

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0684037	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier Ocala Oncology Center	Street Address, City, State 3130 Sw 32 Ave, Ocala, 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 record review and staff interview, the laboratory failed to test hematology proficiency testing samples the same way that it tests patient samples for multiple proficiency testing event reviewed from 2016 until 2018. The findings include: A record review of 2016, 2017, and 2018 American College of Physicians Medical Laboratory Evaluation proficiency testing was done on June 12, 2018. The documentation showed testing of the five hematology proficiency samples was performed on the two hematology analyzers (Cell Dyn 3200 & Cell Dyn Ruby) for the 3rd event in 2016, the 3rd even in 2017, and the 1st event in 2018. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Red cell distribution width (RDW), Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils. The interview with the testing person on 6/12/18 at 11:30am confirmed the hematology samples were tested on both analyzers before reporting one set of results to the proficiency testing company.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p>

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to test chemistry proficiency testing samples the same number of times that it tests patient samples for one proficiency testing event reviewed in 2017. The findings include: A record review of 2016, 2017, and 2018 American College of Physicians Medical Laboratory Evaluation proficiency testing was done on June 12, 2018. The documentation for the 3rd event in 2017 for Chemistry showed the five proficiency testing samples were ran in duplicate. CH-11 was tested on 9/20/17 at 7:47am and 9/22/17 at 10:26am CH-12 was tested on 9/20/17 at 7:48am and 9/22/17 at 10:26am CH-13 was tested on 9/20/17 at 7:49am and 9/22/17 at 10:27am CH-14 was tested on 9/20/17 at 7:50am and 9/22/17 at 10:27am CH-15 was tested on 9/22/17 at 10:28am and 9/25/17 at 9:08am The tests performed were: Phosphorus, Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Total Protein, Albumin, Aspartate Aminotransferase, Alanine Transaminase, Total Bilirubin, Direct Bilirubin, Alkaline Phosphatase, Uric Acid, Magnesium, Iron, Iron Binding Capacity, and Lactate Dehydrogenase. The interview with the testing person on 6/12/18 at 11:30am confirmed the chemistry samples were tested in duplicate in September 2017.

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 record review and staff interview, it was determined that the laboratory's quality assessment (QA) process failed to monitor and correct issues with failed proficiency testing scores for non regulated analytes for two of two years reviewed. The findings include: Record review of the American College of Physicians Medical Laboratory Evaluation test events for 2016 - 2018 showed the following: *2016 3rd Event Chemistry unregulated analytes Uric Acid failed with a score of 60% and Carcinoembryonic antigen (CEA) failed with a score of 50% *2017 1st Event Chemistry for the unregulated analytes Cancer antigen 13 (CA 15-3) failed with a score of 0%, CEA failed with a score of 50%, Prostate-specific antigen (PSA) failed with a score of 50%, and the analyte Vitamin B 12 failed with a score of 50%. *2017 2nd Event Chemistry for the unregulated analyte CA 15-3 failed with a score of 0% *2017 3rd Event Chemistry for the unregulated analytes of CEA failed with a score of 0%, and CA 15-3 failed with a score of 0% *2018 1st Event Chemistry for the unregulated analytes Phosphorus failed with a score of 40%, and Folate failed with a score of 50%. The interview on 6/12/18 at 11:15am with the testing person confirmed the multiple proficiency testing failures and verified that no remedial action had occurred.