge was cleared by the FDA (Food and Drug Administration) for arterial and venous whole blood as moderate complexity on February 28, 2020. 2. Interview with testing personnel, staff A, on September 21, 2020 at 11:45 AM confirmed the laboratory did not evaluate performance characteristics (accuracy, precision, reportable range, or reference intervals) for the Abbott i-STAT CHEM8+ cartridge. Item 2 Based on surveyor review of laboratory records and interview with testing personnel, the laboratory did not evaluate the automated differential results from the Abbott CELL-DYN Emerald hematology analyzer when the analyzer was replaced in June 2019. Findings include: 1. Review of laboratory records showed no evidence the laboratory evaluated the automated differential results from the Abbott CELL-DYN Emerald hematology analyzer. 2. Interview with testing personnel, staff A, no September 22, 2020 at 10:30 AM confirmed the laboratory did not evaluate the differential test results from the Abbott CELL-DYN Emerald hematology analyzer or demonstrate that it could obtain performance specification comparable to those established by the manufacturer for differentials.
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 laboratory records and interview with testing personnel, the laboratory has not performed two control materials of different concentrations for testing performed using Abbott i-STAT CHEM8+ cartridges and did not develop an Individualized Quality Control Plan (IQCP). Findings include: 1. Review of laboratory quality control records for the i-STAT CHEM8+ cartridge from 2020 showed the laboratory tests and evaluates one level of control for chemistry analytes and one level of control for the hematology analytes on the CHEM8+ cartridge each month. 2. Interview with testing personnel, staff A, on September 21, 2020 at 11:45 AM confirmed the laboratory did not test two levels of control materials each day of patient testing and had not developed an IQCP.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records from 2020 and interview with testing personnel, the laboratory director did not ensure an approved corrective action plan was followed when the laboratory received unacceptable hematology results for the erythrocyte, hematocrit, and platelet tests on one of five samples in the second event. Findings include: 1. Review of PT records from the second hematology event in 2020 showed the laboratory had unacceptable results on sample AT-8 for the erythrocyte, hematocrit and platelet tests. No evidence of review or a corrective action plan is present. 2. Interview with testing personnel, staff A, on September 22, 2020 at 10:45 AM confirmed the laboratory had not developed or followed a corrective action plan in response to the three unacceptable results. This is a repeat deficiency previously cited on June 13, 2012.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form CMS-209) and personnel records, and interview with testing personnel, the laboratory did not have documentation showing the technical consultant met the qualification requirements. Findings include: 1. The laboratory did not have documentation to show the identified technical consultant met the qualification requirements of 493.1411 of this subpart. This is a repeat deficiency previously cited on June 25, 2014.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the

	technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form CMS-209) and personnel records, and interview with testing personnel, the laboratory did not have documentation showing the technical consultant met the qualification requirements. Findings include: 1. Review of Form CMS-209 showed staff C was identified as the technical consultant for the laboratory. 2. Review of personnel records did not show the bachelor's degree held by staff C was earned in a chemical, physical, or biological science or medical technology. 3. Interview on September 21, 2020 at 11:30 AM and email on October 5, 2020 at 1:22 PM with testing personnel, staff A, confirmed documentation of the field of study for the bachelor's degree held by staff C was not available.