Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0670375	06/22/2021
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
D0000	During a routine recertification onsite survey conducted on 06/22/2021, a random sampling review of laboratory's records found the laboratory to be in substantial compliance with federal regulations at 42 C.F.R. 493, Clinical Laboratory Requirements for SARS CoV-2 reporting.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review of the laboratory's testing personnel competency records and interview with the laboratory general supervisor (GS) the laboratory failed to follow written policies and procedures to assess one of three employee competency in accordance with CLIA regulations and the laboratory's policy and procedures. Findings include: 1. The laboratory CMS-209 personnel report indicated that the labortory had one new testing personnel since the last surey with a start date of 06/08 /2020. 2. The laboratory had no documentation of annual competency performed for the testing of SARS CoV-2 for the new Medical Laboratory Technician (MLT) testing personnel. 3. The laboratory general supervisor confirmed by interview on 06/22/2021 that the annual competency for the MLT had not been performed. 4. The laboratory records indicate the laboratory has performed 11,591 SARS CoV-2 tests from 11/20 /2020 to survey date 06/22/2021.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's chemistry quality control (QC) records, personnel training and competency records and interview with the laboratory general supervisor (GS) the laboratory failed to have a policy and procedure for reviewing and documenting general laboratory systems quality assessment activities which includes a review of the effectiveness of corrective actions taken to resolve quality control failures, discussion of general laboratory systems quality assessment reviews with appropriate staff, and to ensure all testing personnel had the required six month and annual competency evaluations performed. Findings include: 1. The laboratory does not have a QA policy or procedure for reviewing corrective actions and the effectiveness of corrective actions taken and discussion with pertinent laboratory staff regarding corrective actions taken. See D 5783. 2. The laboratory does not have a QA policy or procedure for ensuring all testing personnel have a competency assessment documented during their first six months of testing and annually thereafter, resulting in one (1) of (3) three testing personnel not having an annual competency performed. See D 5209 5. The laboratory GS confirmed by interview on 06/22/2021 at 1:30 p.m. that the laboratory does not have a QA policy/procedure which covers pre-analytic, analytic ad postanalytic testing and personnel competency. 6. The laboratory reports performing 36,241 moderate complexity tests annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's chemistry quality control (QC) records and interview with the laboratory general supervisor (GS) the laboratory failed to follow their established policy and procedure for correcting, documenting and reviewing corrections made when quality control materials fall outside of the laboratory's established range. Findings include: 1. A random review of 10 patient records and the laboratory's QC records from 07/09/2019 to 06/21/2021 revealed four days in April 2021, in which the SerumQC2 materials for N-terminal pro b-type natriuretic peptide (NT-proBNP) results were above the laboratory's established range of 143 - 213 pg /ml. Date Result 04/05/2021 215.0 pg/ml 04/08/2021 216.0 pg/ml 04/12/2021 214.4 pg /ml 04/14/2021 216.5 pg/ml 2. The laboratory's NT-pro-BNP SerumQC2 result print out, on April 12, 2021, indicated that the testing personnel adjusted the mean. There was no documentation indicating which direction the mean was adjusted, why this action was taken and if the change corrected the issue. a. The laboratory's documented mean was 207 for the months of March and April. b. The laboratory is enrolled in Unity QC with Siemens and the mean indicated for the laboratory for April 2021 was

	206.9, and in the previous month (March) the mean was 207. 3. The laboratory's corrective action log did not include documentation for the failed QC level for the four dates listed above, and what corrective actions were taken. 4. The laboratory did not have documentation regarding if the corrective actions taken had been effective. 5. The laboratory GS confirmed by interview on 06/22/2021 at 1:30 p.m. that the laboratory did not document the corrective actions taken for failed QC for the dates listed. 6. The laboratory reports performing 40 NT-pro-BNP tests annually.