Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1046970	10/09/2019
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
D0000	493.51 Notification requirements for laboratories issued a certificate of compliance. Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in --(1) Ownership. This standard is not met as evidenced by: Based on review of the laboratory's ownership form from the December 5, 2017 recertification survey, the current ownership form, review of the Aspen Web 116 System and interview with testing personnel number two, the laboratory failed to notify the state agency of change in ownership within thirty days of the change in 2018. 1. Review of the laboratory's ownership form from the December 5, 2017 recertification survey revealed a different owner than the one listed on the current ownership form. 2. Review of the Aspen Web 116 System revealed no documentation that the state agency was notified of the ownership change. 3. Interview with testing personnel number two on October 9, 2019 at 12:00 p. m. confirmed the laboratory failed to notify the state agency of the change in ownership within thirty days in 2018. The ownership of the laboratory changed in June 2018.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, employee personnel records for 2018 and 2019, and interview with testing personnel number two, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the competency assessment procedure: direct observation of routine patient test performance; monitoring the recording and

	reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Review of the 2018 and 2019 employee personnel records revealed no documentation of competency assessment for the six required criteria. 3) Interview on October 9, 2019 at 12:00 p.m. with testing personnel number two confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
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 and interview with testing personnel number two, the laboratory failed to label saline with open date and expiration date in 2019. The findings include: 1. Observation of the laboratory on October 9, 2019 at 8:15 a.m. revealed a dropper bottle labeled Normal Saline 0.9% Sodium Chloride. No open date or expiration date was recorded on the vial. 2. Interview with testing personnel number two confirmed the laboratory failed to label saline with open date and expiration date in 2019.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient complete blood count (CBC) test reports and interview with testing personnel number two, the laboratory failed to maintain a record of testing personnel for three of four patient CBCs in 2018 and 2019. The findings include: 1. Review of the laboratory's instrument printout for CBC for patient numbers one, two, and four revealed no identity of the person who performed the patient testing. 2. Interview with testing personnel number two on October 9, 2019 at 12:00 p.m. confirmed the identify of the testing personnel performing CBC patient testing for three of four patients (patient numbers one, two, and four) was not maintained in 2018 and 2019.