

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0937845	(X3) Date Survey Completed 03/02/2023
Name of Provider or Supplier Eastern Ky Tender Care Pediatrics Lcc	Street Address, City, State 400 University Drive, Ste 101, Prestonsburg, KY	
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 was conducted on 03/02/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with a deficiency cited.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manual and package insert, observation and interview, it was determined the facility failed to label one (1) of one (1) sets of complete blood count (CBC) quality controls with an open date. The findings include: Review of the "Resource and Validation Manual" for the Sysmex XP-300 Hematology Analyzer, dated 02/25/2015, indicated, "2. Open vial stability is fourteen (14) days when promptly refrigerated after each use. 3. Record the date on each vial upon opening". Review of the package insert for the "Eightcheck 3WP X-TRA Hematology control for Sysmex analyzers with 3-part differentials", revised 03/2021, revealed "Storage and shelf life after first opening, Opened and recapped vials and vials whose caps have been pierced will retain stability for fourteen (14) days if stored at 2 - 8 [degrees] Celsius after being re-capped". During the laboratory tour, on 03/02/2023 at 12:50 PM, current vials of CBC quality controls in use were requested. The laboratory coordinator (LC) presented the surveyor with a cup with one (1) set of three (3) vials of Eightcheck 3WP X-TRA hematology quality controls, lot number 2361, with a printed expiration date of 04/05/2023. The quality controls were not labeled with an opened date and there was no way to determine how long the quality controls had</p>

been in use. The LC stated the quality controls were used "about two (2) to three (3) weeks until the quality controls got low."