Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1084044	09/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kidzcare Pediatrics Pllc	119 Epperson St, Athens, TN	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the manufacturer operator's manual, laboratory procedures, patient records, lack of documentation, and staff interview, the laboratory failed to follow the manufacturer's instructions for performing quality control on the Abaxis Piccolo Xpress chemistry analyzer used for patient testing from March 2023 to September 2024. The findings include: 1. An observation of the laboratory on 09.10.2024 at 9:30 a.m. revealed an Abaxis Piccolo Xpress chemistry analyzer (serial number P23803) for patient testing. 2. A review of the manufacture operator's manual revealed the following statement: "Abaxis recommends control testing as follows: -At least every 30 days -Whenever laboratory conditions have changed significantly -When training or retraining of personnel is indicated -When test results do not match patient symptoms or clinical findings -With each new lot (CLIA waived tests in waived status labs)" 3. A review of the laboratory's procedures titled "CMP Panel" and "Lipid Panel" revealed the following statement: "Quality Control Procedure: Internal controls are built in, ran, and evaluated with patient test. External controls must be run and documented monthly as a check on storage and ran with each new operator." 4. A review of patient records revealed the following: Patient ID 97512, CMP performed 03.07.2023 Patient ID 110958, CMP performed 03.20.2023 Patient ID110957, CMP performed 05.01.2023 Patient ID 7444, CMP performed 06.21.2023 Patient ID 7444, CMP performed 06.22.2023 Patient ID 95151, CMP performed 06.22.2023 Patient ID 85191, CMP performed 07.14.2023 Patient ID 73477, CMP performed 07.24.2023 Patient ID 103642, CMP performed 09.11.2023 Patient ID 111858, CMP performed 09.21.2023 Patient ID 99366, CMP performed

	09.22.2023 Patient ID 80103, CMP performed 09.28.2023 Patient ID 103659, CMP performed 02.01.2024 Patient ID 74441, CMP performed 05.31.2024 Patient ID 103642, CMP performed 06.26.2024 Patient ID 103642, CMP performed 08.06.2024 Patient ID 864156, lipid panel performed 02.02.2024 5. No external quality control testing documentation on the Abaxis Piccolo Xpress was available for review from March 2023 to September 2024. 6. An interview with the laboratory lead on 09.10.2024 at 12:15 p.m. confirmed the above survey findings. Word Key: CMP = Comprehensive Metabolic Panel CLIA = Clinical Laboratory Improvement Act of 1988
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure, review of patient test records, and staff interview, the laboratory failed to follow its policy protocol when the instrument flagged Complete Blood Count (CBC) results for four of four patients reviewed from 2023 and 2024. The findings include: 1. Observation of the laboratory on 09.10.2024 at 9:30 a.m. revealed a Horiba ABX Micros 60 (serial number 101CS98825) hematology analyzer used for CBC patient testing. 2. A review of the "CBC Alert Value Flag Procedure" revealed the following statements in the white blood cell count (WBC) section. "L1- Might suggest platelet that aggregates, uncharted reb blood cell count or atypical lymphocytes. Will send to nearest hospital lab for peripheral smear." "M2- This might indicate presence of lymphoblasts, myelocytes, abnormal lymphocytes and too many Basophils. Will sent patient to nearest hospital lab for repeat CBC and peripheral smear." "G1- This might indicate too many Eosinophils, Myelocytes and Neutrophil, Polynucleose. Will send patient to nearest hospital lab for repeat CBC and peripheral smear." "G2- This might indicate granulocyte cell membrane abnormalities, small granulocytes, possible lyse flow error, fluidic errors and old blood. Will repeat CBC in office, if this persists, send patient to nearest hospital lab for repeat CBC and peripheral smear." 3. A review of patient test records revealed the following: -Patient number: 98029, CBC performed on 04.27.2023. Results flagged with a WBC flag for M2, G1, and G2. -Patient number: 92709, CBC performed on 12.18.2023. Results flagged with a WBC flag of L1, G1, and G2. -Patient number: 114524, CBC performed on 09.09.2024. Results flagged with a WBC flag for M2, G1, and G2. -Patient number: 109268, CBC performed on 09.09.2024. Results flagged with a WBC flag of G1 and G2. There was no evidence that the samples were repeated or sent to the nearest hospital laboratory for peripheral smear. 4. An interview with the laboratory lead on 09.10.2024 at 11:55 a.m. confirmed the above survey findings.