Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0697857	10/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Owyhee Community Health Facility	1623 Hospital Loop Rd, Owyhee, NV	

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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Chemistry quality control (QC) records and interview via telephone with the laboratory director on October 22, 2020, the laboratory failed to ensure control materials met the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. The findings included: 1. During random review of patient testing records from June 2018 through August 2020, one of the nine records reviewed, identified the QC values were outside of the laboratory's established range and patients specimens were ran and released. Date 12/19/2018 Run 1 level Test Result Test Range QC1 LIPL 102 105-125 U/L QC3 CA 1.2 2.4-13.6 U/L ALB -0.1 3.8-4.3 U/L ALPI 275 283-323 U/L ALTI 188 189-213 U/L URCA 0.0 8.8-9.8 U/L LIPL 491 570-650 U/L After repeated runs the SerumQC3 ALPI and ALTI were still not within the laboratory's established range. Repeat (2) QC3 ALPI 273 283-323 U/L ALTI 179 189-213 U/L Repeat (3) QC3 ALPI 273 283-323 U/L ALTI 187 189-213 U/L 2. The laboratory performed and released three patient ALPI/ ALTI results on 12-19-2018, while the SerumQC3 values remained outside of the laboratory's established range. HRN# 5013 HRN# 20575 HRN# 11114 3. The laboratory technical consultant confirmed by interview via telephone conference on October 22, 2020 that the laboratory had released patients' results when chemistry QC values did not meet the laboratory's criteria for acceptability. 4. The laboratory reports performing and reporting approximately 4,265 patient chemistry results 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 by telephone with the laboratory director on October 22, 2020, the laboratory failed to document corrective actions taken for QC values that fell below the laboratory's established acceptable range. The findings included: 1. During random review of patient testing records from June 2018 through August 2020, two of the nine records identified where the QC values were outside of the laboratory's established range. Date 12/19/2018 Run 1 QC level Test Result Test Range QC1 ALPI 32 32-43 U/L ALTI 30 30-38 U/L LIPL 102 105-125 U/L QC3 CA 1.2 12.4-13.6 U/L ALB -0.1 3.8-4.3 U/L ALPI 275 283-323 U/L ALTI 188 189-213 U/L URCA 0.0 8.8-9.8 U/L LIPL 491 570-650 U/L After repeated runs, the QC3 ALPI and ALTI analytes were still not within the laboratory's established range. Repeat (2) QC3 ALPI 273 283-323 U/L ALTI 179 189-213 U/L Repeat (3) QC3 ALPI 273 283-323 U/L ALTI 187 189-213 U/L b. Date 3/16/2019 QC level Analyte Result Test Range QC1 Lipase 99 104-125 U/L QC3 CA 12.3 12.4-13.6 U/L Repeat (2) QC3 CA 12.4 12.4-13.6 U/L The laboratory QC records on 3/6/2019 did not indicate if the QC1 Lipase level had been rerun, only that there were no patient specimens with Lipase orders ran on that day. 2. The laboratory performed and released three patient ALPI, ALTI results on 12-19-2018, (when the QC3 values remained outside of the laboratory's established range), and eight patients CA results on 3-16-2019; with no documentation of corrective actions taken. 3. The laboratory failed to evaluate patient test results obtained for the unacceptable test runs since the last acceptable test run to determine if patient test results had been adversely affected. 4. The laboratory director confirmed by interview on October 22, 2020 at 1:00 p.m. that the laboratory did not review and document patient test results during the failed quality control runs identified. 5. The laboratory reports performing approximately 4,265 patient Chemistry specimens annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records for 12/19/2018 and 3/6/2019 and by interview with the laboratory director and the laboratory consultant on 10/22/2020, the laboratory failed to perform and document analytic systems

	assessments for QC failures and what corrective actions were taken to resolve the problems and the effectiveness of corrective actions for QC failures taken to resolve the problems. The findings include: 1. During a random review of the laboratory's QC chemistry records from June 2018 to August 2020, there were two of nine records reviewed with instances in which the laboratory experienced QC failure and failed to resolve the failed analyte/s QC levels and continued to test patients even though additional chemistry QC analyte values were borderline for the laboratory's established acceptable range. See D5783 2. The laboratory had no documentation analytical quality assessments during the time of QC failures for 12/19/2018 and 3/6 /2019. 3. The laboratory director and technical consultant confirmed by interview on October 22, 2020 at 1:15 p.m. that there had not been a quality assessment performed during the QC failures identified. 4. The laboratory reports performing approximately 4,265 patient chemistry tests annually.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel on October 21, 2020, and interview with the laboratory director on October 22, 2020, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. The findings include: 1. The laboratory testing personnel confirmed by interview on 10/21/2020 at 4:00 p.m. that the current testing personnel's initial training had been provided on site by the laboratory assistant and by the laboratory technical consultant through virtual training. The laboratory failed to document the current testing personnel's initial training and competency prior to performing and reporting patient specimen tests. 2. The laboratory consultant performed a competency assessment summery on the current testing personnel on 10 /05/2020. The competency summery failed to identify the testing methodology's reviewed covering the full scope of the testing being performed by the current testing personnel. 3. The laboratory director confirmed by phone interview on October 22, 2020 that the laboratory could not perform onsite training and competency on the contracted testing personnel due to government shut down in 2018 and the current public health emergency during the spring of 2020. 4. The laboratory reports performed approximately 5, 296 moderate complexity tests and 1,186 waived tests annually.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results

	are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, and quality assessment (QA) reports on 10/21/2020 and interview with the laboratory technical consultant (TC) on 10/22/2020, the TC failed to ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. The findings include: 1. On 3/6/2019 the laboratory's chemistry SerumQC1 calcium (CA) and Lipase analyte values fell below the laboratory's established range, and upon repeat testing the CA level came into range just at the lowest cutoff value of the laboratory's established QC range. The lipase SerumQC1 was not repeated. See D5481, D5783, D5793. 2. The laboratory did not have corrective actions identified or quality assessments documented for the chemistry QC failures on 12/19/2018 or 3/6/2020. 3. The laboratory TC confirmed by interview on 10/22/2020 at 1:30 p.m. that a quality assessment not been performed and corrective actions had not been documented for the dates of QC failure identified. 4. The laboratory reports performing 4,265 patient chemistry tests annually.