

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0680709	(X3) Date Survey Completed 02/24/2021
Name of Provider or Supplier Honorhealth Cancer Care	Street Address, City, State 3621 N Wells Fargo Avenue, Scottsdale, 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on the severity and number of deficiencies cited for quality control practices identified during the survey conducted on February 24, 2021, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the specialty of Hematology. See D5445 and D5791 for findings.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
 Based on lack of Quality Control (QC) records, review of patient test reports and interview with the Technical Consultant, the laboratory failed to perform control procedures using the frequency established by the laboratory. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing in the specialty of Hematology on the Sysmex XN-450 analyzer with an approximate annual test volume of 16,900. 2. The laboratory's established policy titled, "Quality Control VGPCCN-Osborn" states, "No patient test should be reported unless QC for that test is complete and correct". The policy lists the frequency and level of QC for the Sysmex XN-450 as each day of patient testing, using 3 levels of controls (Low, Normal, High). 3. Review of patient test report (sample# 1015407369) from testing performed on 8/23/2019 and lack of QC documentation from that date indicated the laboratory failed to perform QC testing for the Sysmex XN-450 (Low, Normal or High) on 08/23/2019. Approximately 26 patient tests were performed that day. 4. Review of patient test report (sample# 1018689491) from testing performed on 3/20/2020 and lack of QC documentation from that date indicated the laboratory failed to perform QC testing for the Sysmex XN-450 (Low, Normal or High) on 03/20/2020. Approximately 21 patient tests were performed that day. 5. The exact number of days from January 1, 2019 through the date of the survey conducted on February 24, 2021 in which QC was not performed each day of patient testing could not be determined at the time of the survey. 6. The technical consultant confirmed that the laboratory failed to perform control procedures as required for CBC testing on the dates indicated above.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on review of Quality Assessment (QA) documentation, Quality Control (QC) records, and interview with the technical consultant, the laboratory failed to identify problems associated with Quality Control performance. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing in the specialty of Hematology on the Sysmex XN-450 analyzer with an approximate annual test volume of 16,900. 2. The laboratory performs a monthly review, specific to QC, titled, "VGPCCN Hematology Monthly Review", for testing performed on the Sysmex XN-450 analyzer. The monthly QC review consists of a checklist to include: QC Parallel Lot Study Complete, Background Checks printed and reviewed, Supply/Reagent Inventory Complete, Instrument Maintenance Complete, Equipment Failure or Service- printed and reviewed, QC printed and reviewed, Notable QC issues and Corrective Action. 3. The monthly QC checklists submitted for review during the survey for the months of August 2019 and March 2020 failed to identify issues with the lack of QC performance on 8/23/19 and 3/20/20, in which patient testing occurred. See D5445 for findings. 4. The technical consultant acknowledged that the laboratory's QA process at the time of the survey failed to identify whether or not QC was performed each day of patient testing.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Due to the number and severity of deficient practices identified during the survey conducted on February 24, 2021, the Condition of Laboratory Director was found to be not met as evidenced by: D6020 - failure to ensure the quality control program is maintained to assure the quality of laboratory services provided.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on the number and severity of deficient practices identified during the survey related to Quality Control (QC), the laboratory director failed to ensure that the laboratory's QC program is maintained to assure the quality of laboratory services provided. See D5445 and D5791 for findings.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Due to the number and severity of deficient practices identified during the survey conducted on February 24, 2021, the Condition of Laboratory Testing Personnel was found to be not met as evidenced by: D6072 - Failure of each individual performing moderate complexity testing to adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of daily logs, review of the laboratory's established Quality Control procedures and interview with the Technical Consultant, the testing personnel failed to adhere to the laboratory's quality control policies. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing in the specialty of Hematology on the Sysmex XN-450 analyzer with an approximate annual test volume of 16,900. 2. The laboratory's established policy titled, "Quality Control VGPCCN-Osborn" states, "No patient test should be reported unless QC for that test is complete and correct". The policy lists the frequency and level of QC for the Sysmex XN-450 as each day of patient testing, using 3 levels of controls (Low, Normal, High). 3. It is the practice of the laboratory to maintain a Sysmex Daily Log for each month, which is documented by the testing personnel each day of patient testing. The Sysmex Daily Log requires the initials of the individual who performed each item on the list. The items listed include: the date, QC Lot/Exp. Date, Daily QC/Initials, Shut Down /Initials, Weekly Cleaning/Initials. 4. Review of the Sysmex Daily Log for August 2019, specifically 8/23/2019, revealed the initials of the Testing Personnel in each of the following columns: Daily QC/Initials and Shut Down/Initials. The initials of the Testing Personnel indicate the task was completed for that day. 5. Review of the Sysmex Daily Log for March 2020, specifically 3/20/20, revealed the initials of the Testing Personnel in the column, Daily QC/Initials. The initials of the Testing Personnel indicate the task was completed for that day. 6. No evidence was presented for review to indicate the Testing Personnel followed laboratory policy and performed QC each day of patient testing for the two dates indicated above (see D5445 for findings), despite the initials that were documented on each respective Daily log indicating the task was completed. 7. The Technical Consultant acknowledged that the testing personnel failed to follow the laboratory's established policy and perform QC each day of patient testing, and also marked the form indicating QC was performed when QC was not performed.