

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0928366	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Norton Children's Medical Group - Jeffersonville	Street Address, City, State 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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed include two control materials of different concentrations at least once a day patient specimens are assayed for one of one test (Bilirubin) performed in the subspecialty of Routine Chemistry for one (PT#10) of five Bilirubin patients reviewed. Findings included: 1. Review of patients records indicated PT#10 had a billirubin test performed on 8/5/2021 at 9:13 am. 2. Review of the quality control log for "Unistat Bilirubinometer" indicated no quality control had been performed on 8/5/2021 when PT#11 had been tested. 3. Manufacturer's instructions for the "Reichert Unistat Bilirubinometer" revised 2003 states, "7.1 Use of Commercial Serum Controls Analysis of at least a normal and abnormal level of a commercial serum control, assayed for total bilirubin, is recommended for checking performance of the Reichert Unistat Biliruinometer." 4. On 12/14/201 at 2pm, SP3 (CMA Manager) acknowledged the quality control log showed that no quality control was performed on 8/5/2021 when PT#10 had been tested. 5. Annual Test Volume for Bilirubin is approximately 300.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems</p>

identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow their policy for quality assessment monitoring for three of four quarters in 2021 (Quarters 1, 2, and 3) and 1 (Quarter 1) of four quarters in 2020 for one of one test (Bilirubin) performed in the subspecialty of Routine Chemistry and for one of four quarters in 2020 and one of two quarters (Quarter 1) when testing was performed in 2021 for five of five tests (White blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), and Platelet (PLT)) performed in the specialty of hematology. Findings include: 1. Review of the policy "Quality Assurance Monitoring", last revision 3/26 /2014, indicated, "All quality monitoring results will be reviewed by the laboratory director (or designee) quarterly. These results will also be reviewed with appropriate staff quarterly in staff meetings. All quality assurance monitoring data will be retained for 2 years." 2. Review of quality assessment documents for 2020 and 2021 indicated the following: a. There was no review of Quarter four data for 2020 (October, November, and December) for the Routine Chemistry and Hematology testing performed. b) There was no review of quality assurance documents for Quarter 1, Quarter 2 or Quarter 3 for 2021 for the Routine Chemistry testing performed. c) Hematology testing stopped in March of 2021 and did not continue until Quarter 4, 2021. The "Quarterly Quality Assurance" documents dated March 2021 indicated the Hematology machine was "down" and testing ceased waiting on the new machine. i) The "Quarter Quality Assurance" document: dated March 2021 and reviewed by the laboratory director on 3/31/2021, marked "N" or no for "Quality control is run according to our written policies. Any corrective Action is documented in the QC log." and "N" or no for a review of charts being completed. ii) The only documentation for corrective actions was that the hematology machine was down. iii) A review of Routine Chemistry (bilirubin) testing was not documented on this document for Quarter 1 2021 and no other "Quarter Quality Assurance" documents had been completed for 2021. 3. Review of medicinal records indicated Routine Chemistry testing continued through 2021 and one of five patients reviewed failed to have quality control performed on the day the patient was testing (PT#10 (8/5/2021) (Refer to D5447). 3. In interview on 12/14/2021 at 3:14 pm, SP3 indicated all quality assessment activities were in the binder presented and that quality assurance should be performed quarterly for all non-waived testing. 4. Annual test volume for Routine Chemistry is approximately 300 and Hematology is approximately 3,972.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
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 and interview, the laboratory failed to have two of three personnel (SP2 and SP6) performing the duties of a technical consultants meet the qualification requirements (refer to D6034).

D6034

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on document review and interview, two of three personnel who performed duties of the technical consultants failed to be qualified (SP2 and SP6). Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209) signed by the laboratory director on 12/13/2021 indicated SP2 was a technical consultant and SP6 was a testing person. 2. Review of personnel records indicated the following: a. SP6 performed the annual competency assessment for SP7, Testing Person, on 12/1/2021. b. SP2 Performed the annual competency assessment for SP7, Testing Person, on 12/1/2020. c. SP2 Performed six-month competency assessment for SP6, Testing Person, on 6/8/2021. d. SP2 had the duties of a technical consultant delegated on 9/2/2020 by the laboratory director, including evaluating the competency of all testing personnel and assuring the staff maintain their competency including "initial", "midterm", and "annual competency". e. SP6 had the duties of a technical consultant delegated on 10/29/2021 by the laboratory director, including evaluating the competency of all testing personnel and assuring the staff maintain their competency including "initial", "midterm", and "annual competency". f. SP2 had a high school diploma and did not qualify as a technical consultant. g. SP6 did not have documentation of education and did not qualify as a technical consultant (refer to D6065) 3. Review of patient records indicated: a. SP7 performed patient testing as follows: 1. Patient #1 (12-15-2020) 2. Patient #3 (3-2-2021) 3. Patient #11 (11-1-2021) b. SP6 performed patient testing as follows: 1. Patient #12 (3/23/201) 4. In interview on 12-14-2021 at 10:53 am, SP3 acknowledged SP2 and SP6 had performed the competency assessments for SP7 and SP6. SP3 further acknowledged the SP2 and SP6 had the duties of the technical consultant delegated to them by the laboratory director, but both had a high school education.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on document review and interview, one of two (SP6) personell performing moderate complexity testing failed to meet qualification requirements (Refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on document review and interview, one of two (SP6) personnel performing moderate complexity testing failed to qualify. Findings include: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 12/13/2021, indicated SP6 was a testing personnel. 2. Review of personnel records indicated the laboratory did not have education documentation for SP6. Education documentation was not provided within seven days of the survey date. 3. In interview on 12/14/2021 at 11:27 am, SP3 (CMA Manager) and SP1 (Practice Manager) indicated the laboratory did not have education documentation for SP6. 4. Review of medical records indicated SP6 performed bilirubin testing on PT#12 on 3/23/2021.