Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D1051987	04/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
A Caring Touch Pediatrics	230 Fountain Ct, Suite 260, Lexington, 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 04/25/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, procedure manual, and confirmed in staff interview, the laboratory failed to label 5 of 5 in-use controls with revised expiration dates. Findings Include: 1. Observed on 4/25/2024 at 10:45 AM, in the testing area, open controls stored in the refrigerator included: a. One open bottle of Eight Check-3WP X-TRA Low Control, Lot number 40510710 b. One open bottle of Eight Check-3WP X-TRA Normal Control, Lot number 40510711 c. One open bottle of Eight Check-3WP X-TRA High Control, Lot number 40510712 d. One open bottle of Liquichek Pediatric Bilirubin Control Level 1, Lot number 225771 e. One open bottle of Liquichek Pediatric Bilirubin Control Level 2, Lot number 225772 The laboratory failed to label the bottles with revised expiration dates specified by the manufacturer. 2. Review of manufacturer's instructions: a. Liquichek Pediatric Bilirubin Control Levels 1 and 2 titled "Storage and Stability" stated, "Once the control material is thawed and opened all analytes will be stable for 14 days when stored tightly capped at 2 to 8C." b. Eightcheck 3WP X-TRA Hematology Control titled "Storage and shelf life after first opening" stated, "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2

	to 8C after being recapped." 3. Review of the lab procedures manual titled, "Policy on In House Labs": a. Point 7 stated, "Make sure lab supplies needed to perform test are not expired or damaged." b. Point 8 stated, " Perform each lab test as per written procedure, or test package insert." 4. In an interview on 4/25/2024, at 10:55 AM in the testing area, the TP1 was asked if expiration dates were placed on the controls. TP1 stated the dates were not placed on the vials. This confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of patient test reports and confirmed in staff interview, the laboratory failed to verify 4 of 4 reference intervals for Complete Blood Cell counts (CBC) for their patient population. Findings include: 1. Review of 4 patient test reports titled "Mode WB" for years 2023 and 2024 revealed 4 specific age reference intervals for CBC results: "0-2 yrs hgb (g/dL) 11.0-13.0 hct (%) 29-42 RBC (mill /mm3) 3.1-4.9 MCV (fL) 70-96 plts (x1000/mm3) 250-600 WBC (x1000/mm3) 6.0-17.0 Neutrophils (%) 20-48 Lymphs (%)35-76 Mids (%) 6-20 2-12 yrs hgb (g/dL) 11.5-14.5 hct (%) 34-47 RBC (mill/mm3) 3.9-5.0 MCV (fL) 75-95 plts (x1000/mm3) 250-550 WBC (x1000/mm3) 5.0-15.5 Neutrophils (%) 28-75 Lymphs (%) 28-65 Mids (%) 3-17 12-adult fem. hgb (g/dL) 12-15.0 hct (%) 36-44 RBC (mill/mm3) 4.0-4.9 MCV (fL) 78-100 plts (x1000/mm3) 150-450 WBC (x1000/mm3) 4.5-13 Neutrophils (%) 40-77 Lymphs (%) 25-45 Mids (%) 3-17 12-adult male hgb (g/dL) 12-16.5 hct (%) 36-50 RBC (mill/mm3) 4.5-5.5 MCV (fL) 78-100 plts (x1000/mm3) 150-450 WBC (x1000/mm3) 4.5-13 Neutrophils (%) 40-77 Lymphs (%) 25-45 Mids (%) 3-17" 2. During an interview on 04/25/2024 at 12:15 p.m. in the breakroom, the Laboratory Director (LD) was asked to provide documentation of verification of the reference intervals in use for their patient population. No documentation was provided. This confirmed the findings. Word Key: % = percentage x1000/mm3 = multiplied by 1000 per cubic millimeter dL = deciliter fem. = Female fL = femtoliters g = gram hgb = hemoglobin hct = hematocrit MCV= mean corpuscular volume mill/mm3 = millions per cubic millimeter plts = platelets yrs = Years WBC= white blood cell Lymphs = lymphocytes Mids = mid cells, other cells that are not classified as lymphocytes or granulocytes