

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0677022	(X3) Date Survey Completed 10/08/2025
Name of Provider or Supplier Memphis Children's Clinic	Street Address, City, State 6615 Kirby Center Cove, Memphis, 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 on 10/8/2025, the laboratory was found out of compliance with the following condition: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) 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 samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) Hematology Proficiency Testing (PT) records for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) and staff interview, the laboratory failed to retain proficiency testing records for a minimum of two years from the date of the proficiency testing event for four of four events reviewed. The findings include: 1. A review of the laboratory's API PT records for Hematology CBC w/Diff revealed the following: The PT program instructions were not retained for 2024 Event Two, 2024 Event Three, 2025 Event One, and 2025 Event Two. The attestation statements were not retained for 2024 Event Two and 2025 Event Two. The data submission report was not retained for 2025 Event 2. 2. The technical consultant confirmed the survey findings during an interview on 10/08/2025 at 11:40 a.m.</p>
D2128	HEMATOLOGY

CFR(s): 493.851(e)

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's API Hematology PT records, surveyor review of the PT records, and staff interview, the laboratory failed to determine the cause of PT failures for the Hematology specialty and the Red Blood Cell, Hematocrit, Hemoglobin, and Platelet analytes and perform corrective action to prevent future occurrences. The findings include: 1. A review of the laboratory's API Hematology 2025 Event Two performance evaluation report revealed the following unsatisfactory scores: 70% overall score for Hematology, 60% for Red Blood Cell Count, 60% for Hematocrit, 60% for Hemoglobin, and 60% for Platelet analytes. The documented corrective action for the unsatisfactory scores was "Samples appear to have not been mixed well. Will retrain associates when next PT comes in. QC was acceptable." 2. Surveyor review of the API Hematology 2025 Event Two PT performance evaluation report and the Sysmex XN 330 instrument PT printouts revealed that 33 of 90 results were entered incorrectly during result submission. 3. The technical consultant confirmed the survey findings during an interview on 10/8/2025 at 12:30 p.m.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(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.

This STANDARD is not met as evidenced by:

Based on laboratory observation and staff interviews, the laboratory failed to ensure that Becton Dickonson (BD) Microtainer Serum Separator Tubes (SST) blood collection tubes had not exceeded the expiration date provided by the manufacturer. The findings include: 1. Laboratory observation on 10/8/2025 at 8:39 a.m. revealed two expired packages of BD Microtainer SST tubes (Lot number 331280, expiration date 1/31/25, and Lot number 3352768, expiration date 2/28/25). 2. On 10/08/2025 at 8:40 a.m., Testing Personnel #1 stated the BD SST tubes were used to collect neonatal bilirubin samples that were sent to a reference laboratory, confirmed the survey findings, and discarded the expired tubes.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document

all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on laboratory observation, reviews of the laboratory procedure manual, patient testing records, the laboratory's quality control records, and the Quality Assessment Plan, Quality Assessment documentation, and a staff interview, the laboratory's quality assessment process was not effective in preventing laboratory errors and performing corrective action for the failure to follow established quality control procedures for the Sysmex XN 330 Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) for one of four dates selected for review. The findings include: 1. Laboratory observation on 10/8/2025 at 12:00 p.m. revealed the Sysmex XN 330 used for patient CBC w/Diff testing. 2. Review of the laboratory's Sysmex CBC Analyzer Procedure revealed that "Tri-level controls are run once every 24 hours," "after daily start up procedures are completed," and "results are confirmed to be within acceptable limits prior to reporting patient results." 3. Review of patient test results and Sysmex XN 330 CBC w/Diff instrument printouts revealed that on 7/30/2025, Patient Number 197853 was performed at 8:34 a.m. and Patient Number 198647 was performed at 8:46 a.m. 4. A review of the laboratory's CBC w/Diff quality control records revealed quality control was not performed prior to patient testing on 7/30/2025. 5. Review of the laboratory's Quality Assessment Plan stated review included "control and calibration testing are being performed according to written policy and procedures" under Instrumentation Evaluation Criteria. 6. Review of Quality Assessment documentation performed by the Technical Consultant on 8/14/2025 revealed no evidence that the error in quality control performance was detected or that corrective action was taken. 7. The technical consultant confirmed the survey findings during an interview on 10/8/2025 at 12:30 p.m.

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 personnel records and staff interview, the laboratory failed to provide educational documentation that qualified testing person four to perform moderately complex testing for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) (One of nine testing personnel reviewed). 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 a review of the laboratory's personnel records and staff interview, the laboratory failed to provide educational documentation that qualified testing person four to perform moderately complex testing for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) (One of nine testing personnel reviewed). The findings include: 1. A review of testing personnel records revealed educational documentation provided for testing person four did not meet the requirements for moderately complex testing for CBC w/Diff. 2. The technical consultant confirmed the survey findings during an interview on 10/8/2025 at 2:00 p. m.