Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0697857	06/14/2018
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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of laboratory instrumentation, quality control (QC) materials, patient test reports covering the period from December 29, 2016 to December 21, 2017 and interview with the laboratory director and testing personnel, it was determined that the laboratory failed to not use QC materials when they have exceeded their expiration date. The findings include: a. During examination of the laboratory's QC materials used for patient testing it was discovered that two bottles of Bio-Rad Liquichek Immunoassay Plus had expired. Reagent Lot Number Expiration 40901 2017-10-31 40903 2017-10-31 b. On June 14, 2018, the laboratory director and testing personnel affirmed that the expired QC materials have been used for patient testing. c. Based on the laboratory's annual test volume declaration the laboratory analyzed and reported approximately 5,026 chemistry procedures annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on review of laboratory equipment maintenance documentation, patient test reports covering the period from December 29, 2016 to December 21, 2017, and interview with the laboratory director and testing personnel, it was determined that the laboratory failed to establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The findings include: a. During examination of the laboratory's equipment and instrumentation used to perform laboratory testing it was discovered that the laboratory's pipettes used for prothrombin time patient testing was last serviced and calibrated 8/10/15. b. The laboratory failed to provide documentation of a maintenance protocol that ensures equipment and instrument performance necessary for accurate and reliable test results. c. On June 14, 2018, the laboratory director and testing personnel affirmed that the pipettes labeled with a service and calibration date of 8/10/15 are being used for prothrombin time testing. d. Based on the laboratory's annual test volume declaration the laboratory analyzed and reported approximately 71 prothrombin time procedures annually.
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 laboratory instrumentation, manufacturer package insert, quality control (QC) materials, QC records, patient test reports covering the period from December 29, 2016 to December 21, 2017 and interview with the laboratory director and testing personnel, it was determined that the laboratory failed to test a negative and positive control material at least once a day patient specimens are examined for each qualitative procedure. The findings include: a. During examination of the laboratory's QC materials and records used to perform Bio-Rad drugs of abuse testing it was discovered that negative and positive control materials were not tested each day of patient testing. b. Review of Bio-Rad's manufacturer package insert titled, "TOX /See Protocol Sheet," stated "The use of external positive and negative control material is recommended to test each new lot or shipment of product and every 30 days thereafter." c. The laboratory's QC records similarly stated, "QC(Positive and Negative controls run with new kit and monthly of use)" d. On June 14, 2018, the laboratory director and testing personnel affirmed that control materials were tested following the aforementioned manufacturer package insert protocol. e. Based on the laboratory's annual test volume declaration the laboratory analyzed and reported approximately 81 toxicology procedures annually.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that

	ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: 1. Based on review of laboratory's policy and procedure (P&P), patient test reports covering the period from December 29, 2016 to December 21, 2017, American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory director and testing personnel, it was determined that the laboratory failed to follow corrective action P&P to thoroughly investigate unsatisfactory PT performance. The findings include: a. The laboratory's P&P titled "LABORATORY ERROR" states, "It is important to identify the cause of the error (if one exists) to prevent further errors or discrepancies. Prompt and specific reporting of suspected errors is essential to rectify and prevent mistakes." b. A review of the performance summary report provided to the laboratory by API (customer # 34169) showed the following unsatisfactory PT scores: Analyte Score Event/Year C-Reactive Protein 50% 3/2016 PSA 67% 1/2017 c. No corrective action was documented for the aforementioned analytes. d. On June 14, 2018, the laboratory director and testing personnel affirmed that the laboratory failed to perform corrective action investigations. e. For two (2) out of four (4) random patients sampled during the testing period from December 29, 2016 to December 21, 2017 the laboratory failed to investigate unsatisfactory PT performance. f. Based on the laboratory's annual test volume declaration the laboratory analyzed and reported approximately 229 C-Reactive Protein and 79 PSA procedures annually. 2. Based on review of laboratory's policy and procedure (P&P), patient test reports covering the period from December 29, 2016 to December 21, 2017, American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory director and testing personnel, it was determined that the laboratory failed to follow corrective action P&P to thoroughly investigate PT performance. The findings include: a. A review of the performance summary report provided to the laboratory by API (customer # 34169) showed the following PT scores: Analyte Score Event/Year CK, Total 20% 3/2016 Troponin 20% 3/2016 Blood Cell ID 80% 3/2017 b. Although the laboratory did perform corrective actions for the aforementioned analytes, the laboratory failed to include a thorough investigation to determine whether or not patients were affected. c. The API results for the 2nd event of 2016 showed a score of 0% for lymphocytes. The corrective action for this PT event ended with, "But I am at a lost as to the why lymphs% being wrong." The laboratory failed to complete its corrective action investigation. d. For two (2) out of four (4) random patients sampled during the testing period from December 29, 2016 to December 21, 2017 the laboratory failed to thoroughly investigate PT performance. e. On June 14, 2018, the laboratory director and testing personnel affirmed that the laboratory failed to perform complete corrective action investigations. f. Based on the laboratory's annual test volume declaration the laboratory analyzed and reported approximately 5,026 chemistry and 963 hematology procedures annually.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory instrumentation, manufacturer's package insert for the International Sensitivity Index (ISI) number, the laboratory's mean normal prothrombin time (MNPT), patient results and interview with the laboratory director and testing personnel, it was determined that the laboratory failed to ensure that the reported International Normalized Ratio (INR) was calculated accurately prior to reporting final patient test results. The findings include: a. The laboratory uses the Siemens BFT II analyzer to perform INR testing. The manufacturer package insert requires the laboratory to input a lot-specific and technique-specific ISI value into the analyzer. Additionally, the laboratory is also required to input the laboratory's MNPT. The ISI and MNPT values are critical components to the calculation of the INR result. b. The current lot in use at the time of the survey, Siemens Dade Innovin lot number 539377, stated an ISI value for the BFT II analyzer to be 0.87. c. The ISI value from the BFT II analyzer revealed 0.85, which remained from the previous Dade Innovin lot number 539351. d. As a follow up to the incorrect ISI value in the analyzer the testing personnel was asked to provide the data used to determine the laboratory's MNPT. The testing personnel was not able to provide such documentation. e. On June 14, 2018, the laboratory director and testing personnel affirmed that the laboratory failed to input the correct ISI and the laboratory could not provide documentation used for the laboratory's MNPT. f. For five (5) out of five (5) random patients sampled during the testing period from April 25, 2018 to June 12, 2018, the laboratory failed to ensure that the reported INR was calculated accurately. g. Based on the laboratory's annual test volume declaration the laboratory analyzed and reported approximately 71 prothrombin time procedures annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The findings include: a. The laboratory director failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (See D6018). b. The laboratory director failed to ensure that patient test results were reported only when the system is functioning properly (See D6025).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory's policy and procedure, patient test reports covering the period from December 29, 2016 to December 21, 2017, American Proficiency Institute proficiency testing records, corrective action reports, and interview with the laboratory director and testing personnel, it was determined that the laboratory director failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (See D5779).
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of laboratory documentation, QC materials, manufacturer package inserts, instrumentation, random patient sampling covering the period from December 29, 2016 to December 21, 2017 and interview with the laboratory director and testing personnel, it was determined that the laboratory director failed to ensure that patient test results were reported only when the system is functioning properly (See D5417, D5433, D5449, and D5801).