Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0919829	10/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Colonial Family Practice	325 Broad Street, Sumter, SC	

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: During an onsite recertification survey on 10/17/2019, based on based on the Gene expert analyzer operator's guide, lack of documetnation, and testing personnel interview, the laboratory failed to ensure that a routine calibration was performed on the analyzer at least every year or at 2,000 tests as required by the manufacturer for 2 of 2 years reviewed (2017 and 2018). Findings include: 1. The Gene expert analyzer operator's guide stated that a calibration and calibration verification should be performed at least every year or at 2,000 tests 2. Documentation of a calibration and calibration verfication for the analyzer was unavailable for review on the day of the survey for the years 2017 and 2018. 3. Testing personnel confirmed during an onsite interview on 10/17/2019 at 2:00pm that the laboratory had failed to ensure that a routine calibration and calibration verification was performed on the analyzer at least every year or at 2,000 tests .
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: During an onsite recertification survey on 10/17/2019, based on CMS 209 review, Hitachi CLA User Manual review, personnel record review and testing personnel interview, it was determined that the laboratory director/technical consultant failed to document initial and annual competency evaluation for the Hitachi CLA analyzer for 11 of 11 testing personnel performing testing for 2 of 2 years reviewed (2017 and 2018). Findings include: 1. The laboratory listed 11 testing personnel on the CMS 209 on the day of the survey. 2. Review of the Hitachi CLA User manual revealed that documentation of training personnel appropriate for testing prior to analysis of patient specimens is required for instrument use. 3. On the day of the survey, initial and annual competency evaluations for the years 2017 and 2018 for the Hitachi CLA analyzer were unavailable for review for testing personnel 1 through 11 on the CMS 209. 4. During an interview at 1:00 pm on 10/17/2019, testing personnel confirmed that the Hitachi CLA analyzer had been put into use in 2017 and that the laboratory director/technical consultant failed to document initial and annual competency evaluation for the Hitachi CLA analyzer for 11 of 11 testing personnel.