| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>18D0937845 | (X3) Date Survey Completed<br><br>09/09/2020 |
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| **Name of Provider or Supplier**<br><br>Eastern Ky Tender Care Pediatrics Lcc | **Street Address, City, State**<br><br>400 University Drive, Ste 101, Prestonsburg, 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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on staff interview and complete blood count (CBC) testing policy review on 09/09/2020, the laboratory failed to include: reference intervals for patient results, criteria for reporting abnormal or panic values, corrective action procedure for when quality control is out of acceptable range, and procedure for when the analyzer is out of service. The findings include: 1. Policy review conducted on 09/09/2020 revealed the laboratory did not have all the necessary procedural requirements for the policy regarding CBC testing on the Sysmex XP-300 analyzer. 2. Interview with the laboratory staff on 09/09/2020 at 10:00 AM confirmed that the laboratory did not |

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| | have a system in place to ensure that all the policies and procedures contained all the information needed to perform and report the test. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview on 09/09/2020, the laboratory director failed to ensure two (2) levels of quality control were performed and recorded each day of testing between 01/06/2020 and 07/15/2020. Findings include: 1. Patient # one (1) Complete Blood Count (CBC) test was performed and reported on 01/06/2020 with no documented quality control. 2. Patient # two (2) Complete Blood Count (CBC) test was performed and reported on 07/15/2020 with no documented quality control. 2. An interview with the laboratory staff on 09/09/2020 at 10:30 AM revealed the laboratory failed to have a system in place to ensure two (2) levels of quality control were documented prior to patient testing. |