Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0677386	04/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Childrens Clinic	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
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 Personnel Report (CLIA) (Form CMS-209), laboratory policy, personnel records, and staff interviews, the laboratory failed to follow the personnel policy for competency assessment of testing personnel that performed complete blood count (CBC) patient testing in 20223 and 2024. The findings include: 1. A review of Form CMS-209 submitted for the laboratory survey performed on 04/18/2024 revealed four testing personnel that performed CBC patient testing. 2. A review of the laboratory policy titled " Quality Assurance Plan" section "Personnel Assessment" revealed that testing personnel would have competency assessment performed prior to patient testing. 3. A review of the laboratory's personnel records revealed no documentation of competency assessment for testing person two (hired December 2023) or testing person four (hired January 2024). 4. Interview on 04/18/2024 at 4:30 pm with the technical consultant confirmed the laboratory failed to follow the policy for testing personnel competency assessment for testing persons two and four who were performing patient testing on the date of the survey (04/18/2024) hired in 2023 and 2024.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of Form CMS-209, laboratory personnel records, and staff interviews, the laboratory director failed to ensure that testing personnel (two of four reviewed) had documented training and demonstrated accuracy prior to patient CBC testing in 2023 and 2024 (Refer to D5209). The findings include: 1. A review of Form CMS-209 submitted for the survey on 04/18/2024 revealed four testing personnel that performed CBC patient testing. 2. A review of the laboratory personnel records revealed no documentation of training or demonstration of accuracy before patient CBC testing in 2023 and 2024 for testing persons two or four (two of four reviewed). 3. Interview on 04/18/2024 at 4:30 pm with the technical consultant confirmed thesurvey findings during interview on 04/18/2024 at 4:30 pm.