

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0691847	<b>(X3) Date Survey Completed</b> 10/25/2018
<b>Name of Provider or Supplier</b> East Tn Childrens Hospital Primary Care Corp	<b>Street Address, City, State</b> 502 Winfield Dunn Parkway, Sevierville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: ===== Based on manufacturer's storage requirement for bilirubin control materials, freezer temperature documentation for 2018 and interview with Primary Laboratory Supervisor, determined the laboratory failed to ensure bilirubin controls were stored at the correct temperature. The findings include: 1. Manufacturer's storage requirement for bilirubin control materials is less than minus 20 degrees Celsius. 2. Freezer temperature documentation where bilirubin control materials are stored has been documented out of range low (warmer than minus 20 degrees Celsius) for 2018. 3. Interview with the primary laboratory supervisor at approximately 3:00 p.m. October 25, 2018 confirmed the bilirubin control materials were not stored at temperatures less than 20 degrees Celsius for 2018. =====</p>
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within</p>

the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

===== Based on calibration verification requirements for the Reikert Bilirubin instrument, lack of documentation of daily calibration verification for 2017 and 2018 and interview with the primary laboratory supervisor, determined the laboratory failed to perform daily calibration verifications for the two year period. The findings include: 1. Calibration verification is required to be performed daily using known calibration cuvettes for the Reikert Bilirubin instrument. 2. Lack of documentation of daily calibration verification for 2017 and 2018. 3. Interview with the primary laboratory supervisor at approximately 3:30 p.m. October 25, 2018 confirmed there was no daily calibration verifications documented for the two year period. =====

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

===== Based on lack of training and/or competency documentation for 2 of 2 testing personnel, who transferred to current facility in 2018, and upon interview with the primary laboratory supervisor, determined the laboratory director failed to ensure all personnel have documented training and/or competency prior to patient testing. The findings include: 1. Lack of training and/or competency documentation for 2 of 2 testing personnel, upon transfer from a sister facility in 2018, who have been performing Complete Blood Counts (CBC's) and bilirubin testing. 2. Interview with the primary laboratory supervisor at approximately 3:00 p.m. October 25, 2018 confirmed there was no documentation of training and/or competency for 2 of 2 testing personnel upon transferring from a sister facility in 2018, prior to performing CBC's and bilirubin testing. =====