Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0663011	07/09/2018
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 July 9, 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.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a random review of the continuous recording thermograph charts for the blood storage refrigerator from August 2016 through July 2018, a review of the manually recorded temperature logs for the blood storage refrigerator for the same time period and an interview with the laboratory supervisor, the laboratory failed to review, assess and document corrective action for blood storage temperature recordings that were found to be outside of the acceptable range for blood storage. Findings include: 1. A random review of the continuous recording thermograph charts for the storage of blood for patient transfusion from August 2016 through July 2018 found the continuous recording thermograph charts had recorded temperatures outside of the acceptable range of 2 to 8 degrees centigrade with no corrective action taken. 2. The continuous recording thermograph chart from 7/31/17 through 8/7/17 revealed the temperature chart had recorded temperatures as low as minus 1 degree centigrade. 3. The continuous recording thermograph chart from 8/07/17 through 8/14/17 revealed

	the temperature chart had recorded temperatures as low as minus 1 degree centigrade. This was confirmed by the laboratory supervisor on July 9, 2018 at approximately 2: 30 pm. The laboratory performs approximately 72 patient immunohematology tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the verification records for all tests performed on the newly introduced Dimension EXL 200 chemistry analyzer and an interview with the laboratory supervisor, the laboratory director failed to show evidence that the verification results of the newly introduced chemistry analyzer was reviewed and the results of the verification was acceptable. Findings include: The laboratory director failed to indicate that the results of the verification of accuracy, precision and linearity for the newly introduced Dimension EXL 200 chemistry analyzer had been reviewed and found to be acceptable. This was confirmed by the laboratory supervisor on July 9, 2018 at approximately 2:00 pm. The laboratory performs approximately 5148 patient chemistry tests annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure manual, a review of the verification records for the newly introduced Dimension EXL 200 chemistry analyzer and an interview with the laboratory supervisor, the laboratory director failed to ensure that the laboratory policy and procedure manual included a a policy for the validation or verification of new patient laboratory testing methodologies or instruments. Findings include: The laboratory director failed to have a policy or procedure for the validation or verification of new patient test methods or new instruments introduced into the laboratory. This was confirmed by the laboratory supervisor on July 9, 2018 at approximately 2:30 pm. The laboratory performs approximately 7514 patient tests annually.