

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2145450	(X3) Date Survey Completed 11/23/2021
Name of Provider or Supplier Comprehensive Hematology Oncology, Llc	Street Address, City, State 425 South Parson Avenue Suite 101, Brandon, 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
D0000	A special focused COVID-19 reporting survey was conducted on 11/23/21 at Comprehensive Hematology Oncology LLC, a clinical laboratory in Brandon, FL. Comprehensive Hematology Oncology LLC was not in compliance with Code of Federal Regulations (CFR), Part 493, requirements of clinical laboratories. The following Condition was cited: D3000-Facility Administration 493.1100
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to report SARS-CoV-2 antigen results to the Department of Health (DOH) from 08/18 /2021 through 11/17/2021 for a total of 59 Patient results. The findings included: Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) signed by the Laboratory Director on 11/15/2021 revealed that the laboratory performed Abbott Binnox Now COVID-19 Antigen testing. On 11/23/2021 at 11:20 AM, per phone call, the Office Manager stated that they did not report the COVID-19 Antigen results to the DOH.</p>