Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2134034	07/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Main Street Family Care	211 Church Street, Tiptonville, 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
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the complete blood count (CBC) quality control (QC) records, the CBC corrective action documentation records, the technical consultant onsite quality assessment (QA) records, and interview with the laboratory liaison, the laboratory failed to have an effective corrective action documentation for the October to December 2018 CBC QC. The findings include: 1) Observation of the laboratory on July 2, 2019 at 9:11 a.m. revealed the Coulter Ac*T diff 2, serial number BA33368, in use for patient CBC testing. 2) Review of the October 23, 2018 to December 2, 2018 CBC QC instrument daily printout records revealed the low QC lot number 067700 has an expiration date of 10-22-18; normal lot number 077700 has an expiration date of 10-22-18 and high QC lot number 087700 has an expiration date of 10-22-18. 3) Review of the October 23, 2018 to December 21, 2018 CBC corrective action documentation records revealed the CBC normal and high QC lot numbers and expiration dates were not corrected to the correct CBC QC lot numbers and expiration dates. 4) Review of the technical consultant onsite QA records revealed that on the November 6, 2018 QA documentation there was no review of the October 23, 2018 to November 6, 2018 CBC QC records and no corrective action documentation for incorrect lot numbers, expired QC and incorrect ranges in use. The January 3, 2019 onsite QA records revealed, "12-3 to 1-3-19 data all ok" but the incorrect normal and high CBC QC lot numbers and expiration dates were not corrected. 5) Interview on July 2, 2019 at 11:

	30 a.m. with the laboratory liaison confirmed the November 2018 and January 2019 technical consultant onsite QA documentation and the corrective action documentation were not effective when the October 23 to November 6, 2018 CBC QC was not reviewed with the 11-6-18 onsite QA. The January 3, 2019 onsite QA documentation did not correct the CBC QC incorrect normal and high QC lot numbers and expiration dates for the CBC QC from October 23, 2018 to January 2, 2019.