Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0652730	09/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mt Grant General Hospital Laboratory	200 South A Street, Hawthorne, 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 September 5, 2018. 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.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) evaluations, review of CASPER Report 155, and interview with the laboratory manager, the laboratory failed to initiate and document remedial action for an unacceptable analyte result. Findings include: 1. Review of the API PT evaluation showed an unacceptable result for creatine kinase for one out of five PT samples tested from the second testing event of 2017. 2. Review of the CASPER Report 155 showed a score of 80% for creatine kinase from the second testing event of 2017. 3. The laboratory manager stated during the on-site survey on 9/05/18 at approximately 1:30 PM that the unacceptable result was not noticed and there was no remedial action taken and documented.

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 patient test reports, laboratory incident reports, quality control results, corrective actions, and interview with the laboratory manager, the laboratory reported patient test results for sodium, potassium and chloride on 8/09/18 before quality controls tested on 8/09/18 met the acceptability criteria. Findings include: 1. Review of the laboratory incident reports for four patients, sample #s: 10039349, 10039371, 10039403, and 10039120 revealed that a doctor notified the laboratory on 8 /09/18 at approximately 7:30 AM that four out of four of his inpatients had elevated sodium results. 2. Review of the quality control reports for sodium, potassium, and chloride showed that the quality control tested on 8/09/18 at 7:46 AM was unacceptable. The repeat quality control tested on 8/09/18 at 9:54 AM was acceptable. The four patient reports showed that the patient test results were reported on 8/09/18 between 4:30 and 6:00 AM. 3. The laboratory manager interviewed during the on-site survey on 9/05/18 at approximately 11:30 AM stated that the patient results were released by the technologist based on the acceptable quality control results from the previous day on 8/08/18 at 6:25 AM. The laboratory performs approximately 58,500 chemistry 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 patient test reports, laboratory incident reports, quality control results, and corrective actions, the laboratory failed to document evaluation of all patient test results for sodium, potassium and chloride from 8/08/18, 6:25 AM when the last acceptable quality control was tested to 8/09/18, 9:54 AM when the next acceptable quality control was tested. Findings include: 1. Review of the laboratory incident reports for four patients, sample #s: 10039349, 10039371, 10039403, and 10039120 revealed that a doctor notified the laboratory on 8/09/18 at approximately 7: 30 AM that four out of four of his inpatients had elevated sodium results. 2. Review of the quality control reports for sodium, potassium, and chloride showed that the last acceptable quality control was tested on 8/08/18, 6:25 AM and the next acceptable quality control was tested on 8/09/18, 9:54 AM. 3. The four patient reports showed that the patient samples were tested on 8/09/18 between 4:53 and 5:56 AM. Incident reports were generated for these four patient reports and corrective actions were taken and documented on the incident reports. 4. There was no documentation on the

	incident reports whether other patient results whose samples were tested between 8/09 /18, 6:25 AM to 8/09/18, 9:54 AM were evaluated to determine if patient test results may have been adversely affected. The laboratory performs approximately 58,500 chemistry tests annually.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must 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 patient test reports, laboratory incident reports, quality control results, and corrective actions, the laboratory director failed to ensure that patient test results are reported only when the system is functioning properly. Findings include: 1. Review of the laboratory incident reports for four patients, sample #s: 10039349, 10039371, 10039403, and 10039120 revealed that a doctor notified the laboratory on 8 /09/18 at approximately 7:30 AM that four out of four of his inpatients had elevated sodium results. 2. Review of the four patient reports showed that the patient reports were released on 8/09/18 between 4:30 and 6:00 AM. Review of the quality control reports showed results from 8/09/18 at 7:46 AM were unacceptable. Quality control tests repeated on 8/09/18 at 9:51 AM were acceptable. 3. The laboratory did not verify that the Dimension EXL was functioning properly prior to releasing patient test results when quality controls were tested after patient results were released on 8/09/18. The laboratory performs approximately 58,500 chemistry tests annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of patient test reports, laboratory incident reports, personnel training and competency assessments, and interview with the laboratory manager, the technical supervisor failed to ensure that testing personnel maintained their competency to report test results promptly, accurately, and proficiently. Findings include: 1. Review of the laboratory incident reports for four patients, sample #s: 10039349, 10039371, 10039403, and 10039120 revealed that a doctor notified the laboratory on 8/09/18 at approximately 7:30 AM that four out of four of his inpatients had elevated sodium results. 2. Review of the four patient reports showed that all four of the patients' sodium results were above the reference range of 135-146 mmol/L. 3. In an interview with the laboratory manager on 9/05/18 at approximately 2:00 PM, the laboratory manager indicated that the technologist failed to follow laboratory procedure to review the delta checks (comparison of laboratory test results with results obtained on previous samples from the same patient) before releasing the patients' sodium test results. 4. Review of the personnel training and competency

	assessments revealed the technologist's initial training was completed on 7/05/17, six month competency assessed on 10/05/17, and the annual competency assessed on 4/05 /18. The laboratory manager stated that the technologist was counseled and reinstructed on the proper procedure to release test results on 8/09/18 and would be re-evaluated for competency again in December 2018. The laboratory performs approximately 58,500 chemistry tests annually.