

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2145185	(X3) Date Survey Completed 10/11/2023
Name of Provider or Supplier Honorhealth Cancer Care	Street Address, City, State 9250 N 3rd St Ste 3010, Phoenix, AZ	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct inspection of three levels of Sysmex Quality Control (QC) vials, review of the manufacturer's package insert and interview with the Technical Consultant (TC-1), the laboratory failed to label the Sysmex QC vials with the correct open expiration date. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing on patient specimens using the Sysmex XN-450 hematology analyzer. 2. Review of the manufacturer's package insert indicates the Sysmex QC material has an open expiration date of 15 days. 3. Direct inspection of the Sysmex QC vials (QC lot numbers: Level 1 - 32101401, Level 2 - 32101402, Level 3 - 32101403) in use at the time of the survey failed to include the open expiration date. 4. The TC-1 interviewed on 10/11/23 at 11:20 AM confirmed the laboratory failed to label the Sysmex QC vials with the open expiration date. 5. The laboratory's annual test volume in the specialty of Hematology is 20,046.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported</p>

from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and interview with the Technical Consultant (TC-1), the laboratory failed to follow their established policy to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. Findings include: 1. The laboratory performs patient testing on the Sysmex XN-450 hematology analyzer. Test results and patient-specific data are electronically interfaced from the analyzer to EPIC, the Laboratory Information System (LIS). 2. The laboratory's Patient Test Management policy states, "The Sysmex 450 has a bi-directional interface with EPIC, allowing the patient unique identification number to cross to the instrument and the results cross from the instrument back to EPIC. This interface will be checked yearly for proper result transmittal from the analyzer to EPIC as part of the QA program." 3. No documentation from 2021 and 2022 was presented for review to indicate the laboratory followed the policy referenced above to ensure patient test results and patient-specific data are accurately and reliably electronically interfaced from the Sysmex XN-450 analyzer to EPIC. 4. The TC-1 interviewed on October 11, 2023 at 11:15 AM confirmed the laboratory failed to follow their established policy to verify the accuracy of patient test results and patient-specific data which are electronically interfaced from the Sysmex XN-450 analyzer to EPIC during 2021 and 2022. 5. The laboratory performs approximately 20,046 patient tests annually under the specialty of Hematology