Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2195828	08/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laramie Peak Rural Health Clinic	1356 Shiek Street, Wheatland, WY	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to report 247 negative SARS-CoV-2 patient tests results, as required, for 10 months of testing reviewed (10/15/20 to 8/11/21). The findings were: 1. Review of the laboratory's documentation showed 345 SARS-CoV-2 tests were performed using the Quidel Sophia 2 test system since 10/15/20. There was no evidence the 247 negative SARS-CoV-2 patient results had been reported to the State Public Health Laboratory. 2. Interview with laboratory director on 8/11/21 at 10:20 AM confirmed the negative SARS-CoV-2 patient test results had not been reported to the State Public Health Laboratory.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory failed to retain the MEDTOXScan instrument printout for drugs of abuse screening for 6 of 6 patients reviewed from 4/7/21 through 8/11/21. The laboratory had performed 6 MEDTOXScan drugs of abuse screenings. The findings were: 1. Review of the laboratory's records from 4/7/21 through 8/11/21 showed no evidence the MEDTOXScan instrument printouts had been retained for 6 patient drugs of abuse screens performed. 2. Interview with testing personnel #1 on 8/11/21 at 9:25 AM revealed the results of the patient's tests were manually entered into the patient's electronic medical record and then the laboratory discarded the MEDTOXScan instrument printout.
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 procedure manual review and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results for 1 of 1 SARS-CoV-2 test method. The findings were: 1. Review of the laboratory's procedures showed no evidence the laboratory had developed a policy and procedure for reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 2. Interview with the laboratory director on 8/11/21 at 10:20 AM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 test results.
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 laboratory's records, review of manufacturer's operator's manual, and staff interview, the laboratory failed to monitor and document the room temperature in 1 of 1 testing and reagent storage area. The laboratory conducted approximately 20 MEDTOXScan drugs of abuse screens per year. The findings were: 1. Review of the laboratory's records failed to include documentation of the room temperature in the testing and reagent storage area. 2. Review of the MEDTOXScan operator's manual for the MEDTOXScan test system showed the test cartridges and

	quality control vials must be stored between 2 and 25 degrees Celsius (C) and the minipets must be stored between 18 and 25 degrees C. 3. Interview with testing personnel #1 on 8/11/21 at 8:55 AM confirmed the laboratory staff had not monitored the laboratory's room temperature.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, review of the patient testing log, and staff interview, the laboratory failed to perform two levels of QC each day of testing for 3 of 4 days (5/11/21, 6/11/21, and 7/5/21) of MEDTOXScan drugs of abuse screening panels. This failure affected 4 patient samples. The findings were: 1. Review of the MEDTOXScan patient testing log showed the laboratory performed patient testing on 5/11/21, 6/11/21, and 7/5/21. 2. Review of the 4/7/21 through 8/11 /21 MEDTOXScan QC records failed to include evidence QC had been performed on 5/11/21, 6/11/21, and 7/5/21. 3. Interview with the laboratory director on 8/11/21 at 9: 20 AM confirmed QC had not been performed on each day of patient testing for the MEDTOXScan drugs of abuse screening tests.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of the MEDTOXScan drugs of abuse screening patient test records, lack of documentation, and staff interview, the laboratory failed to ensure the laboratory's test records included the identity of the personnel who performed the testing for 6 of 6 patient drugs of abuse (#1, #2, #3, #4, #5, #6) screens reviewed. The findings were: 1. Review of patients' test records showed the laboratory failed to document the identity of the testing personnel performing the test for the following MEDTOXScan drugs of abuse screening results: a. Patient #1 collected on 4/7/21. b. Patient #2 collected on 4/7/21. c. Patient #3 collected on 5/11/21. d. Patient #4 collected on 6/11/21. e. Patient #5 collected on 7/5/21. f. Patient #6 collected on 7/5 /21. 2. Interview with the laboratory director and testing personnel #1 on 8/11/21 at 9: 25 AM confirmed the laboratory's test records did not include the identity of the testing personnel.