Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0538919	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Comprehensive Cancer Centers Of Nevada-Twain	**Street Address, City, State** 3730 S Eastern Ave, Las Vegas, 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 generated as a result of the on-site CLIA recertification survey conducted at your facility on February 28, 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.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing results from testing years 2016 and 2017 for the laboratory testing categories of General Immunology, Routine Chemistry, Urinalysis, Endocrinology and Hematology and an interview with the laboratory area manager, the laboratory failed to maintain a copy of all records of documentation for each step in the testing and reporting of results for all proficiency testing samples. Findings include: 1. The laboratory failed to have documentation of the attestation statement for API proficiency testing performed in 2016 for the testing categories of General Immunology, Routine Chemistry,

	Urinalysis, Endocrinology and Hematology. 2. The laboratory failed to maintain a copy of the laboratory testing records for proficiency testing samples performed in the testing categories of General Immunology, Routine Chemistry, Urinalysis, Endocrinology and Hematology. This was confirmed by the laboratory area manager on February 28, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,403,067 patient laboratory tests annually in the testing categories of General Immunology, Routine Chemistry, Urinalysis, Endocrinology and Hematology.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of the laboratory temperature recording logs from January 1, 2016 through December 31, 2017 and an interview with the laboratory area manager, the laboratory failed to follow the established freezer temperature requirement for the storage of reagents and patient specimens for laboratory analysis. Findings include: 1. The laboratory failed to follow the freezer temperature requirement of minus 14 degrees centigrade or below for the storage of reagents and patient specimens for laboratory analysis. 2. The freezer temperature recording log for January 2016 found 20 of 20 freezer temperature recordings that were outside of the established acceptable temperature range with no corrective action taken. This was confirmed by the laboratory area manager on February 28, 2018 at approximately 3:00 PM. The laboratory performs approximately 1,403,067 laboratory tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure manual and an interview with the laboratory area manager, the laboratory failed to have a policy and documentation that twice a year evaluates the relationship between test results performed on different instruments. Findings include: 1. The laboratory had no policy or procedure for the twice a year evaluation and correlation of the same laboratory tests that are performed on different instruments or that use different methodologies. 2. There was no documentation for the twice a year testing and evaluation of correlation for 20 different analytes using two different Siemens 1800 chemistry analyzers. This was confirmed by the laboratory area manager on February 28, 2018

	at approximately 2:00 PM. The laboratory performs approximately 1,128,408 chemistry 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 a review of the director approved policy and procedure for Quality Assessment, a review of the monthly documents used for the evaluation of quality assessment performed by the laboratory from February 1, 2016 through December 31, 2017 and an interview with the laboratory area manager, the laboratory director failed to ensure that the quality assessment program is maintained to assure the quality of the laboratory services provided. Findings include: 1. The laboratory failed to follow the director approved policy for Quality Assessment by performing daily chart reviews to determine if there were any missed orders and incorrect tests or panels ordered. 2. There was no documentation of daily chart review from May 2017 through November 2017. This was confirmed by the laboratory area manager on February 28, 2018 at approximately 2:30 PM. The laboratory performs approximately 1,403,067 patient laboratory tests annually in the testing categories of General Immunology, Routine Chemistry, Urinalysis, Endocrinology and Hematology.
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 a review of the testing personnel's training and competency records and an interview with the laboratory area manager, the technical supervisor failed to evaluate and document the competency of personnel that were performing moderate and high complexity patient testing at least semiannually during the first year the individuals were performing laboratory tests. Findings include: There was no semiannual competency evaluation for the performance of moderate and high complexity patient testing for three of eight laboratory testing personnel. This was confirmed by the laboratory area manager on February 28, 2018 at approximately 11:30 AM. The laboratory performs approximately 1,403,067 patient laboratory tests annually in the testing categories of General Immunology, Routine Chemistry, Urinalysis, Endocrinology and Hematology.