

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0628209	(X3) Date Survey Completed 08/02/2022
Name of Provider or Supplier Lake District Hospital	Street Address, City, State 700 South J Street, Lakeview, OR	
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: Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing showed the laboratory had unsuccessful participation for two consecutive testing event 1st and 2nd event 2022 in the specialty Endocrinology and Immunohematology. Refer to D2099, D2107, D2173, D2179 and D2181.</p>
D2099	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory</p>

performance.

This STANDARD is not met as evidenced by:
Proficiency Testing (PT) desk review of the American Association of Bioanalyst (AAB) showed the laboratory failed to attain an overall testing event score of 80 percent for two consecutive events in the specialty Endocrinology. Findings include: 1. 1st event 2022 Endocrinology = 33% 2. 2nd event 2022 Endocrinology = 33%

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing showed the laboratory has had unsuccessful performance for two consecutive events for the analytes Free Thyroxine and Thyroid Stimulating Hormone in the specialty Endocrinology. Findings include: 1. 1st event 2022 Free Thyroxine = 0% 2. 2nd event 2022 Free Thyroxine = 0% 3. 1st event 2022 Thyroid Stimulating Hormone = 0% 4. 2nd event 2022 Thyroid Stimulating Hormone = 0%

D2173

COMPATIBILITY TESTING
CFR(s): 493.863(a)

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing showed the laboratory had failed to attain an overall testing event score of 100% for two consecutive events for Compatibility Testing in the specialty Immunohematology. Findings include: 1.. 1st event 2022 Compatibility Testing = 80%. 2. 2nd event 2022 Compatibility Testing = 80%.

D2179

COMPATIBILITY TESTING
CFR(s): 493.863(d)

(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing showed the laboratory had unsuccessful performance for

two consecutive events for Compatibility testing in the specialty Immunohematology. Findings include: 1. 1st event 2022 Compatibility Testing = 80%. 2. 2nd event 2022 Compatibility Testing = 80%.

D2181

COMPATIBILITY TESTING
CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing showed the laboratory had unsuccessful performance for two consecutive events for Compatibility testing in the specialty Immunohematology. Findings include: 1. 1st event 2022 Compatibility Testing = 80%. 2. 2nd event 2022 Compatibility Testing = 80%.