Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0646339	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Idaho Bureau Of Laboratories	2220 Old Penitentiary Road, Boise, ID	

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 review of the Quality Assurance procedure, Thermo Fisher TaqPath COVID-19 manufacturer's instructions, documentation of freezer temperatures, observation of quality control (QC) material stored in the freezer, and interview with the technical supervisor's (TS) #1, #2, the laboratory failed to follow the manufacturer's instructions for storage of Thermo Fisher TaqPath COVID-19 positive control material since July 2021. Findings: 1. Review of the Quality Assessment procedure showed "Laboratory room temperature and humidity are recorded as well as the temperature in refrigerators, freezers, ovens and incubators." 2. Review of the Thermo Fisher TaqPath COVID-19 manufacturer's instructions revealed, " controls must be stored at less than or equal to minus 70 degrees Celsius (C)." 3. Review of the laboratory's temperature charts revealed the laboratory failed to document the temperature for the REVCO minus 70 degrees freezer named "Sweetums". 4. Observation of the REVCO laboratory freezer showed 1 box of Thermo Fisher TaqPath COVID-19 positive control currently in use in the laboratory. 5. Interview with the TS #1 and TS #2 on February 15, 2022 at 11:00 am confirmed the laboratory failed to properly monitor the freezer temperature and store QC materials and supplies per manufacturer's instructions.

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of 2020 and 2021 quality control (QC) logs, three of three patient results, and interview with the technical supervisor (TS) #2, the laboratory failed to perform a titered positive control for BD VDRL Syphilis testing. Findings: 1 No titered QC was performed at least once a day for BD VDRL Syphilis testing. 2. Review of three of three patient results showed the laboratory reports titered results but failed to report the titer of the positive control for 2020 and 2021. 3. Approximately 235 of VDRL tests are reported annually for 2020 and 2021. 4. Interview with TS #2 on February 16, 2022 at 11:00 am confirmed the laboratory failed to report the titer of the known positive control material each day of testing.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel competency documentation and interview with the laboratory director (LD) and technical supervisor (TS) #1, the LD failed to ensure competency for three of three TS positions and three of three general supervisor (GS) positions for 2020 and 2021. Findings: 1. Review of 2020 and 2021 personnel competency documentation revealed the laboratory failed to perform competency assessments for three of three TS and three of three GS positions. 2. Interview with the LD and TS #1 February 16, 2020 at 1:30 pm confirmed the laboratory failed to ensure competency of three of three TS and three of three GS for 2020 and 2021.