

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D0656919	<b>(X3) Date Survey Completed</b> 05/26/2021
<b>Name of Provider or Supplier</b> Wallowa Memorial Hospital Lab	<b>Street Address, City, State</b> 601 Medical Parkway, Enterprise, 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>D0000</b>	A special survey of Wallowa Memorial Hospital Lab located in Enterprise, OR was conducted on May 25 & 26, 2021. The Laboratory was found to be in substantial compliance with the CLIA Condition-level regulation (42 CFR, Part 493.41) pertaining to COVID-19 reporting requirements. No deficiencies were cited.
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Microbiology Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to ensure end user QC was performed on each new lot of microbiological media received from outside vendors. Findings include: 1. Upon review of the QC logs for Microbiology, no record of end user QC could be found. 2. During an interview with the TS on 05/25/2021 at approximately 1500, she confirmed that end user QC was not being performed on purchased Microbiological media.</p>
<b>D6106</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p>

This STANDARD is not met as evidenced by:

Based on review of several procedure manuals during the survey 05/25/2021 and 05/26/2021, the Laboratory Director (LD) failed to sign off on several procedures. Findings include: 1. During review of the Blood Bank Quality Control (QC) manual, it was noted that the Daily Reagent QC procedure had not been signed off/approved by the current LD. 2. During review of the Chemistry Calibration manual, it was noted that the Calibration Verification for Chemistry Lab procedure had not been signed off/approved by the current LD. 3. During review of the Hematology Procedure manual, it was noted that four (4) out of nine (9) procedures reviewed had not been signed off/approved by the current LD. 4. The Technical Supervisor confirmed during interview that these procedures had not been approved by the current LD during interview at approximately 1400 on 05/26/2021.