Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0677022	04/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Children's Clinic	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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory procedure, and staff interviews, the laboratory failed to follow the procedure for the Sysmex XN complete blood count (CBC) instrument when it did not perform quality controls (QC) after reagent changes in 2023 and 2024. The findings include: 1. Observation of the laboratory on 04/18/2024 at 9:00 am revealed a Sysmex XN 330 (Serial # 14732) used for CBC patient testing. Testing persons two and four were present and asked to describe QC procedures during the observation. The testing persons stated they did not perform QC after reagent changes. 2. A review of the manufacturer's basic operation manual for the Sysmex XN 330 instrument, Chapter 3, titled "Performing Quality Control (QC)" 3.2.2 "When QC analysis is performed" revealed reagent replenishment or replacement required personnel to perform QC. 3. Interview on 04/18 /2024 at 1:00 pm with the technical consultant confirmed the laboratory failed to follow the procedure for QC after a reagent change in 2023 and 2024.
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 observation of the laboratory, review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), QC records, quality assessment records, and staff interview, the laboratory's quality assessment process failed to identify incorrect instrument dates and times for the instrument used to perform CBC patient testing for two of four months reviewed in 2023 or 2024. The findings include: 1. Observation of the laboratory on 04/18/2024 at 9:00 am revealed a Sysmex XN 330 (Serial # 14732) used for patient CBC testing. 2. A review of the Form CMS-116 submitted for the survey performed on 04/18/2024 revealed hours of operation for the laboratory of 8:00 am - 5:00 pm (0800-1700) Monday through Friday and 8:00 am - 12:00 pm (0800-1200) on Saturday. 3. A review of the laboratory's CBC QC records printed from the Sysmex XN 330 instrument revealed 29 of 30 days in March 2023 and 25 of 25 days in March 2024 that the recorded time that QC was performed was inconsistent with the laboratory's hours of operation. 4. A review of the laboratory's quality assessment records revealed no corrective action performed for the incorrect instrument times in 2023 or 2024. 5. Interview on 04/18/2024 at 1:fpm with the technical consultant confirmed the laboratory's quality assessment process failed to identify the instrument date and time was accurate in 2023 and 2024.