Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1027844	(X3) Date Survey Completed 03/19/2019
Name of Provider or Supplier Southern Nevada Public Health Laboratory	**Street Address, City, State** 700 S Martin L King Blvd, Las Vegas, NV	

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
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 laboratory personnel interview and mycobacteriology quality control record review on March 19, 2019, the laboratory failed to establish statistical parameters for unassayed quality control materials used to monitor patient Quantiferon TB Gold Plus testing over time through concurrent testing of quality control materials having previously determined statistical parameters. Findings included: a. In mycobacteriology, the laboratory used the Quantiferon TB Gold Plus test system to detect possible patient Mycobacterium tuberculosis (TB) infections. It was the practice of the laboratory to use unassayed quality control materials to monitor Quantiferon TB Gold Plus patient test runs. b. Laboratory records indicated that on March 18, 2019 the laboratory tested 20 patient samples using the Quantiferon TB Gold Plus test system. The laboratory maintained no documentation to indicate that the statistical parameters for the positive and negative unassayed quality control materials used to monitor the March 18, 2019 Quantiferon TB Gold Plus patient test

	run had been established over time through concurrent testing of quality control materials having previously determined statistical parameters. c. Laboratory personnel confirmed that the statistical parameters for the unassayed quality control materials used to monitor patient Quantiferon TB Gold Plus testing had not been established over time by the laboratory through concurrent testing of quality control materials having previously determined statistical parameters. d. According to laboratory personnel, the laboratory performed approximately 50 patient Quantiferon TB Gold Plus tests weekly.