| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 44D0973032 | 01/25/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| East Tn Children's Hospital Primary Care Corp | 125 Mountain View Dr Suite 200, Vonore, TN | |

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 |
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| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>_____ Based on review of the Taxo Disc quality control sheets for 2016 and 2017, which lacked lot numbers and expiration dates with no quality assessment review to show problem identified and corrected and an interview with the Laboratory Manager, determined the laboratory failed to establish and follow a procedure for acknowledging and correcting problems associated with not documenting lot numbers and expiration dates for Taxo Discs used. The findings include: 1. Review of the Taxo Disc quality control sheets with designation for lot numbers and expiration dates which failed to be documented for the 2 year period and no quality assessment review to show problem identified and corrected. 2. Interview at approximately 2:00 p.m. January 25, 2018, with the Laboratory Manager, confirmed the laboratory failed to establish and follow a procedure for acknowledging and correcting problems associated with not documenting lot numbers and expiration dates for taxo discs for the two year period.<br>_____ |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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 |

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| | 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;<br><br>This STANDARD is not met as evidenced by:<br>_____ Based on review of the Hematology Proficiency Testing (PT) results for the 2nd event of 2017 which showed unacceptable scores with no corrective action and an interview with the Laboratory Manager, determined the laboratory director failed to review and evaluate the unacceptable PT scores to ensure problems are identified and corrected. The findings include: 1. Review of the Hematology PT results for the 2nd event 2017 showed Red Blood Cell score of 60%; Hemoglobin score of 40% and Hematocrit score of 60% with no corrective action documented. 2. An interview at approximately 2:00 p.m. January 25, 2017 with the Laboratory Manager confirmed there were unacceptable PT scores for the 2nd event of 2017 with no review performed to identify problems that may have required corrective action. _____ |