

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0976510	(X3) Date Survey Completed 07/17/2024
Name of Provider or Supplier Norton Children's Medical Group-Shelbyville	Street Address, City, State 150 Frankfort Rd, Ste 101, Shelbyville, 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 07/17/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with a deficiency cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy review, observation, document review, and confirmed in staff interview, the laboratory failed to ensure testing personnel (TP) followed written procedures for labeling of specimens. This was noted for 1 out of 4 testing events observed. Findings included: Review of the laboratory's "Standard Operating Procedure" (SOP) titled, "Specimen Collection/Rejection," effective 07/16/2020, revealed, "SPECIMEN LABELING AND HANDLING CRITERIA 1. Specimens on registered patients are labeled with the following information (usually using a computer generated label): a. Patient name b. Patient medical record number or date of birth c. Date and Time of collection d. Initials of person collection [sic] specimen." The SOP further specified specimens should be rejected if, "4. No labels on the tube at all." On 07/17/2024 at 10:50 AM, TP #8 was observed performing a neonatal bilirubin test. The specimen container was not labeled. Review of a document titled, "Testing Personnel/Moderate Complexity Job Description," signed by TP #8 on 07/02/2024, revealed, "RESPONSIBILITIES 1. Specimen Collection and Handling Testing personnel must run only the tests ordered by the provider or in established standing</p>

orders or protocols. Follow established protocol to correctly identify the patient, collect the proper specimen on the correct patient under the appropriate circumstances, and label the specimen with all required information." Review of TP #8's initial "Competency Assessment," dated 07/02/2024, and a "Hematology and Chemistry Quiz," undated, revealed that as part of TP #8's initial competency validation, TP #8 was observed performing proper preanalytic specimen handling procedures and correctly answered a question about specimen labeling. During an interview on 07/17/2024 at 10:55 AM, TP #8 stated the neonatal bilirubin specimen was not labeled, because point of care testing did not have to be labeled. During an interview on 07/17/2024 at 11:05 AM, after reviewing the SOP for "Specimen Collection/Rejection" and the "Testing Personnel/Moderate Complexity Job Description," the Technical Consultant (TC) said there was no exception to labeling requirements for point of care testing. The TC stated that TP #8 was a new employee and recently completed her initial competencies, but she would need re-training.