

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0677246	(X3) Date Survey Completed 06/11/2025
Name of Provider or Supplier Memphis Childrens Clinic	Street Address, City, State 1129 Hale Road, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation and a staff interview, the laboratory failed to ensure that tubes used for collecting fingerstick Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) samples were not expired on the survey date (06/11/25). The findings include: 1. Laboratory observation on 06/11/25 at 9:00 a. m. revealed multiple lot numbers of fingerstick collection tubes with multiple expiration dates used for collecting CBC w/Diff samples in a basket. Seven expired collection tubes were noted with dates of 03/31/24, 10/31/24, and 01/31/25. The tubes were discarded on the survey date. 2. The technical consultant confirmed the survey finding during an interview on 06/11/25 at 9:15 a.m.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, a review of quality control reports, patient test reports, quality assessment reports, and a staff interview, the laboratory failed to document corrective action for shifts/trending in the hematocrit analyte quality control</p>

(QC) for two of two months reviewed that showed QC shifts/trending for the hematocrit analyte. The findings include: 1. Laboratory observation on 06/12/25 at 9:00 a.m. revealed the Sysmex XN 330 (serial number 14731) used for patient testing for CBC w/Diff. 2. A review of the quality control raw data and Levy-Jennings graphs printed from the instrument and the laboratory's Sysmex Beyond Care QC reports revealed the following for the hematocrit analyte: October 2024 Lot 4181 (Levels One, Two, and Three) was used from 10/01/24 to 10/08/24, and Lot 4265 (Levels One, Two, and Three) was used from 10/09/24 to 10/31/24. All three levels of quality control for both lots had recovered values consistently near the upper limit of the acceptable QC range, with shifts to the upper limit observed on the Levy Jennings graphs. Level One for Lot 4181 was repeated on 10/03/24, 10/04/24, and 10/08/24 to obtain values within the acceptable QC range. Level One for Lot 4265 was repeated on 10/10/24 and 10/15/24 for values outside the upper QC limit. Level Two for Lot 4181 was repeated on 10/04/25 for values outside the acceptable QC range. The Beyond Care reports for Lots 4181 and 4265 used in October 2024 revealed that the QC data was trending up beginning in September 2024. March 2025 Lot 4349 (Levels One, Two, and Three) was used from 03/01/25 to 03/25/25, and Lot 5067 (Levels One, Two, and Three) was used from 03/26/25 to 03/31/25. All three levels of quality control for both lots had recovered values consistently near the upper limit of the acceptable QC range, with shifts to the upper limit observed on the Levy Jennings graphs. Level One for Lot 4349 was repeated multiple times on 03/17/25 and 03/25/25 for values outside the upper QC limit. Level Two for Lot 4349 was repeated on 03/17/25 and 03/25/25 for values outside the upper QC limit. Level Three for Lot 4349 was repeated on 03/03/25 for values outside the upper QC limit. The Beyond Care reports for Lots 4349 and 5057 used in March 2025 revealed shifts in the QC data towards the upper range of the acceptable limit beginning in February 2025. 3. A review of patient test results revealed that patient sample number 117657 was reported on 10/21/24 and patient sample number 198263 was reported on 03/08/25 during the periods of the QC shifts/trends. 4. A review of the quality assessment form for October 2024 and March 2025 revealed the following: Trending and Shifts? Without severe up or down trends. Yes was circled. No corrective actions were taken. 5. The technical consultant confirmed the survey findings during an interview on 06/11/25 at 1:15 p.m.