

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0869852	<b>(X3) Date Survey Completed</b>  01/08/2025
<b>Name of Provider or Supplier</b>  Kidz Medical Services Inc D/B/A	<b>Street Address, City, State</b>  927 45th St Ste 201, West Palm Beach, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on December 10, 2024 to January 8, 2025. Kidz Medical Services Inc DBA Childrens Hematology and Oncology Associates clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview, the laboratory testing personnel failed to sign the attestation for three (2023 1st, 3rd, 2024 2nd) of four (2023 1st, 2nd, 3rd; 2024 2nd) events reviewed. Findings: Review of the MLE PT records showed the attestation signatures for the testing personnel were missing for the 2023 1st, 3rd, and 2024 2nd events, On 12/10/2024 at 11:10 AM, Testing Personnel A acknowledged attestation forms were not signed by the testing personnel.</p>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing</p>

samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview, the laboratory failed to retain the instrument printouts for the hematology testing for one (2023 1st) of four (2023 1st, 2nd, 3rd; 2024 2nd) events reviewed. Findings: Review of the MLE PT records showed there were five samples sent to the laboratory to test for each event. Review of the laboratory's PT records revealed the instrument printout for the 2023 1st event was missing. On 12/10/2024 at 11:15 AM, Testing Personnel A acknowledged the instrument printouts were missing.

**D5807**

**TEST REPORT**

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient reports and interview, the laboratory failed to include the normal values for hematology test results for five of five (#1 - #5) patients' reports reviewed. Findings: Review of patient test reports revealed the normal ranges were not listed on the reports for five patient reports reviewed. On 12/10/2024 at 1:15 PM, Testing Personnel A acknowledged the reports were given to patients if they requested a copy, and the normal ranges were not listed on the reports.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to provide management of the laboratory's proficiency testing (PT) for 2 of 2 (2023 - 2024) years. Findings: The Laboratory Director failed to ensure PT was performed as required by Subpart H for three of four (2023 1st, 2nd, 3rd, 2024 2nd) events reviewed. (See D6016) The Laboratory Director failed to sign the PT performance evaluation for three (2023 1st, 3rd, 2024 2nd) of four (2023 1st, 2nd, 3rd; 2024 2nd) events reviewed. (See D6018)

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on record review, and interview, the Laboratory Director failed to ensure proficiency testing (PT) was performed as required by Subpart H for three of four (2023 1st, 2nd, 3rd, 2024 2nd) events reviewed. Findings The Laboratory Director failed to ensure Testing Personnel signed the attestation for three (2023 1st, 3rd, 2024 2nd) of four (2023 1st, 2nd, 3rd; 2024 2nd) events reviewed. (See D2009) The Laboratory Director failed to ensure the laboratory retained the instrument printouts for the hematology testing for one (2023 1st) of four (2023 1st, 2nd, 3rd; 2024 2nd) events reviewed. (See D2015)

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview, the Laboratory Director failed to sign the performance evaluation for three (2023 1st, 3rd, 2024 2nd) of four (2023 1st, 2nd, 3rd; 2024 2nd) events reviewed. Findings: Review of the Quality Assurance Plan policy in the section Proficiency Testing Program noted "Results will be reviewed by laboratory director and/or appropriate laboratory personnel." Review of the MLE PT records showed there was no documentation showing the PT results were reviewed. On 12/10/2024 at 11:15 AM, Testing Personnel A acknowledged there was no documentation that showed the PT results were reviewed.

**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 review of the Laboratory Personnel Report, personnel records, and interview, the laboratory failed to verify educational qualifications (degrees) for 1 Testing Personnel (B) out of 2 Testing Personnel (A, B). (See 6065)

**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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report, personnel records, and interview, the laboratory failed to verify educational qualifications (degrees) for 1 Testing Personnel (B) out of 4 Testing Personnel (A - D). Findings: Review of the Laboratory's Personnel Report, signed by the Laboratory Director on 12/10/2024, showed there were four testing personnel employees listed as moderate complexity testing personnel. Review of the laboratory personnel records showed there was no documentation of the educational degree for Testing Personnel B available for review. On 12/27/2024 at 9:53 AM, Testing Personnel A stated Testing Personnel B was unable to locate her high school diploma.