Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1027844	05/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Southern Nevada Public Health Laboratory	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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the COVID-19 and immunology testing rooms, review of the Thermo Fischer 7500 Fast Track DX Real-Time PCR and Quant Studio DX manufacturer's operating instructions, review of the human immunodeficiency virus (HIV) and hepatitis C virus (HCV) reagent storage instructions, lack of humidity documentation, review of patient results, and interview with the technical supervisors (TS) #1, #2, the laboratory failed to monitor humidity and store reagents according to manufacturer's instructions. Findings: 1. Observation of the COVID-19 testing room showed two 7500 Fast Track DX Real-Time PCR and two Quant Studio DX analyzers for COVID-19 PCR testing. 2. Review of the manufacturer's instructions for proper environmental specifications revealed to operate with a humidity of 20%-80% for the 7500 Fast Track DX Real-Time PCR and 15%-80% for the Quant Studios DX analyzers. 3. No humidity log was available for review. 4. Observation of the -80 degree freezer in the immunology testing room showed eight boxes of HIV/HCV quality control (QC) materials with the manufacturer's required storage range of -15 to -35 degrees Celsius (C) being stored at -77 degrees C. 5. 29,272 COVID-19 results, 124 HIV results, and 4 HCV results were reported between January 1, 2021 and May

	12, 2021. 6. Interview with the TS #1, #2 on May 12, 2021 at 10:00AM confirmed the laboratory failed to monitor humidity in the COVID-19 testing room and failed to appropriately store QC material as required by the manufacturer. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of 2 of 14 laboratory information system (LIS) test reports and interviews with the laboratory director (LD), technical supervisor (TS) #1, #2, the laboratory failed to include the name and address of the performing laboratory. Findings: 1. Review of the printed test report for sample with Orchard ID 232678 with test result for Syphilis Total Antibody IgG & IgM showed that the performing laboratory name and address were not indicated. 2. Review of the printed test report for sample with Orchard ID 232261 with test result for HCV RNA Quant showed that the performing laboratory name and address were not indicated 3. Interviews with the LD and TS #1 and #2 on May 12th, 2021 at 10:30 AM confirmed that result reports for Syphilis Total Antibody IgG & IgM and HCV RNA Quant did not indicate performing laboratory name and address. 4. Between January 1, 2020 and May 12, 2021, the laboratory performed 8,552 Syphilis Total Antibody IgG & IgM tests and 60 HCV RNA Quant tests. Based on a review of 2 of 2 LIS test reports, manufacturer instructions for use, manufacturer result guidance for providers, manufacturer result guidance for patients, and interviews with LD and TS #1 and #2, the laboratory failed to include a clear result interpretation. Findings: 1. Review of the LIS report for Orchard ID 0000217354 2019 Novel Coronavirus Real-time RT PCR (CDC) test, shows that the report indicates both a discrete result of "Not Detected" as well as a comment indicating "Negative based on CDC guielines (SP) for testing". a. Review of the manufacturer instructions for use CDC-006-00019, Revision: 02 (2019-nCoV rRT-PCR Diagnostic Panel Results Interpretation Guide; chart on page 32), the result interpretation should be indicated as "Not Detected". b. Review of CDC provided required accompanying materials (Fact Sheet for Patients and Fact Sheet for Healthcare Providers) reference test results as "Negative", not as "Not Detected". 2. Interviews with the LD and TS #1 and #2 on May 12th, 2021 at 10:30 AM confirmed that there was more than one interpretation included in the result for the 2019 Novel Coronavirus Real-time RT PCR (CDC) test. 3. Between January 1, 2020 and May 12, 2021, the laboratory performed 106,185 2019 Novel Coronavirus Real-time RT PCR (CDC) tests.