

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0869852	(X3) Date Survey Completed 09/27/2022
Name of Provider or Supplier Kidz Medical Services Inc D/B/A	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Kidz Medical Services Inc. DBA Childrens Hematology & Oncology Associates on 09/27/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 Laboratory Testing Personnel 493.1421
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to perform competency evaluations on 1 (Testing Person #A) out of 3 (Testing Personnel #A-#C) Testing Personnel. Findings Included: Review of competency evaluations for 2020, 2021, and 2022 revealed that Testing Person #A did not have any competency evaluations. Interview on 09/27/2022 at 11:00 AM the Laboratory Manager confirmed that no competencies had been done on Testing Person #A.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview the laboratory failed to monitor the room temperature and humidity in the laboratory where testing was being done on the Sysmex XN-330 CBC (Complete Blood Count) Hematology analyzer since installed 02/16/2022. Findings Included: Review of instrument validation on the Sysmex XN-330 revealed that it was installed on 02/16/2022. Review of the performance specifications for the Sysmex XN-330 revealed that the room temperature must be 15-36 degrees Celsius and have a relative humidity of 20-85%. Review of temperature charts revealed no documentation of room temperature or humidity. Interview on 09/27/2022 at 11:12 AM the Laboratory Manager confirmed that room temperature and humidity had not been documented.

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 record review and interview the laboratory failed to verify the education of 1 (Testing Person #B) out of 3 (Testing Personnel #A-#C) Testing People reviewed (See 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 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 record review and interview the laboratory failed to verify the education of 1 (Testing Person #B) out of 3 (Testing Personnel #A-#C) Testing People reviewed. Findings Included: Review of Testing Person #B revealed that they had a diploma from Columbia. There was no foreign diploma equivalency performed. She was hired on 05/26/2022. Interview on 09/27/2022 at 11:00 AM the Laboratory Manager confirmed that there was no foreign diploma equivalency.