Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326962	02/04/2020
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview on 02/04/2020, the laboratory failed to verify the performance specifications established by the manufacturer, for precision and accuracy prior to reporting patient test results when the Reichert Unistat Bilirubinometer was installed 05/22/2018. Findings include: 1. Review of records of installation performed 05/22/2018, failed to reveal verification of accuracy to ensure the testing method produced correct results. 2. Review of records of installation performed 05/22/2018, failed to reveal assessments of day-to-day, run-to-run, and with-in run precision to ensure reproducibility was verified prior to reporting patient results. 3. Testing Personnel acknowledged in an interview at 11:15 AM on 02/04/2020, the laboratory failed to have a system in place to ensure accuracy and precision performance specifications were verified and comparable to those established by the manufacturer prior to patient testing.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview 02/04/2020, the laboratory failed to perform calibration verification every six months from 10/10/2018 to 02/04/2020 for the neonatal bilirubin analyte performed on the Reichert Unistat Bilirubinometer analyzer. Findings include: 1. The laboratory failed to provide documentation of calibration verification including a minimal (zero), mid-point, and a maximum value to verify the reportable range for bilirubin performed on the Unistat Bilirubinometer. 2. Testing personnel acknowledged in an interview at 11:15 AM on 02/04/2020, the laboratory failed to have a system in place to ensure calibration verification was performed every six months on the Unistat Bilirubinometer.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of Hematology proficiency testing results from The American Academy of Family Physicians (AAFP) testing agency and staff interview on 02/04 /2020, the laboratory director failed to ensure proficiency testing results were reviewed by staff for six of six testing events in 2018 and 2019. Findings include: 1. There was no evidence of review of hematology proficiency testing results from AAFP for three testing events in 2018. 2. There was no evidence of review of hematology proficiency testing results from AAFP for three testing events in 2019. 3. Testing personnel acknowledged in an interview at 10:30 AM on 02/04/2020, the

	laboratory director failed to have a system in place to ensure proficiency testing results received from AAFP were reviewed by appropriate staff to evaluate the laboratory's performance.