Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0663011	03/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Grover C Dils Medical Center	700 N Spring Street, Caliente, 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 March 1, 2021. 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.
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: Based on a review of laboratory maintenance and temperature records for laboratory testing years 2018, 2019 and 2020 and an interview with the laboratory manager and laboratory director, the laboratory failed to take corrective action and document the corrective actions for equipment that was performing outside of the established parameters. Findings include: 1. The laboratory failed to take and document corrective action for the Dimension Chemistry analyzer when the established cuvette temperature was found to be outside of the established acceptable range. 2. The Dimension Chemistry analyzer cuvette temperature for November 2019, which has an acceptable temperature range from 36.8 degrees Centigrade (C) to 37.2 degrees C,

	was recorded to be outside of the acceptable range 30 of 30 times with no documentation of corrective action. 3. The Dimension Chemistry analyzer cuvette temperature for March 2020, which has an acceptable temperature range from 36.8 degrees Centigrade (C) to 37.2 degrees C, was recorded to be outside of the acceptable range 31 of 31 times with no documentation of corrective action. This was confirmed by the laboratory manager and the laboratory director on March 1, 2021 at approximately 2:30 PM. The laboratory performs approximately 4,638 patient laboratory tests in Chemistry.
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 a review of the American Proficiency Institute (API) proficiency testing reports from testing years 2018, 2019 and 2020 and an interview with the laboratory manager and laboratory director, the laboratory director failed to have the appropriate staff review and evaluate the proficiency testing reports to identify any problems that would require corrective action. Findings include: 1. The laboratory director failed to ensure that all proficiency testing results received are reviewed by the appropriate staff to determine if the tested analytes are within the acceptable limits stipulated by the proficiency testing organization and if there are any problems that require corrective action. 2. The laboratory failed to review the Immunology /Immunohematology third event 2020 that revealed a performance for Blood Bank Antibody Screen for sample SER-11 that was not graded and indicated an expected result that stated to "See Data Summary". 3. The laboratory failed to review and document corrective action for the second event 2020 Chemistry Core for NT pro-BNP which had an unacceptable result for specimen CM-07. 4. The laboratory failed to review the Hematology/Coagulation third event 2020 that revealed a performance for Blood Cell Identification for sample BCI-11 that was not graded and indicated an expected result that stated to "See Data Summary". 5. The laboratory failed to review the Hematology/Coagulation third event 2020 that revealed a performance for Microscopy/Urine Sediment for sample US-06 that was not graded and indicated an expected result that stated to "See Data Summary". 6. The laboratory failed to review the Hematology/Coagulation third event 2019 that revealed a performance for Educational Blood Cell Identification for sample ECI-15 that was not graded and indicated an expected result that stated to "See Data Summary". 7. The laboratory failed to review the Hematology/Coagulation third event 2019 that revealed a performance for PPM/Urine Sediment for sample US-02 that was not graded and indicated an expected result that stated to "See Data Summary". 8. The laboratory failed to review the Hematology/Coagulation first event 2019 that revealed a performance for PPM/Urine Sediment for sample VKP-01 that was not graded and indicated an expected result that stated to "See Data Summary". 9. The laboratory failed to review the Hematology/Coagulation first event 2019 that revealed a performance for PPM/Urine Sediment for sample VA-01 that was found to be

	unacceptable and had no corrective action taken. 10. The laboratory failed to review the Hematology/Coagulation second event 2018 that revealed a performance for Blood Cell Identification for sample BCI-13 that was not graded and indicated an expected result of Blast when the laboratory reported a result of Lymph, reactive (atyp, variant). 11. The laboratory failed to review the Hematology/Coagulation second event 2018 that revealed a performance for Blood Cell Identification for sample BCI-09 that was not graded and indicated an expected result of Nucleated red blood cell when the laboratory reported a result of Plasma cell. 12. The laboratory failed to review the Hematology/Coagulation second event 2018 that revealed a performance for Blood Cell Identification for sample BCI-10 that was not graded and indicated an expected result that stated to "See Data Summary". This was confirmed by the laboratory manager and the laboratory director on March 1, 2021 at approximately 1:30 PM. The laboratory performs approximately 8,555 patient laboratory tests in Chemistry, Hematology and Immunohematology.