

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0287613	(X3) Date Survey Completed 02/07/2018
Name of Provider or Supplier Boca Nephrology Pa	Street Address, City, State 2900 N Military Trl Ste 195, Boca Raton, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of complete blood cells (CBC) analyzer, review of CBC quality control (QC) records and interview with testing person, the laboratory failed to ensure laboratory personnel did not use outdated controls as reference for their QC. Findings include: 1) Observation on 2/7/2018 at 11:30 am, showed the CBC controls in use outdated 1/23/2018 (lot number 31709 for low, normal and high value. 2) QC records for years 2016, 2017 and for year 2018 months January and February showed outdated lots used: Lot 31521 (normal, low and high) expired 4/23/2016 used on 4/25/2016. Lot 31506 (normal, low and high) expired 10/26/2016 used from 10/27/2016 to 11/1/2016. Lot 31609 (normal, low and high) expired 1/24/2017 used 1/25/2017. Lot 31612 (normal, low and high) expired 4/24/2017 used 4/25-26/2017. Lot 31706 (normal, low and high) expired 10/23/2017 used 10/24/2017 to 11/2/2017. Lot 31709 (normal, low and high) expired 1/23/2018 used 1/24/2018 to 2/7/2018. 3) The laboratory reported 201 patients with outdated controls. 4) On February 7th 2018 at 12:00 pm testing person confirmed that the laboratory used outdated controls.</p>