

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2059352	(X3) Date Survey Completed 02/11/2026
Name of Provider or Supplier Chattanooga Childrens Clinic	Street Address, City, State 403 Spring Creek Rd, Chattanooga, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 a review of the laboratory's proficiency testing (PT) records and staff interviews, the laboratory director failed to sign four PT attestation statements (four of five) reviewed from 2024 and 2025. The findings include: 1. A review of the laboratory's American Proficiency Institute (API) PT records revealed the laboratory director did not sign the attestation statements for the following events: - 2024 Hematology/Coagulation Event 3 - 2025 Hematology/Coagulation Events 1, 2 and 3 2. The technical consultant and clinic manager confirmed the survey findings during an interview on 02/11/2026 at 1:45 p.m. .</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer's control package insert and assay sheet, and staff interviews, the laboratory failed to label six of six</p>

control vials used for performing quality control on the Complete Blood Count (CBC) hematology analyzer with an open date and a corrected expiration date on the date of the survey, 02/11/2026. The findings include: 1. Observation of the laboratory on 02/11/2026 at 12:45 p.m. revealed the Horiba ABX Micros 60 CBC Analyzer (serial number 404CS94023) used for patient testing, and three levels (six vials) of ABX Minotrol 16 Hematology controls that were not labeled with an open date and a corrected expiration date. Current lot - Low Abnormal: Lot 53211601, Expiration date 02/14/2026 - Normal: Lot 53211602, Expiration date 02/14/2026 - High Abnormal: Lot 53211603, Expiration date 02/14/2026 New lot - Low Abnormal: Lot 60121601, Expiration date 04/11/2026 - Normal: Lot 60121602, Expiration date 04/11/2026 - High Abnormal: Lot 60121603, Expiration date 04/11/2026 2. A review of the manufacturer's control package insert revealed the following: "After opening, ABX Minotrol 16 is stable throughout the open-vial dating, as indicated on the assay sheet, when stored at 2 C - 8 C (35 F to 46 F). A review of the ABX Minotrol 16 assay sheet revealed an open-vial stability requirement of 30 days. 3. The technical consultant and clinic manager confirmed the survey findings during an interview on 02/11/2026 at 1:45 p.m. Word Key: C = degrees Celsius F = degrees Fahrenheit .

D6018

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

(e)(4)(iii) 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; and

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's proficiency testing (PT) records and staff interviews, the laboratory director failed to document a review of three PT performance evaluations (three of five) reviewed in 2024 and 2025. The findings include: 1. A review of the laboratory's 2024 and 2025 American Proficiency Institute (API) PT testing records revealed that the laboratory did not document a review of the performance evaluation for the following events: - 2024 Hematology/Coagulation Event 3 - 2025 Hematology/Coagulation Events 1 and 2 2. The technical consultant and clinic manager confirmed the survey findings during an interview on 02/11/2026 at 1:45 p.m. .

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report CLIA (Form CMS-209), laboratory personnel records, and staff interviews, the technical consultant (TC) failed to perform competency assessments for one testing personnel (TP) (one of seven reviewed) who performed complete blood count (CBC) patient testing in 2024 and 2025. The findings include: 1. A review of Form CMS-209 revealed seven TP and

one TC for moderately complex CBC patient testing. 2. A review of the laboratory personnel records revealed that the TC did not perform annual competency evaluations for TP#1 in 2024 and 2025. 3. The technical consultant and clinic manager confirmed the survey findings during an interview on 02/11/2026 at 1:45 p.m.