Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0658941	(X3) Date Survey Completed 03/18/2021
Name of Provider or Supplier South Dakota Public Health Laboratory	**Street Address, City, State** 615 East Fourth Street, Pierre, SD	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of COVID-19 procedure manual, maintenance logs and general supervisor (GS) interview, the laboratory failed to follow procedures to clean and decontaminate the PCR COVID-19 extraction room area. Findings include: 1. Review of the PCR COVID-19 procedure manual states, "work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, DNAZap, or RNaseAWAY to minimize risk of nucleic acid contamination". 2. No documentation was available for the cleaning and decontamination of the PCR COVID-19 extraction room area for 2020 and 2021. The laboratory currently performs approximately 30 COVID-19 extractions daily. 3. In an interview conducted on March 18, 2021 at 10:00 AM, GS #4 confirmed the laboratory did not kept a log for documenting the cleaning and decontamination of the PCR COVID-19 extraction room area.
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 1 Vidas SARS-COV-2 IgG antibody kit and 10 Vidas SARS-COV-2 IgM antibody kits stored in the refrigerator, review of manufacturer's instructions, review of documentation of refrigerator temperatures, and interview with the laboratory director (LD), the laboratory failed to follow the manufacturer's instructions for storage of reagents. Findings: 1. Observation on March 17, 2021 at 10: 20 AM of the laboratory refrigerator located in the microbiology media room showed 1 Vidas SARS-COV-2 IgG antibody kit and 10 Vidas SARS-COV-2 IgM antibody kits available for use in the laboratory. 2. Review of the manufacturer's instructions for Vidas SARS-COV-2 IgM and IgG antibody kits showed the kits must be stored at 2-8 degrees Celsius (C). 3. No refrigerator temperature monitoring documentation was available for review. 4. Interview with the LD on March 17, 2021 at 11:00 AM confirmed the laboratory failed to properly monitor the refrigerator and store reagent materials per manufacturer's instructions. Based on observation of 2 of 2 COVID-19 PCR laboratory rooms, the tuberculosis bacillus (TB) anti-room and the specimen receiving area, review of manufacturer's instructions, temperature and humidity monitoring logs, and interview with the technical supervisor #1 (TS), the laboratory failed to monitor and document room temperature and humidity. Findings: 1. Observation of the specimen receiving area on March 17, 2021 at 9:20 AM showed Abbott COVID-19 ID NOW kits and COVID-19 Ag BinaxNOW cards stored on shelves in the hallway. 2. Observation of 2 of 2 rooms used for COVID-19 PCR testing showed 5 Applied Biosystems 7500 Fast Dx Real-Time PCR analyzers. Observation of the TB anti-room showed one Maldi analyzer for identification. 3. Review of the manufacturer's instructions for Abbott COVID-19 ID NOW kits and COVID-19Ag BinaxNOW cards showed to store the kits at 2-30 degrees C. 4. Review of the manufacturer's instructions for the Maldi analyzer showed to operate in a temperature of 16-30 degrees C with 20-75 perent noncondensing humidity. 5. Review of the manufacturer's procedure for Applied Biosystems 7500 Fast Dx Real-Time PCR instrument showed to operate the systems at a temperature of 15-30 degrees C and 20-28 percent relative humidity noncondensing. 6. No temperature monitoring and documentation for the specimen receiving area and 2 of 2 rooms used for COVID-19 PCR testing was available for review. No documentation was available for humidity monitoring for all areas of the laboratory. 6. Interview with the TS #1 on March 18, 2021 at 10:00 AM confirmed the laboratory failed to monitor temperature and humidity for proper storage of reagents and test system operation.