

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2279621	(X3) Date Survey Completed 11/21/2024
Name of Provider or Supplier A Pediatrics	Street Address, City, State 920 Richmond Rd, Irvine, 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	An abbreviated survey investigating Complaint KY00043817 was conducted on 11/21/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory quality control log, and confirmed in staff interviews, the laboratory failed to ensure testing was completed within the expiration dates specified by the manufacturer requirements for 1 of 1 testing kit. Findings include: 1.The following waived test kit was observed on 11/21/2024 at 10:30AM in the testing area: a.True Metrix Self Monitoring Glucose Test Strips, Lot ZA5135S, 1 box of 100 test strips 2. Manufacturer's instructions for the testing kit indicated an expiration date: a.True Metrix Self Monitoring Glucose Test Strips, Expiration date of 08/15/2024 3.Review of laboratory's quality control log revealed that Glucose testing was completed from 09/25/2023 to 04/23/2024. 4. In an interview on 11/21/2024 at 11:19 a.m. by mobile device and at the time of the exit interview, the Laboratory Director stated that she had no prior knowledge of the True Metrix Self Monitoring Glucose Test Strips being expired in the testing area. This confirmed the findings.</p>