

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0948367	(X3) Date Survey Completed 04/05/2018
Name of Provider or Supplier Patient First - Newtown Road	Street Address, City, State 332 Newton Road, Virginia Beach, VA	
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	An announced CLIA recertification survey was conducted at Patient First-Newtown Road on April 5, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a laboratory tour, review of package insert, and an interview, the laboratory failed to ensure that four (4) of four (4) hematology quality control (QC) vials in use were within the manufacturer's expiration date and of standard quality. Findings include: 1. During a laboratory tour at approximately 12:00 PM, it was noted that four (4) vials of Horiba Diffrol QC were opened and stored in the refrigerator. The open vials were Level 1, 2, 3 (Lot Number 410) and Level 2 (Lot Number 409). The laboratory inspector asked if the opened QC vials were in use for monitoring the Pentra 60 C Plus analyzer for CBC testing. The primary testing personnel confirmed the open vials of Lot 410 were in use. She stated "I am not sure why we still have the vial of Lot 409 in the refrigerator for use". It was noted by the inspector that the Level 2 (Lot Number 409) had signs of deterioration. The inspector inquired how long the four (4) vials had been opened for use and what the protocol was for labeling QC to ensure the material was within expiration date. The primary testing personnel stated: "We are supposed to date all QC once opened and replace the Diffrol every fourteen days. I am not sure why the vials were not dated". The inspector asked if the lab could confirm how long the four (4) QC vials had been opened and in use. The primary testing personnel could not confirm. 2. Review of the Horiba Diffrol QC package</p>

insert revealed stability and storage instructions that state: "Opened tubes are stable for fifteen (15) days provided they are handled properly. Do not use product if deterioration is suspected. Verify that the lot number on the tube matches the lot number on the assay sheet." 3. During an interview with the technical consultant at approximately 12:30 PM, it was confirmed that the laboratory failed to ensure that the QC materials listed above were not used beyond the expiration dates or when the control had deteriorated.