

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0277889	(X3) Date Survey Completed 05/02/2024
Name of Provider or Supplier Oncology Care Partners Of Florida, Llc	Street Address, City, State 3700 Washington St Ste 100, Hollywood, 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 recertification survey conducted on 05/02/2024 found the ONCOLOGY CARE PARTNERS OF FLORIDA LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview, the laboratory failed to have all testing personnel (TP) rotate through the testing of Proficiency Testing (PT) for the Hematology specialty in three out of six events reviewed. Findings included: Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 05/02/2024 revealed the laboratory had three TP listed (TP#A, TP# B and TP#C). -Review of personnel records revealed that TP#A, TP#B and TP#C had annual competencies during 2023. -Review of American Proficiency Institute (API) PT records for 2022 (second and third event), 2023 (first, second and third event) and 2024 (first event), revealed that TP#A had no PT participation during 2023. During an interview on 05/02 /2024 at 11:30 AM, the laboratory Consultant confirmed that the laboratory failed to rotate the PT between all TP for the period of reference.</p>
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p>

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory received an unsatisfactory score for 1 (1st event 2024) out of 6 (2nd event 2022 to 1st event 2024) events reviewed for Hematology specialty. Findings included: Review of American Proficiency Institute (API) proficiency testing (PT) records revealed a score of 0 % for White Blood Cells Differential and 60% for White Blood Cells Count (WBC) tests resulting in an overall score of 76 % in the 1st event of 2024. Review of Quality Control (QC) records for the day that the laboratory tested the PT samples revealed that the laboratory failed to run at least two levels of QC on the day they ran the PT samples. During an interview on 05/02/2024 at 11:00 AM, the laboratory Consultant confirmed the proficiency testing failure and that the laboratory failed to run QC on the day they tested the PT samples.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to retain daily maintenance records for 1 out of 24 months for the Sysmex Complete Blood Counter (CBC) XN-430 analyzer in the last 2 years. Findings included: Review of Daily Maintenance log for Sysmex CBC XN-430 from May 2022 to April 2024, revealed that the laboratory failed to have the Daily Maintenance tasks log for May 2022. During an interview on 05/02/2024 at 11:30 AM, the Laboratory Consultant explained that the laboratory was purchased on October 2023 and the records they have were what they received from previous owner, so she confirmed that the laboratory failed to have the daily maintenance log for May 2022.