Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2144527	03/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ripley Medical Clinic	202 Tucker Street, Ripley, 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
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: Based on observation of the laboratory, review of the verification of performance specification (VoPS) records, the complete blood count (CBC) patient records and interview with the technical consultant, the laboratory failed to perform the VoPS for the CBC instrument, prior to patient testing in 2018. The findings include: 1) Observation of the laboratory on March 6, 2019 at 1:51 p.m. revealed the Sysmex KX-21N CBC instrument in use for patient testing. 2) Review of the VoPS records revealed the VoPS was performed on March 4, 2019. 3) Review of the CBC patient records revealed the first patient CBC was performed on September 28, 2018. 4) Interview on March 6, 2019 at 3:20 p.m. with the technical consultant confirmed the VoPS was preformed two days prior to the survey date.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (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 chemistry quality control (QC) records, the quality assessment (QA) records, the laboratory procedure policies and interview with the technical consultant, the laboratory failed to establish and follow a written policy for performing and documenting corrective action when the chemistry QC was not within acceptable limits, in 2018 and 2019. The findings include: 1) Observation of the laboratory on March 6, 2019 at 1:50 p.m. revealed the Wassermann Ace Alera serial number 13094309, in use for patient testing for the following chemistry analytes: alkaline phosphate (Alk), aspartate aminotransferase (AST), calcium (Ca), high density cholesterol (HDL), total cholesterol (chol), glucose (glu), sodium (Na), trigylcerides (trig), alanine aminotransferase (ALT), total bilirubin (t bili), chloride (cl-), creatinine (creat), potassium (K), total protein (Tpro), and urea nitrogen (BUN). 2) Review of the chemistry QC records revealed in December 2018 the means of the following analytes were changed with no corrective action documented: Glu, T chol, AST, ALP, Ca, and ALT. In February 2019 following analytes were changed with no corrective action documented: Glu, T chol, AST, ALP, Ca, ALT, t.bili, and trig. 3) Review of the QA records revealed review by the technical consultant on 1-22-19 and 2-27-19 with no corrective action or QA documented. 4) Review of the laboratory procedure policies revealed no policy for changing the chemistry analyte mean. 5) Interview on March 6, 2019 at 3:30 p.m. with the technical consultant confirmed the QC means were changed in December 2018 and February 2019, with no corrective action documented, no QA documented. There is no laboratory policy when the chemistry analyte mean can be changed from the established mean.