Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326962	11/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Norton Children's Medical Group-Elizabethtown	1301 Ring Road, Elizabethtown, 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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The laboratory was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 a proficiency testing desk review of the Certification and Survey Provider

	Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2023 records (2nd and 3rd events), the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Routine Chemistry for Bilirubin (Bili, Total) analyte (Refer to D 2088 and D2089).
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(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 a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2023 records (2nd and 3rd event), the laboratory failed to achieve an overall testing event score of satisfactory performance (80%) for two (2) of two (2) consecutive testing events for the specialty of Routine Chemistry. 1. A review of the Casper -0155 report revealed the following: Routine Chemistry 2023 - 2nd Event The laboratory received an unsatisfactory score of 0%. Routine Chemistry 2023- 3rd Event The laboratory received an unsatisfactory score of 0%. 2. A review of proficiency testing records from API 2023 confirmed the above findings.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 and API records 2023 (2nd and 3rd events), the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte for two (2) of two (2) consecutive testing events for the Bilirubin (Bili, Total) analyte. 1. A review of the CASPER-0155 report revealed the following: Bili, Total 2023-2nd Event The Laboratory received an unsatisfactory score of 0%. Bili, Total 2023- 3rd Event The Laboratory received an unsatisfactory score of 0%. 2. A review of proficiency testing records from API 2023 confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 Individual Laboratory Report and API 2023 records (2nd and 3rd events), the laboratory director failed to provide overall management and direction of the laboratory services. (Refer to D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 and API 2023 records (2nd and 3rd events), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. (Refer to D2088 and D2089).