Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0692116	(X3) Date Survey Completed 02/08/2024
Name of Provider or Supplier Children's Medical Center Of Dallas	**Street Address, City, State** 1935 Medical District Drive, Dallas, TX	

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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, direct observation of patient specimens, and confirmed in interview, the laboratory failed to ensure patient secondary specimens were labeled with at least two unique identifiers for two of two patients. Findings included: 1. Review of the laboratory procedure titled "Process Flow for Process of Blood Samples and Procedure Results" stated: " ...Label all the tubes with the patient's identifiers and times." The laboratory policy did not include labeling instructions to reliably identify patients using at least 2 unique patient identifiers to distinguish between specimens. 2. During a tour of the laboratory on 02/08/2024 at 1015 hours, the surveyor observed patient specimens that were poured over into secondary specimen tubes stored in a green rack on the counter as follows: Patient 1: 7 tubes with blue caps labeled with patient last name a draw time. Patient 2: 7 tubes with blue caps labeled with patient last name a draw time. These patients were collected and tested on 02/07/2024. The laboratory failed to label secondary specimen tubes with at least two unique identifiers. 3. During an interview on 02/08/2024 at

	1015 hours, testing person 1 (TP-1) and testing person 2 (TP-2) as listed on the Form CMS-209 confirmed the above findings. Key: CMS - Centers for Medicare and Medicaid Services