Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2018868	09/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pris, Plc	2600 Memorial Avenue - Suite 201-B, Lynchburg, VA	

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	An announced CLIA Recertification survey was conducted at Pris, Plc on September 26, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control (QC) records, lack of documentation, policy and procedures (P&P), patient test log, and an interview with the technical supervisor, the laboratory failed to perform QC materials for the Urine Creatinine analyte each day of patient testing on March 7, 12 and 14, 2019 (3 days) and reporting twenty-nine (29) patients. Findings include: 1. Review of the daily QC records from January 1, 2018 and up to May 31, 2019 revealed lack of documentation of the Cliniqa Corp Liquid QC Urine chemistry controls (Level 1 and 2) for the Urine Creatinine analyte on March 7, 12 and 14, 2019. 2. Review of the P&P "General Laboratory Quality Control (signed by lab director 10/29/14)" revealed the following statement: "3. Laboratory Quality Control- A minimum of two levels of quality control samples will be run prior to and each day of patient testing." 3. Review of the LabTrack patient test logs revealed the following: March 7, 2019- 3 patients assayed, March 12, 2019- 6

	patients assayed and, March 14, 2019- 20 patients assayed. A total of 29 patients and 3 days. 4. An interview with the technical supervisor at approximately 1:30 PM confirmed the findings.