

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1084044	(X3) Date Survey Completed 04/08/2026
Name of Provider or Supplier Kidzcare Pediatrics Plc	Street Address, City, State 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
D0000	During a recertification survey completed on April 8, 2026, the laboratory was found out of compliance with the following conditions: 493.1409 Condition: Laboratories Performing Moderate Complexity Testing; Technical Consultant 493.1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on observations in the laboratory, a review of American Proficiency Institute (API) proficiency testing (PT) records, and a staff interview, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program, resulting in a score of 0% for Hematology 2024 Event 3. The findings include: 1. Observation of the laboratory on 04.08.2026 at 9:00 a.m. revealed a Sysmex XN-330 (serial number 17732) hematology analyzer used for complete blood count with automated differential (CBC w/ diff) patient testing. 2. Review of Hematology 2024 Event 3 API PT records revealed "Failure to Participate" and test scores of 0% for Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count, and White Blood Cell Differential. 3. Interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings. Word Key: % = percent</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2</p>

years.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and a staff interview, the laboratory failed to retain a signed attestation statement for two years for the Hematology 2025 Event 2. The findings include: 1. A review of the laboratory's API proficiency testing records revealed that the signed attestation statement was not retained for two years for Hematology 2025 Event 2. 2. Interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Citation One: Based on observation of the laboratory, a review of the laboratory procedure manual, and staff interviews, the laboratory failed to ensure its competency assessment policy was in compliance with Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulations when it did not include a required semi-annual competency assessment during the first year of patient testing for new personnel and did not include the six required elements defined in Subpart M. The findings include: 1. Observation of the laboratory on 04.08.2026 at 9:00 a.m. revealed the Sysmex XN-330 (serial number 17732) hematology analyzer used for complete blood count with automated differential (CBC w/ diff) patient testing. 2. A review of the laboratory policy titled "General Laboratory Quality Systems", in the "Personnel Competency" section, revealed the procedure did not include a requirement for a semi-annual competency assessment within the first year of patient testing for new personnel, and did not include the six required elements (A. Direct observation of patient testing, B. Monitoring the recording and reporting of test results, C. Record review, D. Direct observation of instrument and maintenance function checks, E. Blind testing, F. Evaluation of problem solving), as defined in Subpart M of the CLIA regulations. 3. An interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the survey findings. Citation Two: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (Form CMS-209), the laboratory's procedures, personnel records, and staff interviews, the laboratory failed to follow the established procedure for annual competency assessment for testing personnel (two of seven reviewed) in 2025. The findings include: 1. A review of the Form CMS-209 completed for the survey on 04.08.2026 revealed seven testing personnel (TP) who performed patient testing for moderately complex complete blood count with automated differential (CBC w/ diff). 2. A review of the laboratory procedure titled "General Laboratory Quality Systems", in the section "Personnel Competency" revealed, "Competency is assessed initially, annually, and when changes occur, with documentation retained". 3. A review of the laboratory's personnel records revealed no documentation of annual competency assessments for TP3 or TP4 for 2025. 4. An interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the survey findings.

<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observations in the laboratory, a review of the laboratory procedure manual, quality control (QC) records, and a staff interview, the laboratory failed to follow its written policy for monthly quality control review for Hematology in 2024, 2025, and 2026, on the survey date 04.08.2026. The findings include: 1. Observations of the laboratory on 04.08.2026 at 09:00 a.m. revealed a Sysmex XN-330 (serial number 17732) hematology analyzer used for complete blood count with automated differential (CBC w/diff) patient testing. 2. A review of the laboratory's "LAB-001, CBC with Differential-Sysmex XN-330" procedure, under Instrument Maintenance 11.3 Monthly, revealed, "Laboratory Director reviews and signs the monthly QC summary." 3. A review of laboratory quality control records for Hematology revealed that the Laboratory Director failed to document monthly quality control reviews for 18 of 18 months reviewed from October 2024 through March 2026. 4. Interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observations of the laboratory and staff interviews, the laboratory failed to ensure that it did not use Becton Dickinson (BD) Dipotassium Ethylenediaminetetraacetic Acid (K2EDTA) capillary microtainer tubes for blood collection for patient testing after their expiration date on the survey date, 04.08.2026. The findings include: 1. Observation of the laboratory on 04.08.2026 at 09:00 a.m. revealed a Sysmex XN-330 (serial number 17732) hematology analyzer used for complete blood count with automated differential (CBC w/ diff) patient testing. Also observed were 129 K2EDTA capillary microtainer blood collector tubes (used for collecting CBC w/ diff samples), lot number 4284969, expiration date 03.31.2026. 2. An interview with the Practice Administrator and testing personnel one (TP1), on 04.08.2026 at 9:05 a.m., confirmed the above survey findings. A subsequent interview via electronic communication on 04.13.2026 at 3:36 p.m. with the Practice Administrator confirmed that 13 patient samples were run for CBC w/ diff from 04.01.2026 through 04.07.2026.</p>
<p>D6028</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>(e)(10) Employ a sufficient number of laboratory personnel with the appropriate</p>

education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), review of personnel records, lack of documentation, and staff interview, the laboratory director failed to ensure that the persons performing technical consultant (TC) duties in 2024 through the survey date (04.08.2026) had the appropriate education to qualify as technical consultants (Refer to D6033 and D6035). The findings include: 1. A review of the Form CMS-209 revealed seven testing personnel (TP) who performed moderately complex complete blood count with automated differential (CBC w/ diff) patient testing and one TC. 2. A review of the laboratory's personnel records revealed the following: Competency Assessments signed by TP7 in the "evaluator" box and the Practice Administrator in the "evaluator signature & date" section. -TP1: New Instrument Competency 01.30.2025, Annual Competencies 03.10.2025, and 01.30.2026 Competency Assessments signed by TP1 in the "evaluator" box. -TP2: New Instrument Competency 01.30.2025, Annual Competency 01.30.2026 -TP3: Initial Competency 07.26.2024 -TP4: Initial Competency 12.18.2024, New Instrument Competency 01.30.2025 -TP5: Initial Competency 07.02.2025 -TP6: Initial Competency 07.09.2025 3. There was no evidence in the personnel records that TP1, TP7, and the Practice Administrator met the minimum regulatory requirements to qualify as a technical consultant at CFR 493.1411. 4. An interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings. Word Key: CLIA = Clinical Laboratory Improvement Amendments CFR = Code of Federal Regulations

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, and staff interview, the laboratory director failed to ensure that two of three new testing personnel had documentation of the highest level of education for performing moderately complex testing (Refer to D6063 and D6065). The findings include: 1. A review of Form CMS-209 revealed three new testing personnel (TP) who performed moderately complex complete blood count with automated differential (CBC w/ diff) patient testing since the last survey date (09.10.2024). 2. A review of TP education verification records revealed that two (TP5 and TP6) of the three did not have documentation of the highest level of education on the survey date (04.08.2026). 3. An interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of testing personnel competency assessments and personnel education verification records, the person(s) who performed testing personnel competency assessments did not meet the minimum requirements to perform technical consultant duties. (Refer to D6035 and D6053)

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December

28, 2024.

This STANDARD is not met as evidenced by:

Based on a review of testing personnel competency assessments, personnel education verification records, and an interview with the Practice Administrator, the persons (TP1, TP7, and the Practice Administrator) who performed technical consultant duties did not have the required education to perform those duties on the survey date (04.08.2026). The findings include: 1. A review of the laboratory's personnel records revealed the following: Competency Assessments signed by TP7 in the "evaluator" box and the Practice Administrator in the "evaluator signature & date" section. -TP1: New Instrument Competency 01.30.2025, Annual Competencies 03.10.2025, and 01.30.2026 Competency Assessments signed by TP1 in the "evaluator" box. -TP2: New Instrument Competency 01.30.2025, Annual Competency 01.30.2026 -TP3: Initial Competency 07.26.2024 -TP4: Initial Competency 12.18.2024, New Instrument Competency 01.30.2025 -TP5: Initial Competency 07.02.2025 -TP6: Initial Competency 07.09.2025 2. A review of the documentation of the highest level of education revealed that TP1, TP7, and the Practice Administrator did not have the required education as defined in the regulations at CFR 493.1411 to perform the TC duties. 3. An interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings. Word Key: TP = Testing Personnel CFR = Code of Federal Regulations

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel (TP) records, and staff interview, the technical consultant failed to evaluate TP competency assessment at least twice within the first year of patient testing for three of seven testing personnel in 2024 and 2025. The findings include: 1. Observation of the laboratory on 04.08.2026 at 9:00 a.m. revealed a Sysmex XN-330 hematology analyzer (serial number 17732) used for complete blood count with automated differential (CBC w/ diff) patient testing. 2. A review of Form CMS-209 revealed seven testing personnel who performed moderately complex patient testing for CBC w/ diff since the date of the last survey (09.10.2024). 3. A review of testing personnel records revealed no documentation of competency assessment twice annually during the first year of patient testing for TP2 (date of hire for laboratory: 01.01.2024), TP3 (date of hire: 06.26.2024), and TP4 (date of hire: 11.18.2024). 4. An interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.

1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), review of testing personnel (TP) records, and staff interviews, two of three new TP since the date of the last survey (09.10.2024), did not qualify to perform moderately complex complete blood count with automated differential (CBC w/ diff) patient testing due to a lack of documentation of the highest level of education. (Refer to D6065)

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form CMS-209), review of testing personnel (TP) education verification records, and staff interview, two of three new TP since the date of the last survey (09.10.2024), did not qualify to perform moderately complex complete blood count with automated differential (CBC w/ diff) patient testing due to a lack of documentation of the highest level of education. The findings include: 1. Observation of the laboratory on 04.08.2026 at 9:00 a.m. revealed a Sysmex XN-330 hematology analyzer (serial number 17732) used for moderately complex CBC w/ diff patient testing (start date of new instrument: 01.30.2025). 2. A review of the Form CMS-209 revealed seven TP (TP1, TP2, TP3, TP4, TP5, TP6, and TP7) listed as performing moderately complex CBC w/ diff patient testing. TP4, TP5, and TP6 were new testing personnel since the last survey (09.10.2024). 3. A review of TP education verification records revealed no documentation of the highest level of education for TP5 and TP6 on the survey date (04.08.2026). 4. An interview with the Practice Administrator on 04.08.2026 at 12:45 p.m. confirmed the above survey findings.