

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1027844	(X3) Date Survey Completed 04/05/2023
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, laboratory procedure review, and laboratory testing personnel interview, it was determined that the laboratory failed to ensure that all reagents, solutions, culture media, control materials, calibration materials, and other supplies were not available for use when they have exceeded their expiration date. Findings include: a. During a tour of the Bacteriology laboratory on day of survey, April 4, 2023, Oxoid Diagnostic Reagents, E.coli O157 Latex Kit, Lot #3406211, date opened September 9, 2022, expiration date March 22, 2023, was found in the same storage area as other reagents and culture media used for patient testing, and therefore available for use in patient testing. b. According to the laboratory's Quality Assurance Plan protocol, 'reagents must be used within their expiration date, processed and stored according to manufacturer's guidelines.' c. The technical supervisor and testing personnel confirmed on April 4, 2023 at 9.15 a.m. that the reagent kit was stored available for use in patient testing when it had exceeded its expiration date.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on laboratory procedure review and laboratory testing personnel interview, the laboratory failed to document all quality control (QC) procedures performed. a. Based on testing personnel interview, it is the practice of the laboratory to perform monthly QC maintenance checks of commercially obtained lyophilized ATCC microorganisms, rehydrated and stored at -70C for use in the QC testing of culture media. b. According to laboratory procedure, "Microbiology Quality Control," quality control organisms including reference strains available from ATCC are stored frozen at -70C, subcultured to appropriate culture media and passed twice before use in QC testing. c. Documentation of monthly QC maintenance checks of rehydrated ATCC microorganisms stored frozen at -70 C was not provided to the surveyors for review at the time of the survey on April 4, 2023 and April 5, 2023. d. Testing personnel (TP#1) affirmed on April 4, 2023 at 9.18 a.m. that monthly QC maintenance checks were not documented.