

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1094020	(X3) Date Survey Completed 06/01/2020
Name of Provider or Supplier Lake Regional Health System - Osage Beach Clinic	Street Address, City, State 1057 Medical Park Drive, Osage Beach, 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
D2016	<p>SUCCESSFUL PARTICIPATION 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 2019 and 2020 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and electronic correspondence with the technical consultant, the laboratory failed to successfully participate in PT. See D-tag 2130, unsatisfactory PT performance for the cell ID /WBC diff analyte for first and third PT testing event in 2019 and first PT testing event in 2020.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

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 2019/2020 and electronic correspondence with the technical consultant, the laboratory failed to achieve satisfactory performance for the cell ID/WBC diff analyte for two of three PT testing events in 2019 and two consecutive PT events in 2019 and 2020. Findings: 1. The laboratory obtained an unsatisfactory score of 47 percent for the cell ID/WBC diff analyte in the first PT event for 2019. 2. The laboratory obtained an unsatisfactory score of 67 percent for the cell ID/WBC diff analyte in the third PT event for 2019. 3. The laboratory obtained an unsatisfactory score of 73 percent for the cell ID/ WBC diff analyte in the first PT event of 2020. 4. Electronic correspondence with the technical consultant on June 1, 2020 at 07:48 AM confirmed the laboratory failed to achieve satisfactory performance for the cell ID/WBC diff analyte in the first and third PT events of 2019 and first PT event of 2020.