Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1046970	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Main Street Family Medicine Inc	1306 Highway 45 North, Henderson, TN	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, and interview with the lab lead, the laboratory failed to establish written policies and procedures for collection of blood samples, urine specimens, wet prep, and failed to have a procedure for specimen labeling. The findings include: 1. Observation of the laboratory on 05/17/23 at 8:15 am revealed a Complete Blood Count instrument and microscope on the counter in use for patient testing for Complete Blood Count wth automated white blood cell differential (CBC w/Diff), wet prep, and urine microscopy. 2. Review of the laboratory procedure manual revealed no procedures were available for performance of venipuncture and fingerstick blood collection, collection of urine samples, wet prep samples, and no specimen labeling policy. 3. Interview with the lab lead on 05/17/23 at 12:45 pm confirmed the laboratory failed have written procedures for specimen collection for wet prep, urine specimens, venipuncture, fingerstick blood samples and no policy for labeling specimen.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, the laboratory procedure manual and interview with the lab lead, the laboratory failed to have a procedure for wet prep on the date of the survey (05/17/23) with patient testing reported on 02/10/23. The findings include: 1. Observation of the laboratory on 05/17 /23 at 8:15 am revealed a microscope on the counter in use for performing patient wet prep procedures. 2. Review of patient test reports revealed patient testing for wet prep performed on 02/10/23 for patient #11. 3. Review of the laboratory procedure manual revealed the complete wet prep procedure could not be located. 4. Interview with the lab lead on 05/17/23 at 12:45 pm confirmed the laboratory did not have a procedure for wet prep.
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 observation of the laboratory, patient chart reviews, the manufacturer operator's manual, and staff interview, the laboratory failed to ensure that one of one patients with flagged CBC results was verified prior to reporting the results to the provider. The findings include: 1. Observation of the laboratory on 05/17/23 at 8:15 am revealed the CELL-DYN Emerald CBC instrument in use for patient testing. 2. Patient chart reviews were performed for four patients from 2020, 2021, 2022 and 2023. Review of the instrument printout for patient #3 performed on 11/15/22 revealed the white blood cell differential was flagged with "s". There was no evidence the result was verified before reporting to the provider. 3. Review of the manufacturer operator's manual revealed the "s" flag could indicate the presence of eosinophils or myelocytes. The specified action to take indicated checking the specimen for clots or agglutination, following the laboratory's review criteria, and redraw and retest the specimen as required. 4. During an interview with the lab lead on 05/17/23 at 12:45 pm the lab lead stated they only repeat CBCs that are flagged with platelet

	agglutination and do not have a policy in place for other flags that might occur on the CBC instrument. This confirmed the survey findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer operator's manual, lack of records and interview with the laboratory lead, the laboratory failed to monitor humidity in the area where the CELL-DYN Emerald CBC instrument was in use for performing patient CBC w/Diff in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 05/17/23 at 8:15 am revealed the CELL-DYN Emerald instrument (serial #1667) in use for performing patient testing for CBC w /diff. 2. Review of the manufacturer operator's manual revealed the following operating conditions: "Maximum relative humidity 80% for temperatures up to 90F" 3. There were records for monitoring of humidity. 4. Interview with the lab lead on 05 /17/23 at 12:45 pm confirmed the laboratory did not monitor humidity in the area where the CELL-DYN Emerald CBC instrument was in use for patient testing in 2021, 2022, and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the control manufacturer package insert, and interview with the lab lead, the lab failed to label controls with corrected expiration for three of three CBC control vials in use on the day of the survey. The findings include: 1. Observation of the laboratory on 05/17/23 at 8:15 am revealed vials used for performing quality control on the CELL-DYN Emerald CBC instrument labeled with an open date of 05/02/23 with no corrected expiration date (Lot 3037, Level Low, Normal, and High). 2. Review of the CELL-DYN 18 Plus control package insert revealed the controls are good for "8 Consecutive-Day Open-Tube Stability. 3. Interview with the lab lead on 05/17/23 at 12:45 pm confirmed the laboratory failed to label three of three vials of CBC controls with corrected expiration date on the date of the survey (05/17/23)
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 observation of the laboratory, review of the control manufacturer package insert, and interview with the lab lead, the laboratory failed to ensure controls were not used past their expiration date from 05/11/23 until the date of the survey on 05/17 /23. The findings include: 1. Observation of the laboratory on 05/17/23 at 8:15 am revealed vials used for performing quality control on the CELL-DYN Emerald CBC instrument labeled with an open date of 05/02/23 (Lot 3037, Level Low, Normal, and High). 2. Review of the CELL-DYN 18 Plus control package insert revealed the controls are good for "8 Consecutive-Day Open-Tube Stability." Based on this information the controls expired on 05/10/23. 3. Interview with the lab lead on 05/17 /23 at 12:45 pm confirmed the laboratory failed to ensure controls were not used past their expiration date from 05/11/23 to the date of the survey on 05/17/23.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the lab lead, the laboratory failed to have a quality control process in place to monitor for shifts and trends over time in 2020, 2021, 2022, and 2023. The finding include: 1. Review of the quality records for CBC control lot numbers 0125, 1263, 2234, and 2318 revealed the laboratory did not have a process in place to monitor CBC data for shifts and trends over time. The controls were in use in 2020, 2021, 2022 and 2023. 2. Interview with the lab lead on 05/17/23 at 12:45 pm confirmed the laboratory did not have a process in place to monitor quality control data for shifts and trends over time for four of four lots reviewed from 2020, 2021, 2022, and 2023.