

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0958910	(X3) Date Survey Completed 06/09/2021
Name of Provider or Supplier Comprehensive Cancer Ctrs Of Nv-Horizon Ridge	Street Address, City, State 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 June 9, 2021. 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.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of May 6, 2019 and May 14, 2021, a review of the laboratory maintenance and quality control records for the Sysmex XP300 hematology analyzer, and an interview with the Laboratory Technical Consultant, the laboratory failed to retain the maintenance logs and the quality control records for at least two years. Findings include: 1. A random patient audit between the dates of May 6, 2019 and May 14, 2021 revealed that the quality control records for the Sysmex XP300 hematology analyzer were not available onsite and could not be retrieved for review for the date of May 6, 2019. 2. A random patient audit between the dates of May 6, 2019 and May 14, 2021 revealed that the maintenance records for the Sysmex XP300 hematology analyzer were not available and could not be retrieved for review for the dates of May 6, 2019, and for July 2, 2019. 3. The Technical Consultant stated that the records were not available onsite for review at the time of the survey during an interview conducted on June 9, 2021 at approximately 2:45 PM. The laboratory performs approximately 78000 hematology tests annually.</p>

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory procedure manual, a random patient audit between the dates of May 6, 2019 and May 14, 2021, a review of quality control records for the Sysmex XP300 hematology analyzer, a review of the manufacturer's package insert for the Sysmex EIGHTCHECK-3 WP X-Tra hematology control, and an interview with the laboratory Technical Consultant, the laboratory failed to establish and maintain a director approved quality control policy and procedure so that the staff could identify when quality control was acceptable to release patient results. Findings include: 1. A random patient audit between the dates of May 6, 2019 and May 14, 2021 revealed that the red cell distribution width (RDW) quality control results were flagged with a "plus" sign for the mid-level quality control control, lot number 02520711 performed on December 18, 2020. There was no documentation of corrective action or acknowledgement of the flags. 2. The results obtained by the laboratory for the RDW were outside the acceptable ranges established by the manufacturer of the Sysmex EIGHTCHECK-3 WP X-Tra hematology control solutions. The control result on December 18, 2021 for the RDW-SD was 37.6 femtoliters (fL), and the control result for the RDW-CV was 10.8 %. A review of the manufacturer's package insert for the Sysmex EIGHTCHECK-3 WP X-Tra hematology control for lot number 02520711, revealed that the established acceptable quality control range for the RDW-SD was listed as 26.2 to 37.0 fL. For the RDW-CV the established acceptable quality control range was listed as 7.0 to 10.2% 3. A review of the procedure entitled "Sysmex XP-300 Automated Hematology Analyzer CLSI Procedure," Section G. entitled "Corrective Action Plan for Out of Range QC Results" stated, "Complete this section with your laboratory's QC action plan for out of range commercial and patient controls." Section H. entitled "Recording and Storage of QC Data" stated, "Complete this section with your laboratory's QC action plan for out of range commercial and patient controls." 4. The laboratory performs three levels of control each day of testing. The Technical Consultant stated during an interview conducted on June 9, 2021 at approximately 3:00 PM that the established policy for quality control acceptability was if two levels of control were in range, and one was outside the range, then the analyzer run would be considered acceptable. The

Technical Consultant also confirmed that the policy was not specified in the Sysmex XP300 policy and procedure during the interview. The laboratory performs approximately 78000 hematology tests annually.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on a random patient audit between the dates of May 6, 2019 and May 14, 2021, a review of laboratory quality control records for the Sysmex XP300 hematology analyzer, a review of the manufacturer's package insert for the Sysmex EIGHTCHECK-3WP X-Tra hematology control solutions, and email correspondence with the Technical Consultant, the laboratory failed to ensure that the Sysmex EIGHTCHECK-3WP X-Tra control solutions were not used beyond the manufacturer's established expiration date. Findings include: 1. A random patient audit between the dates of May 6, 2019 and May 14, 2021 revealed that the normal control level of the Sysmex EIGHTCHECK-3WP X-Tra hematology control solution, lot number 02520711 was expired when it was performed on December 18, 2020. 2. The manufacturer's package insert for the Sysmex EIGHTCHECK-3WP X-Tra hematology control solutions, and the instrument printout of the normal quality control results for December 18, 2020 stated that the expiration date of the control solution, lot number 02520711, was December 16, 2020. 3. The Technical Consultant confirmed the finding via email correspondence received on June 10, 2021 at 3:30 PM. The laboratory performs approximately 78000 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 logs for the Sysmex XP300 hematology analyzer, a review of the manufacturer's instructions for the Sysmex XP300 hematology analyzer, and an interview with the Laboratory Technical Consultant, the laboratory failed to perform and document monthly and every three month maintenance for the Sysmex XP300 hematology analyzer in accordance with the manufacturer's instructions. Findings include: 1. A review of maintenance logs for the Sysmex XP300 hematology logs between the months of May, 2019 and June, 2021 revealed that there was no documentation of the monthly maintenance for the months of August 2019, September 2020, November 2020, December 2020, and January 2021. 2. A review of maintenance logs for the Sysmex XP300 hematology logs between the months of May, 2019 and June, 2021 revealed that there was no documentation of the every three month maintenance for the months of October 2019, October 2020, November 2020, December 2020, and January 2021. 3. The Technical Consultant confirmed the findings during an interview conducted on June 9, 2021 at

approximately 3:30 PM. The laboratory performs approximately 78000 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 quality assurance policy, a review of the completed quality assessment checklists between the months of May, 2019, and May, 2021, a review of the maintenance logs for the Sysmex XP300 hematology analyzer between the dates of May, 2019 and May, 2021, a review of the quality control records for the Sysmex XP300 hematology analyzer between the dates of May, 2019 and May, 2021, a review of the manufacturer's package insert for the Sysmex EIGHTCHECK-3 WP X-tra quality control solutions used on December 18, 2021, and an interview with the Laboratory Technical Consultant, the laboratory director failed to ensure that the established quality assurance program was maintained and was effective to detect and correct failures of quality when they occur. Findings include: 1. A review of the completed quality assurance checklists for the months of August, 2019, October, 2019, September, 2020, October, 2020, November 2020, December 2020, and January, 2021 revealed that there was no documentation of and corrective action for the failure to perform the monthly or every three month maintenance on the Sysmex XP300 hematology analyzer. 2. A review of the completed quality assurance checklists for the month of December 2020 revealed that there was no documentation of and corrective action to address the use of an expired Sysmex EIGHTCHECK-3 WP X-tra normal control on December 18, 2020 to perform the daily quality control on the Sysmex XP300 hematology analyzer. 3. The director approved policy number CCCN-100 entitled "Quality Assurance" stated in section VI entitled, "Procedure" that elements of quality assurance include monthly hematology quality control (QC) review, and biannual hematology analyzer maintenance. The policy also states, "These designated monitors will be evaluated each month and/or periodically and recorded on the CCCN Monthly QA Monitor Log form, along with any appropriate documentation such as CCCN Laboratory Error /Incident/Accident Report Form." 4. The Laboratory Technical Consultant confirmed the findings during an interview conducted on June 9, 2021 at approximately 3:30 PM. The laboratory performs approximately 78000 hematology tests annually.