Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2058723	04/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Western Health And Safety	7251 W 20th St, Greeley, CO	

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 a review of the laboratory's policies, maintenance records, and staff interview, the laboratory failed in January 2018 to document the temperature of the refrigerators, freezers, incubators, the ambient room temperature and humidity on each day of testing. Findings include: a. The policy titled, "Temperature Monitoring" states, "Temperatures in the laboratory must be monitored to ensure that all lab equipment and reagents are kept in the proper operating environment as dictated by the specifications found in package inserts and equipment manuals" and, "The rooms comprising the laboratory are monitored for temperature and humidity" and, "Temperatures will be recorded every morning as part of daily operating routine on the appropriate log." b. The laboratory humidity was not documented on 12 of 22 days of testing. c. The room temperature was not documented on 12 of 22 days of testing. d. The temperatures of the "urine refrigerator" (serial #BA54330454) and the "urine freezer" (serial #BA54330454) were not documented on 12 of 22 days of testing. e. The temperatures of the "urine refrigerator" (serial #BA54328476) and the "urine freezer" (serial #BA54328476) were not documented on 12 of 22 days of testing. f. The temperatures of the "reagent refrigerator" (serial #BA43012937) and the "reagent freezer" were not documented on 12 of 22 days of testing. g. The temperatures of the "LC/MS refrigerator" (serial #BA54328838) and the "LC/MS freezer" were not

	documented on 12 of 22 days of testing. h. The temperatures of the Quincy incubators (serial #F-02469 and serial #F-02208) were not documented on 12 of 22 days of testing. i. The temperature of the "back-up freezer" (serial #WB74247132) was not documented on 12 of 22 days of testing. j. On 4-19-18 at 11:05 a.m., the technical supervisor confirmed that no temperatures were taken on these days of testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: 1. Based on a review of the laboratory's procedures, manufacturer's instructions, validation records, and staff interview, the laboratory failed verify the manufacturer's performance specifications for 2 of 2 Agilent 6400 LC/MS chemistry analyzers prior to patient drug confirmation testing in 2016 and 2017. Findings include: a. The "Validation Protocol" procedure states the laboratory will validate LC/MS instruments in-house for a total of 5 days to include: Accuracy, Precision, Reportable Range, Limit Of Detection, Matrix Interference, Recovery, Specificity and Carryover. b. The "Qualification of Equipment" procedures states all instrumentation and equipment are to be qualified prior to testing laboratory samples when purchasing new equipment, at installation, and when moved to a different location. c. The manufacturer's instructions state to install and verify the performance of the analyzer prior to running patient specimens. d. The laboratory director signed the validation summary sheet for the Agilent LC/MS (BA-1) on 12/15/17. e. The laboratory director signed the validation summary sheet for the Agilent LC/MS (BA-2) on 12/15/17. f. The technical supervisor stated that patient testing began on both Agilent LC/MS analyzers in May 2016. g. On 4/19/2018 at around 11 a.m., the technical supervisor stated he was unaware the analyzers were not validated before patient testing began on the analyzers. h. The technical supervisor confirmed that 2 of 2 Agilent LC/MS chemistry analyzers were not validated before patient testing began in May 2016. Approximately 35,377 patient test results were reported from May 2016 to 12/15/17. 2. Based on a review of the laboratory's procedures, validation records, and staff interview, the laboratory failed to verify the manufacturer's performance specifications for 2 of 2 Thermo Fisher Scientific Indiko Plus chemistry analyzers prior to drug screen testing of patient specimens in 2016 and 2017. Findings include: a. The "Qualification of Equipment" procedures states all instrumentation and equipment are to be qualified prior to testing laboratory samples when purchasing new equipment, at installation, and when moved to a different location. b. The laboratory director signed the validation summary sheet for the Indiko Plus #1 in June 2013 when the analyzer was in use at the laboratory's prior location in Loveland. c. The laboratory moved from Loveland to Greeley in May 2016. No records existed showing a validation of the Indiko Plus #1 analyzer was performed at its current Greeley laboratory location. d. The laboratory failed to provide a validation summary page with a laboratory director signature for the Indiko Plus #2 to include a review of accuracy, precision, and reportable range to verify the manufacturer's performance specifications. e. The

	technical supervisor stated that patient testing began on the Indiko Plus #1 and #2 analyzers in May 2016. f. On 4/19/2018 at around 11 a.m., the technical supervisor stated he was unaware the Indiko Plus #1 and the Indiko Plus #2 were not validated before patient testing began on the analyzer in the new laboratory in Greeley. g. The technical supervisor confirmed that 2 of 2 Thermo Fisher Scientific Indiko Plus chemistry analyzers were not validated before the testing of patient specimens began in May 2016. Approximately 15,022 patient test results were reported from May 2016 to the date of survey on 4/19/2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 1. Based on a review of the laboratory's policies, maintenance records, and staff interview, the laboratory failed in 2017 to perform daily and monthly maintenance on 1 of 2 Thermo Fisher Indiko Plus chemistry analyzers. Findings include: a. The "Equipment Calibration and Preventative Maintenance" procedure states that laboratory personnel will be trained to perform preventative maintenance on equipment. b. Daily maintenance for 2017 was not performed for the Indiko Plus #1 (Serial Number: 864000091004) on 49 of 167 days of testing (Jan.=12 of 22 days, Feb. =7 of 20 days, Mar.=3 of 23 days, Apr.=3 of 20 days, Sep.=4 of 20 days, Oct.=10 of 22 days, Nov.=5 of 20 days, Dec.=5 of 20 days). c. Routine monthly maintenance for 2017 was not performed for the Indiko Plus #1 in January and November. d. The technical supervisor stated that after he was hired in Feb 2018 he had implemented a review process and he noticed the lack of documented instrument maintenance that had occurred in the laboratory in 2017. e. The technical supervisor confirmed that the Indiko Plus chemistry analyzer was not properly maintained on a daily and monthly basis in 2017 as required by their laboratory policy. 2. Based on a review of the laboratory's policies, maintenance records, and staff interview, the laboratory failed in 2018 to perform maintenance on two Eppendorf centrifuges, one Fisher Scientific timer, and one Market Lab thermometer as required by the laboratory's policy. Findings include: a. The "Equipment Calibration and Preventative Maintenance" procedure states that laboratory personnel will be trained to perform preventative maintenance on equipment. b. Daily maintenance was not performed for the Eppendorf 5424R Centrifuge (serial #5404DJ415008) on 17 of 20 days of testing in February 2018. c. Daily maintenance was not performed for the Eppendorf 5430R Centrifuge (serial #5428EM221598) on 19 of 22 days of testing in March 2018. d. Calibration of the Fisher Scientific time (serial #72588116), used for patient specimens placed in the incubator, was not performed after the previous calibration expired on 10-22-09. e. Calibration of the Market Lab thermometer (serial #150752238), used to monitor the room temperature, was not performed after the previous calibration expired on 10-8-17. f. The technical supervisor stated that maintenance of equipment had not been performed on a regular basis, and confirmed that the daily maintenance had not been performed each day, and the calibration of equipment had not been performed when needed as required by their laboratory policy.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, maintenance records, validation documentation, and staff interview, the laboratory failed to establish policies and procedures to monitor the analytic systems on an ongoing basis, and to promptly identify and correct problems in a timely manner in 2016 or 2017. Findings include: a. The laboratory's policy states that the quality assurance program is to prevent problems before they occur rather than address the failures after they happen, and that the analysts are expected to report any unacceptable behavior of the analytical system to the supervisor immediately. b. Daily temperature and humidity monitoring was not performed in January 2018 (Ref D5413). c. Verification of the manufacturer's performance specifications was not performed for 4 of 4 chemistry analyzers in 2016 and 2017 (Ref D5421). d. Maintenance of analyzers and equipment was not performed in 2017 and 2018 (Ref D5429).
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 patient test reports, and staff interview, the laboratory failed to include on the final report the name of the laboratory where urine drug screen and confirmation testing was performed. Findings include: a. The final report indicated the name of the laboratory was "United Diagnostic Services." b. On 4/19/2018 at about 2 p.m., the technical supervisor confirmed the laboratory was doing business as (DBA) "United Diagnostic Services" but the correct laboratory name is "Western Health & Safety".