

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1082475	(X3) Date Survey Completed 07/15/2026
Name of Provider or Supplier All Childrens Pediatric Clinic Pa	Street Address, City, State 4221 North Conway Suite D, Palmhurst, TX	
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 recertification survey was conducted July 15, 2026. The laboratory was found NOT to be in compliance with the following condition level deficiency: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's proficiency testing records from 2025 and 2026, and staff interview, the laboratory failed to ensure 3 of 4 testing personnel participated in proficiency testing. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 4 testing personnel. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2025 (events 1, 2 and 3) and 2026 (events 1 and 2) determined testing personnel number 1 (as listed on Form CMS 209) performed testing for each of the 5 events. 3. The laboratory did not have documentation of testing personnel number 2, number 3 and number 4 participating in proficiency testing. 4. The technical consultant confirmed the findings in an interview conducted on 07/15/2026 at 0900 hours in the office.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's calibration records from 2024, 2025 and 2026, and staff interview, the laboratory failed to have documentation of perform calibrations every six months on the ABX Micros 60 hematology analyzer. The findings included: 1. The laboratory's policy titled "Instrument Operation and Maintenance" stated: "Calibration of all laboratory instruments will be every six months..." 2. A review of the laboratory calibration record from 2024, 2025 and 2026 identified calibrations were performed at the following times: June 2024 August 2025 (14 months later) May 2026 (9 months later) 3. The technical consultant confirmed the findings in an interview conducted on 07/15/2026 at 0915 hours in the office.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the laboratory's ABX Minotrol quality control records from 2026, review of the laboratory's policies, and staff interview, the laboratory failed to have documentation verifying 4 of 4 lots prior to use. The findings included: 1. A review of the laboratory's ABX Minotrol quality control records from 2026 determined 4 lots were placed into use. They were: Lot: 5321 Lot: 6012 Lot: 6068 Lot: 6124 2. The laboratory's policy titled "Quantitative Control Policy" stated: "Controls will be run concurrently with patients for at least 3 days. If the mean of all results is within the stated range, then the stated range will be used as the expected range for this lab." 3. The laboratory failed to have documentation of verifying each of the 4 lots prior to placing them into use. 4. The technical consultant confirmed the findings in an interview conducted on 07/15/2026 at 0910 hours in the office.
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's submitted CMS 209, review of personnel records and staff interview, the laboratory failed to have documentation of education to qualify 1 of 4 testing personnel (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 review of the laboratory's submitted Form CMS 209, review of personnel records and staff interview, the laboratory failed to have documentation of education to qualify 1 of 4 testing personnel. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 4 personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of education for 1 of 4 personnel. It was: Testing personnel number 4 3. The technical consultant confirmed the findings in an interview conducted on 07/15/2026 at 0850 hours in the office.