Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0670375	07/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Warm Springs Health & Wellness Center	1270 Kot-Num Road, Warm Springs, OR	

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
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 a review of available quality control records and an interview with the laboratory supervisor the laboratory failed to retain all quality control records for two years. Findings: 1. A review of quality control (QC) records for Erythrocyte Sedimentation Rate (ESR) revealed no records for 2018 were available for review at the time of the survey. 2. An interview of the laboratory supervisor at 1:15 PM confirmed that the laboratory was unable to find the 2018 ESR QC records.
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 an observation of freezer storage, a review of freezer temperature records, and an interview of the laboratory supervisor the laboratory failed to define the correct

	acceptable range for Freezer Unit #2 for proper storage of all controls stored in the freezer. Findings: 1. Observation of Freezer Unit #2 at 11:20 AM revealed the storage of the following two controls: a. BioRad Liquid Assayed Multiqual with a manufacturer required storage temperature range of -20 to -70 degrees Celsius. b. BioRad Liquichek Immunoassay Plus Control with a manufacturer required storage temperature range of -20 to -70 degrees Celsius. 2. A review of temperature charts for the Freezer Unit #2 revealed a documented acceptable temperature range of -15 degrees Celsius or colder. 3. An interview of the laboratory supervisor on 07/10 /20119 at 11:30 AM confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration records and an interview with the laboratory supervisor the laboratory failed to perform calibration verification every six (6) months, as required for multiple analytes tested on the Dimension EXL 200 chemistry analyzer. Findings: 1. A review of calibration and calibration verification records for the Dimension chemistry analyzer revealed that the laboratory failed to perform calibration verification for Sodium, Potassium, Chloride, Triglyceride and Hemoglobin A1C every six (6) months as required. 2. A review of the calibration and calibration verification records for the Dimension chemistry analyzer, also revealed that the laboratory failed to perform calibration verifications on the analytes AST, ALT, ALKP, and GGT from August 28, 2017 through February 28, 2019. 3. An interview with the laboratory supervisor on July 10, 2019 at 1:10 PM confirmed that the laboratory failed to perform calibration verification for Sodium, Potassium, Chloride Triglyceride, Hemoglobin, A1C, AST, ALT, ALKP and GGT every six (6) months.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the laboratory supervisor, the laboratory failed to test at least 2 levels of quality control materials for the Medtox Verdict II Oxycodone test each day of patient testing since March 20, 2019. Findings: 1. A review of the quality control records for the Medtox Verdict II Oxycodone revealed the laboratory failed to test at least 2 levels of quality control material each day of patient testing between March 20, 2019 and the date of the survey. 2. A review of patients test logs revealed that 88 patient samples had been tested between March 20, 2019 and July 10, 2019. 3. An interview with the laboratory supervisor on July 10, 2019 at 1:30 PM, confirmed the laboratory failed to test at least 2 levels of quality control material prior to testing patients on each day of use.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of instrument maintenance records and an interview with the laboratory supervisor, the laboratory failed to identify and document corrective actions for temperatures that were out of range for the cuvette on the Dimension EXL 200 chemistry analyzer. Findings: 1. A review of the maintenance records for the Dimension EXL 200 chemistry analyzer from January 2019 through July 2019 revealed that temperatures for the cuvette were out of range 11 days in January and 15 days in February with no documentation of corrective action. 2. An interview with the laboratory supervisor on July 10, 2019 at 11:30 AM confirmed the laboratory failed to identify and document corrective action when the cuvette temperatures were out of range for 26 days in January and February 2019.