Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0950605	(X3) Date Survey Completed 04/02/2019
Name of Provider or Supplier Elite Primary Care	**Street Address, City, State** 1718 Reynolds Street, Waycross, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 2, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2118	TOXICOLOGY CFR(s): 493.845(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to maintain satisfactory performance in two of three consecutive events (event 1 of 2017 and event 1 of 2018) resulting in the laboratory's first unsuccessful performance for alcohol. Findings include: 1. Review of the laboratory's 2017 and 2018 API PT records revealed the laboratory failed alcohol on event 1 of 2017 with a score of 33% and again on event 1 of 2018 with a score of 33%, resulting in the first unsuccessful performance. 2. Interview with the technical consultant and testing personnel # 1 on April 2, 2019 at 12 pm in the conference room confirmed the laboratory failed alcohol on event 1 of 2017 and event 1 of 2018.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

	This STANDARD is not met as evidenced by: Based on review of patient testing records and staff interview, the laboratory failed to be in compliance with the State of Georgia Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10. Findings include: 1. Review of patient testing records revealed the laboratory is testing specimens from inmates in correctional institutions and does not have a State of Georgia License to operate a clinical laboratory. Two patient records from Ware county, two records from Brantley county and one patient record from Pierce county were reviewed by the surveyor. 2. Interview with testing personnel # 1 (see CMS 209) on April 2, 2019 at 3 pm confirmed the laboratory does test patient samples from inmates at correctional institutions and revealed these samples are collected by staff at the correctional institution then transported to the laboratory for testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017, 2018 and 2019 quality control (QC) records for testing performed on the Beckman Coulter AU 480 chemistry analyzer (AU 480) and Beckman Coulter Access 2 Immunoassay analyzer (Access 2), review of the package inserts for controls, review of the manufacturer's instructions for use of controls and staff interview, the laboratory failed to establish criteria for acceptability of controls. Findings include: 1. Review of Levey Jennings charts for testing performed on the AU 400 and Access 2 and review of BioRad control assay sheets including Liquid Assayed Multiqual, Immunoassay Plus, and Specialty Liquicheck , revealed the laboratory uses the 3 standard deviation (SD) range given by the manufacturer on the assay sheet to determine the acceptable range of control values and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. 2. Review of control values obtained by the laboratory also revealed the standard deviations calculated on testing performed in their laboratory is much lower than the values used to determine acceptability of patient results. 2. Review of on-line instructions for all controls listed above and obtained from BioRad at www. myeinserts.com revealed each laboratory should establish their own acceptable ranges and use the assayed ranges as a guide. 4. Interview with the technical consultant and testing personnel # 1 (see CMS 209) on April 2, 2019 at 2 pm in the conference room confirmed the laboratory uses the mean and 3 SD ranges from the assay sheets supplied by the manufacturer and those ranges are not indicative of ranges obtained by their laboratory.