Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0958910	02/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Cancer Ctrs Of Nv-Horizon Ridge	2460 W Horizon Ridge Pkwy, Henderson, 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 February 7, 2019. 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.
D2128	HEMATOLOGY CFR(s): 493.851(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 a review of the American Proficiency Institute (API) proficiency testing results for testing years 2017 and 2018 and an interview with the laboratory area manager, the laboratory failed to review and document corrective action for all unacceptable analyte or testing event scores. Findings include: 1. The laboratory failed to review and document action taken for the API second event 2017 for Heme /Coag which received a score of 80% for granulocytes. 2. The laboratory failed to review and document action taken for the API first event 2018 for Heme/Coag which received a score of 80% for granulocytes. This was confirmed by the area laboratory manager on February 7, 2019 at approximately 10:00 AM. The laboratory performs approximately 62,400 patient hematology 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 a review of the laboratory maintenance records for laboratory testing years 2017 and 2018 and an interview with the area laboratory manager, the laboratory failed to perform and document instrument maintenance for hematology instrumentation. Findings include: The laboratory failed to have instrument maintenance documentation for the Hematology Complete Blood Count (CBC) instrument for dates before October 2018. This was confirmed by the area laboratory manager on February 7, 2019 at approximately 10:30 AM. The laboratory performs approximately 62,400 patient hematology tests annually.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure manual regarding Quality Assessment, a review of the API proficiency testing results for testing years 2017 and 2018, a review the Quality Assessment performed by the laboratory and an interview with the area laboratory manager, the laboratory director failed to ensure that the quality assessment programs are maintained to assure the quality of the laboratory services provided. Findings include: 1. The laboratory failed to have a Quality Assessment program that could effectively evaluate the areas of review for pre-analytic, analytic and post-analytic phases of laboratory testing and document corrective action. 2. A random audit of quality control results from 1/14/17 through 1 /07/19 found the current Quality Assessment system failed to address the high level quality control which was outside of the acceptable range on 1/08/18 with no documentation of corrective action. 3. The current Quality Assessment system failed to address the API second event 2017 Heme/Coag result of 80% for granulocytes that had no documentation of corrective action. 4. The current Quality Assessment system failed to address the API first event 2018 Heme/Coag result of 80% for granulocytes that had no documentation of corrective action. This was confirmed by the area laboratory manager on February 7, 2019 at approximately 11:30 AM. The laboratory performs approximately 62,400 patient hematology tests annually.