Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0652730	11/17/2022
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 11/17/2022. 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.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of calibration verification records for the Siemens EPOC blood gas analyzer and interview with the interim laboratory manager, the laboratory failed to ensure that analytic systems records including calibration verification records were retained for at least two years. Findings include: 1. Calibration records reviewed for the Siemens EPOC blood gas analyzer for 2021 and 2022 revealed there were no records of calibration verifications for 2021. 2. The interim laboratory manager interviewed on 11/17/2022 at approximately 3:00 PM indicated that the 2021 records may be stored in a storage area and not easily retrieved. The laboratory performs approximately 83,007 chemistry tests annually.
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 the Blood Bank Quality Control (QC) forms for 9/12/2022 and 9/15/2022 and interview with the interim laboratory manager, the laboratory failed to ensure that laboratory reagents were not used after their expiration date. Findings include: 1. Review of the Blood Bank Quality Control forms for 9/12/2022 and 9/15/2022 revealed that expired reagents were used to perform QC. Anti-A expired on 9/03/2022, Anti-B expired on 8/25/2022, A1 and B1 cells expired on 9/02/2022, Screen cells I and II expired on 9/02/2022, AHG expired on 8/31/2022, check cells expired on 9/02/2022, and corQC reagent cells expired on 9/02/2022. The laboratory performed ABO/Rh, antibody screens, and compatibility testing on 9/12/2022 and 9/15/2022. 2. The interim laboratory manager confirmed the findings during the interview on 11/17/2022 at approximately 2:00 PM. The laboratory performs approximately 289 immunohematology tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records for the Siemens EPOC blood gas analyzer and interview with the interim laboratory manager, the laboratory failed to perform calibration verification at least once every 6 months. Findings include: 1. Calibration records reviewed for the Siemens EPOC blood gas analyzer for 2021 and 2022 revealed there were no calibration verifications records for 2021. Calibration verifications were performed on 4/07/2022 and 11/11/2022. 2. The interim laboratory manager interviewed on 11/17/2022 at approximately 3:00 PM was unable to locate the 2021 calibration verification records and indicated that the records may be stored in a storage area and not easily retrieved. The laboratory performs approximately 83,007 chemistry tests annually.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Triage D-Dimer test procedure, review of the quality control records, review of the laboratory's Individualized Quality Control Plans (IQCP), and interview with the interim laboratory manager, the laboratory failed to perform two levels of external controls each day of testing patient samples. Findings include: 1. The Triage D-Dimer test procedure stated, ". . .external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures." 2. Review of the QC log for the Triage D-Dimer test from January to October 2022 revealed that two levels of external QC were performed every 30 days or with each new lot number or shipment of test cassettes. 3. The laboratory's IQCP procedures did not list the D-Dimer test. 4. The interim laboratory manager interviewed on 11/17/2022 at approximately 2:30 PM confirmed the findings. The laboratory performs approximately 23,961 hematology tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, review of quality control (QC) records, review of calibration verification records, and interview with the interim laboratory manager, the laboratory director failed to ensure that the quality assessment (QA) programs are maintained to assure the quality of laboratory services provided. Findings include: The QA program failed to identify and take corrective action for the following: 1. Personnel competency evaluations reviewed revealed that two of eight high complexity testing personnel did not have evaluations at least semiannually during their first year of employment in the laboratory. (Refer to D6127.) 2. Review of QC records revealed that expired laboratory reagents were used for QC in blood bank (refer to D5417) and the IQCP had not been developed and approved for the Triage D-Dimer test authorizing a QC frequency less than the two levels of QC required each day patient samples are tested (refer to D5447). 3. Review of calibration verification records for the Siemens EPOC blood gas analyzer for 2021 and 2022 revealed that no records were available for review for 2021. (Refer to D3031 and D5439.) The laboratory performs approximately 83,007 chemistry, 23,961 hematology, and 289 immunohematology tests annually.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with the interim laboratory manager, the technical supervisor failed to evaluate and document the performance of two out of eight testing personnel performing high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. Testing personnel performing high complexity testing, designated as #5 on Form CMS-209, who began employment with the laboratory in approximately June of 2021, did not have documentation of the initial and semiannual evaluations. 2. Testing personnel performing high complexity testing, designated as #7 on Form CMS-209, who was employed with the laboratory from 5/25/2021 through March 2022, did not have documentation of the initial and semiannual evaluations. 3. The interim laboratory manager confirmed the findings during the survey on 11/17/2022 at approximately 3:00 PM. The laboratory performs approximately 97,068 laboratory tests annually.