

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0628589	<b>(X3) Date Survey Completed</b>  06/09/2023
<b>Name of Provider or Supplier</b>  Pioneer Memorial Hospital Lab	<b>Street Address, City, State</b>  564 E Pioneer Dr, Heppner, OR	
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>D2026</b>	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing (PT) results from the College of American Pathologists (CAP), and an interview with the laboratory Technical Supervisor (TS), the laboratory failed to document the remedial actions taken for unacceptable PT results. Findings include: 1. Review of the CAP PT results revealed unacceptable results for organism identification, unacceptable Morphology identification, and MIC susceptibility interpretation. Year Event Sample Intended Response 2022 D-C D-19 Bacilli Coccobacilli 2022 D-C D-19 Resistant Susceptible 2022 D-C D-15 K. pneumoniae K. ozaena 2022 D-B D-12 Resistant Susceptible 2022 D-A D-04 K. Kanga Strep Species 2. The laboratory had no documentation for the remedial training as indicated on the laboratory's PT corrective action review forms. 3. The laboratory TS confirmed by interview on 6/8/2023 at 11:20 am, the lack of documented remedial training for unacceptable PT results. 4. The laboratory reports performing 2000 microbiology patient tests annually.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory testing personnel records, lack of policy and procedure, and interview with the Laboratory Technical Supervisor (TS), the laboratory failed to establish policies and procedures for Testing Personnel (TP) and Technical Consultant (TC) competency. Findings include: 1. Review of the laboratory's competency assessment forms for 2021, 2022, and to date of survey 2023, the laboratory failed to assess personnel competency for four of four testing personnel to include the six elements for competency assessment as required by 493.1451(b)(8) 2. Competency assessment forms were changed during 2021 to a new format supplied by the laboratory's Technical Consultant (TC) that included spaces where the six elements were to be captured. 3. The laboratory did not have a policy or procedure providing instructions on how to assess testing personnel competency, including how to document the competency assessments on the new forms. 4. The laboratory TS confirmed by interview on 6/8/2023 at 12:15 pm, the lack of a policy or procedure for testing personnel and TC competency. 5. The laboratory reports performing 65,000 patient tests annually.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview with the laboratory Technical Consultant (TC) the laboratory failed to ensure that culture media was not used when they exceeded their expiration date. Findings include: 1. During the tour of the laboratory microbiology department on June 8th, 2023, it was revealed that the chocolate media had expired on 5/30/2023. Lot Number Expiration Date 644636 05/30/2023 2. The laboratory TC confirmed by an interview on June 8, 2023, at 3:10 pm the use of expired chocolate media. 3. The laboratory reports performing 2000 Bacteriology patient specimens annually.