Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0954692	01/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Norton Children's Medical Group-Stonestreet	9702 Stonestreet, Suite 100, Louisville, KY	

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	A recertification survey was conducted on 01/19/2023 and the facility was found to not be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on interview and record review, the facility failed to meet the condition of participation for proficiency testing (PT): successful participation by not meeting the standard requirements at D2130. Specifically, the facility failed to successfully participate in PT for hematology for two (2) consecutive events (2021-B and 2021-C). The findings include: Review of graded PT reports revealed the facility failed to meet

	the standard requirements at D2130 by failing to successfully participate in two (2) consecutive hematology PT events. The testing scores for 2021-B and 2021-C were as follows: -White blood cell count (WBC) 60% (2021-B) and 60% (2021-C) -Red blood cell count (RBC) 40% (2021-B) and 60% (2021-C) -Hemoglobin (HGB) 60% (2021-B) and 60% (2021-C) -Hematocrit (HCT) 40% (2021-B) and 60% (2021-C) Refer to D2130 for further details.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on interview, record review and review of the facility's policies, the facility failed to achieve satisfactory performance for hematology, as evidenced by proficiency testing (PT) scores of less than 80% for white blood cell (WBC) count, red blood cell (RBC) count, hemoglobin (HGB), and hematocrit (HCT) for two (2) consecutive PT events reviewed (2021-B and 2021-C). The findings include: Review of the facility policy titled, "Proficiency Testing", dated 03/24/2021, revealed "The laboratory shall subscribe on a continuous basis to a PT program, which is recognized and acceptable to CMS (Centers for Medicare and Medicaid Services)". The policy further revealed "Review of all PT results and alternative assessment results are completed within one (1) month of the date reports and results become available to the laboratory". Additionally, the policy revealed "All unacceptable PT results and alternative assessment results are documented, investigated, and corrective action taken appropriate to the nature and magnitude of the problem". Review of the PT evaluation reports from the American Academy of Family Physicians (AAFP) revealed the laboratory was enrolled for hematology PT in 2021. The reports revealed scores of less than 80% for the following PT events: -White blood cell count (WBC) 60% (2021-B) and 60% (2021-C) -Red blood cell count (RBC) 40% (2021-B) and 60% (2021-C) -Hemoglobin (HGB) 60% (2021-B) and 60% (2021-C) -Hematocrit (HCT) 40% (2021-B) and 60% (2021-C) Interview with Testing Personnel (TP) #1, on 01/19/2023 at 10:50 AM, revealed personnel retraining on how to handle PT samples was conducted on 07/25/2022 when a new Technical Consultant (TC) started working with the laboratory.