Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0876062	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Carson Valley Health	1107 Us Highway 395 N, Gardnerville, 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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on 8/15/18. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) evaluations, review of laboratory records, and interview with the laboratory manager, the laboratory failed to verify the accuracy of the sperm morphology test consisting of the sperm classification and per cent (%) normal sperm for 2017. Findings include: 1. The laboratory did not have a system in place to verify the accuracy of the sperm morphology test at least twice annually when the API PT test evaluations of the laboratory results were not graded. 2. Review of the API PT evaluations and laboratory records revealed for the first event of 2017 that four of ten sperm classification results were not graded and two of two % normal sperm results were not graded. 3. For the second test event (identified by API as the third event) of 2017, five of ten sperm classification results were not graded and two of two % normal sperm results were not graded. The laboratory manager confirmed the finding during the on-site survey on 8/15/18 at approximately 10:00 AM and indicated that the laboratory performed approximately six sperm morphology tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) evaluations, review of laboratory records, and interview with the laboratory manger, the laboratory failed to document PT evaluations and PT verification activities for sperm morphology consisting of sperm classification and percent (%) normal sperm for the two PT events of 2017 and the first PT event of 2018. Findings include: 1. Review of the API PT sperm morphology evaluation for the first event of 2017 showed that two of ten PT reported results for sperm classification did not match the expected results. No corrective action was documented for the two results that did not match the expected results. 2. Review of the API PT sperm morphology evaluation for the third event of 2017 showed that one of ten PT reported results for sperm classification did not match the expected result. No PT evaluation was documented for this PT event and no corrective action was documented for the one result that did not match the expected result. 3. Review of the API PT sperm morphology evaluation for the first event of 2018 showed that four of ten PT reported results for sperm classification did not match the expected results. No corrective action was documented for the four results that did not match the expected results. 4. There was no documentation of corrective action taken for two of two % normal sperm results from the first event of 2018. For sample SM-01, the laboratory reported 62% normal sperm with the mean of participant results of 13.7% normal sperm; and for SM-02, the laboratory reported 70% normal sperm with the mean of participant results of 29.4% normal sperm. The laboratory manager confirmed the findings during the on-site survey on 8/15/18 at approximately 10:00 AM and indicated that the laboratory performs approximately six sperm morphology tests annually.
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: Based on observation and interview with the laboratory supervisor, the laboratory failed to follow manufacturer's instructions and laboratory policy to perform annual pipette calibration checks. Findings include: Eppendorf pipette, serial number A11610251, and Finnpipette, serial number AN7128, were found in the laboratory with a pipette calibration check due date of 3/2017. The laboratory supervisor confirmed that the laboratory's policy was to send the pipettes out for calibration checks annually and stated during the on-site survey on 8/15/18 at approximately 1:30 PM that the laboratory was behind schedule for the annual calibration of these two pipettes . The laboratory performs approximately 308,404 chemistry tests annually.
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: Review of laboratory equipment maintenance records from January 2017 to August 2018 and interview with the laboratory supervisor revealed that the laboratory failed to take corrective action on days when the cuvette temperature was above the acceptable range from 7/01/17 to 11/20/17 for the Dimension EXL chemistry analyzer . Findings include: 1. Review of the Dimension EXL maintenance record showed the cuvette temperature was sporadically above the acceptable range of 36.8 to 37.2 degrees Celsius (C): eight days in July 2017, eight days in August 2017, seven days in September 2017, 12 days in October 2017, and six days in November 2017. 2. No corrective actions were taken on days when the cuvette temperature was above 37.2 degrees C until 11/21/18 when the cuvette temperature was recalibrated. 3. Maintenance records showed that preventative maintenance was also performed by the manufacturer's service representative on 11/07/17, but the out of range cuvette temperatures were not flagged and the problem was not corrected. The laboratory supervisor confirmed the finding during the on-site survey on 8/15/18 at approximately 1:15 PM. The laboratory performs approximately 308,404 chemistry tests annually.