

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0538919	(X3) Date Survey Completed 01/23/2020
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 created as a result of an on-site CLIA recertification survey conducted at your facility on January 23, 2020. 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	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing results in Hematology for testing years 2018 and 2019 and an interview with the laboratory manager, the laboratory failed to take and document corrective action for analytes that were found to have unacceptable results or failures. Findings include: 1. The laboratory identified failures for the Hematology/Coagulation second event for 2018 for the RDW-CV (0%), Reticulocyte Count (Hem-5S) (0%), Basophils (Hem-5S) (0%), Eosinophils (Hem-5S) (0%), Lymphocytes (Hem-5S) (60%), Monocytes (Hem-5S) (20%) and Neutrophils (Hem-5S) (0%) but failed to take and document corrective action so that the deficiency would not recur. 2. The laboratory identified a failure for the Hematology/Coagulation third event for 2019 in which the White Cell Count (Hem-5S) result for sample XE-14 was reported as 71.2 instead of the actual</p>

result of 17.2 which was within the acceptable range for that analyte. There was no corrective action taken and documented so that this deficiency would not recur. This was confirmed by the laboratory manager on January 23, 2020 at approximately 11:00 AM. The laboratory performs approximately 206,982 patient Hematology tests annually.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a review of the API proficiency testing results in Chemistry and Hematology for testing years 2018 and 2019 and an interview with the laboratory manager, the laboratory failed to review, evaluate and document all results that were obtained from the proficiency testing agency. Findings include: 1. The laboratory failed to review, evaluate and document corrective action for the API first event Chemistry-Miscellaneous for 2018 in which the CEA (Immunoassay) (0%) and CEA (Tumor Markers) (0%) failed due to transcription error. There was no corrective action taken and documented. 2. The laboratory failed to review, evaluate and document the API first event Chemistry-Miscellaneous for 2018 in which the Folate sample IA-01 had a result of "Not Graded". 3. The laboratory failed to review, evaluate and document the API second event Hematology/Coagulation for 2018 the Blood Cell Identification in which three of seven samples indicated results that were "Not Graded". The sample number BCI-09 for Blood Cell Identification revealed an unacceptable result with no documentation of review and corrective action taken. 4. The laboratory failed to review, evaluate and document corrective action for the API second event Chemistry-Miscellaneous for 2018 in which all three results for Beta-2 Microglobulin revealed results of "Not Graded". The analyte PSA (67%) failed the event but there was no corrective action taken and documented. The analyte CEA (Tumor Markers) (67%) failed due to transcription error but there was no corrective action taken and documented. 5. The laboratory failed to document the review and evaluation the API third event Hematology/Coagulation for 2019 in which 16 samples from the Educational Blood Cell Identification revealed results of "Not Graded". This was confirmed by the laboratory manager on January 23, 2020 at approximately 11:00 AM. The laboratory performs approximately 341,986 General Immunology, 1448,231 Chemistry and 206,982 Hematology patient laboratory tests annually.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on a review of the API proficiency testing results for testing years 2018 and 2019 and an interview with the laboratory manager, the laboratory failed to verify the accuracy of all non-regulated non-waived tests performed by the laboratory. Findings include: 1. The laboratory failed to verify, at least twice during the testing year 2018, the accuracy of CEA (Tumor Markers). 2. The laboratory failed the 2018 API

Chemistry-Miscellaneous first event for CEA (Tumor Markers) with a score of 0% and failed the second event for the same analyte with a score of 67%. This was confirmed by the laboratory manager on January 23, 2020 at approximately 11:00 AM. The laboratory performs approximately 1,448,231 patient Chemistry tests annually.