

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1085196	(X3) Date Survey Completed 03/14/2018
Name of Provider or Supplier Comprehensive Cancer Centers Of Nv-Wigwam	Street Address, City, State 1505 Wigwam Pkwy Ste 130, 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 generated as a result of the on-site CLIA recertification survey conducted at your facility on March 14, 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.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the director approved laboratory policy and procedure manual and an interview with the laboratory area manager, the laboratory failed to have the laboratory director approve changes that were made to the policy and procedure manual. Findings include: 1. The laboratory failed to have 17 revised policy and procedures be approved by the laboratory director. 2. The laboratory director last signed and dated the laboratory policy and procedure manual on 1/25/16. There were 17 revised policy and procedures that had been added to the manual that had the signature and date of another person that was not the director of this laboratory. This was confirmed by the laboratory area manager on March 14, 2018 at approximately 3: 00 PM. The laboratory performs approximately 56,059 patient Hematology tests annually.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper</p>

storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory temperature recording logs from February 1, 2016 through March 14, 2018 and an interview with the laboratory area manager, the laboratory failed to follow the established temperature requirements for room temperature and freezer temperature for the storage of laboratory supplies and patient specimens. Findings include: 1. The laboratory failed to follow the freezer temperature requirement of minus 15 degrees centigrade or below for the storage of patient specimens that were to be sent to reference laboratories for test analysis. 2. The laboratory failed to follow the room temperature requirement of 15 to 25 degrees centigrade for the storage of laboratory supplies and reagents. 3. The freezer temperature recording logs for August 2016 and September 2016 found 24 of 38 freezer temperature recordings that were outside of the established acceptable temperature range with no corrective action taken. 4. The room temperature recording logs from July 1, 2016 through September 29, 2016 found 25 of 57 room 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 March 14, 2018 at approximately 3:00 PM. The laboratory performs approximately 56,059 patient Hematology tests annually.