

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0445875	<b>(X3) Date Survey Completed</b>  05/11/2021
<b>Name of Provider or Supplier</b>  Lake Regional Health System - Laurie Clinic	<b>Street Address, City, State</b>  156 Missouri Blvd Ste B, Laurie, MO	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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: Based on review of hematology proficiency testing (PT) results for 2020/2021 reported to the CLIA database by the PT provider and electronic correspondence with the technical consultant on May 10, 2021, the laboratory failed to successfully participate in PT. Refer to D-tag 2130; failed to achieve satisfactory performance for the same analytes in two consecutive testing events. Refer to D-tag 2131; failed to achieve an overall testing event score of satisfactory performance for two consecutive testing events.</p>
<b>D2130</b>	<b>HEMATOLOGY</b>

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive 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 2020/2021 and electronic correspondence with the technical consultant the laboratory failed to achieve satisfactory performance for the same analytes in two consecutive PT events. Findings: 1. The laboratory obtained an unsatisfactory score of 60 percent for the RBC, hematocrit, hemoglobin and WBC analytes in the third PT event of 2020 2. The laboratory obtained an unsatisfactory score of 40 percent for the RBC, hematocrit, hemoglobin analytes and unsatisfactory score of 60 percent for the WBC analyte in the first PT event of 2021. 3. Electronic correspondence with the technical consultant on May 10, 2021 at 3:34 PM confirmed the laboratory failed to achieve satisfactory performance for same analytes in two consecutive PT events.

**D2131**

**HEMATOLOGY**

CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing 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 2020/2021 and email correspondence with the technical consultant, the laboratory failed to achieve an overall testing event score of satisfactory performance for two consecutive testing events. Findings: 1. The laboratory obtained unsatisfactory performance (73 percent) for the third hematology testing event of 2020. 2. The laboratory obtained unsatisfactory performance (60 percent) for the first hematology testing event of 2021. 3. Email correspondence with the technical consultant on May 10, 2021 at 3:34 PM confirmed the laboratory failed to achieve overall testing event scores of satisfactory performance for the third testing event of 2020 and first testing event of 2021.