Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0928366	07/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Norton Children's Medical Group - Jeffersonville	3118 E 10th Suite B, Jeffersonville, IN	

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 completed on 7/18/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation 42 Code of Federal Regulation (CFR) 493.1409 Technical Consultant - Moderate Complexity
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 document review and interview, the laboratory failed to successfully participate in American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing (PT) programs for one of one analyte (bilirubin, total) tested in the subspecialty of Routine Chemistry. The laboratory had 0

	percent PT testing scores for two out of three PT testing events 2022 (Event C) and 2023 (Event 1) for both bilirubin and routine chemistry (Refer to D2096).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to successfully participate in American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing (PT) programs for one of one analyte (bilirubin, total) tested in the subspecialty of Routine Chemistry. The laboratory had 0 percent PT testing scores for two out of three PT testing events 2022 (Event C) and 2023 (Event 1) both bilirubin and routine chemistry. Findings include: 1. Review of the AAFP "Proficiency Testing Evaluation AAFP PT 2002-C" indicated the laboratory received 0 percent scores for chemistry and bilirubin (total). 2. Review of the API "Proficiency Summary 2023 Chemistry- Core- 2nd Event" indicated 0 percent scores for chemistry and bilirubin, total. Notes stated, "Failure to Participate". 3. On 7 /18/23 at 11:15am, SP-1 (Technical Consultant) acknowledged that the laboratory received 0 percent scores for chemistry and bilirubin, total for events C, 2022 and event 2, 2023. SP-1 further indicated samples were not submitted properly for event 2, 2023 due to a block by Norton Security after a security breach. Clerical person (not listed on the CMS 209) tried to submit in by phone but was unsuccessful. 4. Patients' records indicated two of ten patients reviewed had testing performed when the PT failures occurred: Patient Date Test PT6 12/28/22 Bilirubin PT8 6/05/23 Bilirubin 5. Annual Test Volume for Routine Chemistry is approximately 100.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to attain an overall event score of at least 80 percent in the American Academy of Family Physicians (AAFP) proficiency testing (PT) program for six of six regulated analytes (cell identification or white blood count differential, red blood cell count, hematocrit, hemoglobin, and platelet count) tested in the subspecialty of Hematology. The laboratory had 0 percent PT testing scores for PT testing events 2022 (Event C). Findings include: 1. Review of the AAFP "Proficiency Testing Evaluation AAFP PT 2002-C" indicated the laboratory received 0 percent scores for Hematology and the following regulated analytes: cell identification or white blood count differential, red blood cell count, hematocrit, hemoglobin, and platelet count. 2. On 7/18/23 at 11: 15am, SP-1 (Technical Consultant) acknowledged that proficiency test the laboratory received 0 percent scores for Hematology and cell identification or white blood count differential, red blood cell count, hematocrit, hemoglobin, and platelet count for event C, 2022. 3. Patients' records indicated the following patient had Complete Blood

	Count (CBC) with Differential testing performed with included all hematology analytes when the unsatisfactory performance occurred: Patient (PT) Date Test PT5 11 /09/22 CBC 5. Annual Test Volume for Hematology is approximately 1,500.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on document review, the laboratory failed ensure one (SP-2) of two personnel performing responsibilities of a Technical Consultant (TC) was qualified from January 24/2023 to date of the survey (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

	This STANDARD is not met as evidenced by: Based on record review, the laboratory director failed ensure one (SP-2) of two personnel performing responsibilities of a Technical Consultant (TC) was qualified from January 24/2023 to date of the survey (refer to D6035). Findings Include: 1. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 7/10/2023 indicated the following: a) SP-1 is a Technical Consultant. b) SP-2 is a testing person. c) SP-5 is a testing person. 2. Review of personnel file for SP-2 indicated the highest education completed was a high school diploma. 3. Review of "Competency Evaluation Profile" for SP-5 signed by SP-2 (testing person) on 1/24/23 revealed SP-2 initialed as the preceptor/trainer for competency involving "CBC functions/daily control/ Review/ procedures" on analyzer Sysmex XN330, SN: 13836. 4. Review of Standard Work Instruction document, under "Personnel Assessment" states, all laboratory staff will be evaluated annually for competency, but did not specify who was responsible for competency evaluation. 5. Annual Test Volume for Routine Chemistry is approximately 100.