

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2004557	(X3) Date Survey Completed 04/11/2018
Name of Provider or Supplier Comprehensive Hematology Oncology, Llc	Street Address, City, State 5000 Park St N Ste 1017 North, Saint Petersburg, FL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) Hematology proficiency testing records for the last two out of two years (2016-1st, 2nd, 3rd Event, 2017- 1st, 2nd, 3rd Event, and 2018 1st Event) and interview with the technical consultant, the laboratory failed to have two (#1, #3) of three Testing Personnel participate in proficiency testing. Findings included: During API proficiency testing record review for 2016 - 1st, 2nd, 3rd Events, 2017 - 1st, 2nd, 3rd Events, and 2018 1st Event revealed only Testing Personnel #2 had participated in proficiency testing. During an interview on 04/11/18 at 09:55 AM, the Technical Consultant confirmed the API proficiency testing had not been rotated among the 3 Testing personnel. There was no evidence of proficiency testing for Testing Personnel #1 and #3.</p>
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on review of CMS 209, review of Testing Personnel files, and interview with the Technical Consultant, the laboratory failed to ensure one (#3) of three Testing Personnel had the proper qualifications before testing patients. (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 education record review and interview with the Technical Consultant, the laboratory failed to ensure one (#3) of three Testing Personnel had the proper qualifications before testing patients. Findings included: Review of the CMS 209 (signed and dated on 4/11/18 by the Laboratory Director) revealed that there were three (#1, #2, and #3) Testing Personnel. During education record review it was found that Testing Personnel #3 had a foreign university diploma from a university in the Dominican Republic. During an interview on 04/11/18 at 10:00 AM, the Technical Consultant confirmed the laboratory had not obtained foreign equivalents for Testing Personnel #3.