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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>26D0445864 | <b>(X3) Date Survey Completed</b><br><br>12/26/2018 |
| <b>Name of Provider or Supplier</b><br><br>Lake Regional Health System - Eldon Clinic                                      | <b>Street Address, City, State</b><br><br>416 S Maple Ste C, Eldon, MO     |                                                     |
| 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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| D2016              | <p>SUCCESSFUL PARTICIPATION<br/>CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of 2018 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the technical consultant, the laboratory failed to successfully participate in PT. See D-tag 2130, unsatisfactory PT performance for the hematocrit analyte for three consecutive testing events</p> |
| D2130              | <p>HEMATOLOGY<br/>CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of hematology proficiency testing (PT) results for 2018 and phone interview with the technical consultant, the laboratory failed to achieve satisfactory performance for the hematocrit analyte in three consecutive PT events. Findings: 1. The laboratory obtained an unsatisfactory score of 40 percent for the hematocrit analyte in the first PT event of 2018. 2. The laboratory obtained an unsatisfactory score of 60 percent for the hematocrit analyte in the second PT event of 2018. 3. The laboratory obtained an unsatisfactory score of 40 percent for the hematocrit analyte in the third PT event of 2018. 4. Phone interview with the technical consultant on December 26, 2018 at 11:00 AM confirmed the laboratory failed to achieve satisfactory performance for the hematocrit analyte.