Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326943	03/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Elizabethtown Pediatrics	103 Financial Dr, Suite 100, Elizabethtown, 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 03/06/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on observation, document review, and confirmed in staff interview; the laboratory failed to ensure quality control (QC) material for hematology testing was not used past the open vial stability date for 3 (Lot 22310) of 3 Quality Control materials utilized. Findings included: Observation on 03/06/2024 at 10:40 AM revealed the laboratory utilized a Medonic M-series hematology analyzer. Review of the analyzer's manufacturer manual revealed that the CDS Boule Con-Diff was the recommended QC material. Review of the package insert for the CDS Boule Con-Diff controls revealed that the open vial stability of the QC material was 14 days after opening when returned to the refrigerator after each use. Review of a document titled "For Medonic M-series with barcode reader" revealed a handwritten open date of 12 /01/2023 for lot numbers 22310-51, 22310-52, and 22310-53. Review of QC records revealed patient testing was performed on 12/21/2023, 12/28/2023, 01/08/2024, 01/09 /2024, and 02/01/2024 after the QC material had exceeded the open vial stability date. During an interview on 03/01/2024 at 10:45 AM, Testing Personnel (TP) #1 stated the hematology analyzer controls were used for daily QC until the vial was finished or the printed expiration date was reached. TP #1 stated the current controls were opened on

	03/01/2024. During an interview on 03/01/2024 at 1:00 PM, TP #1 acknowledged the laboratory failed to ensure QC material for hematology testing was not used past the open vial stability date of 14 days.