

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0885113	(X3) Date Survey Completed 07/10/2018
Name of Provider or Supplier City Of Hope Cancer Care, North Shore	Street Address, City, State 9300 Waukegan, Morton Grove, IL	
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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review the CASPER Individual Laboratory Profile (Report 0155), the laboratory's proficiency testing (PT) reports, and an interview with the testing personnel (TP), the laboratory failed to attain satisfactory performance for each analyte in each testing event in the specialty of Hematology. Findings: 1. The Report 0155 showed that the laboratory received an unsatisfactory analyte performance score for Red Blood Cell Count (RBC) analysis during 2016. 2. The laboratory's PT reports confirmed that the laboratory missed 2 out of 5 PT samples, thus receiving the score of 60% for RBCs analysis during Event #3 of 2016. No documented evidence was presented as proof that the PT failure was investigated and corrective action taken, if necessary. 3. On a Recertification survey conducted on 07/10/2018 at 12:30 PM, the TP and laboratory manager confirmed the above findings.</p>
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>

This STANDARD is not met as evidenced by:
Based on the surveyor's review the laboratory's proficiency testing (PT) records, policies and procedures, and an interview with the testing personnel (TP), the laboratory failed to take remedial action when the laboratory received an unsatisfactory performance in the specialty of Hematology during the year of 2016. Findings: 1. The laboratory received an unsatisfactory analyte performance score of 60% for Red Blood Cell Count (RBC) analysis during Event #3 of 2016. 2. The laboratory's "Proficiency Testing-QA Tracking Sheet", the "Proficiency Testing Results Review" sheet and the "Proficiency Testing Check List" completed for Event #3 of 2016, does not document or acknowledge the failed score received for RBC analysis during this event. 3. No other documented evidence was presented as proof that the above PT failure was investigated and corrective action taken, if necessary. 4. On a Recertification survey conducted on 07/10/2018 at 12:30 PM, the TP and laboratory manager confirmed the above 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:
Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, records, and an interview with the laboratory manager, the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for testing personnel (TP). Finding: 1. The laboratory failed to ensure laboratory personnel meet the education qualification requirements for performing moderately complex testing in the specialty of Hematology. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the Laboratory Personnel Report (CMS-209), employee files, records, and an interview with the laboratory manager, the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing in the specialty of Hematology. Findings:

1. The CMS 209 lists 5 testing personnel (TP) performing Hematology in the laboratory. 2. Employee P4B (listed on line 6) files included the following: a). The training to perform hematology testing on 12/16/2016; b). Annual competencies on 06/22/2017 and 06/27/2018 and c). Medical Assisstant certification. No documentation was provided as proof that Employee P4B met the education requirement to perform moderately complex testing in the specialty of Hematology. 3. On a Recertification survey conducted on 07/10/2018 at 12:30 PM, the TP and laboratory manager confirmed the above findings.