

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0677386	(X3) Date Survey Completed 10/07/2025
Name of Provider or Supplier Memphis Childrens Clinic	Street Address, City, State 7705 Poplar Ave Suite 230 Bldg B, Germantown, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) Form CMS-209, a review of testing personnel records, a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, a review of patient test records, and staff interview, testing personnel (TP) who routinely performed patient testing for Complete Blood Count with automated White Blood Cell differential (CBC w/Diff) failed to participate in proficiency testing in 2024 and 2025. The findings include: 1. A review of Form CMS 209 revealed nine testing personnel who performed patient testing for CBC w/Diff (four primary TP and five fill-in (float) TP). 2. A review of the four primary TP's records revealed that TP1 was hired on 08/14/24, TP2 on 07/16/24, TP3 on 05/09/25, and TP4 on 05/26/25. 3. A review of the laboratory's API proficiency testing records revealed that TP 1 had performed all PT events received since her hire date of 08/14/24 (2024 Event Three, 2025 Event One, and 2025 Event Two). 4. A review of patient test records revealed patient testing for CBC w/Diff that was performed by other testing personnel (patient 206102 performed by TP 2 on 11/18/24, patient 190760 performed by TP 5 on 03/08/25, and patient 143127 performed by TP 3 on 08/18/25). 5. The technical consultant confirmed the survey findings during an interview on 10/07/25 at 4 p.m.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</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.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's API CBC w/Diff PT records and staff interview, the testing personnel and laboratory director/designee failed to sign one of five PT attestation statements from 2024 and 2025. The findings include: 1. A review of the laboratory's API PT records revealed that the attestation statement for 2024 Event Two was not signed by the testing personnel or the laboratory director/designee. 2. The technical consultant confirmed the survey findings during an interview on 10/07/25 at 3:45 p.m.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory procedure manual, a review of testing personnel records, a review of patient test reports, and staff interview, the laboratory failed to follow the policy for testing personnel training and competency assessment prior to patient testing for TP Two (one of four new testing personnel who performed Complete Blood Count with Automated White Blood Cell Differential (CBC w/ Diff)). The findings include: 1. A review of the laboratory's policy titled "QUALITY ASSURANCE PLAN" revealed the following statement: "All testing associates are trained, and competency is evaluated prior to the initiation of patient testing and reporting patient results." 2. A review of testing personnel records revealed the following for TP 2: The date of hire was listed as 7/16/24. Initial training was not documented until 05/16/25. There was no documentation that an initial competency assessment was performed. A six-month competency was documented on 02/07/25. 3. A review of patient test reports revealed patient testing performed by TP 2 on 11/17/24 for patient 206102 prior to documentation of initial training and documented competency assessment. 4. The technical consultant the survey findings during an interview on 10/07/25 at 4:00 p.m.