

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0618613	<b>(X3) Date Survey Completed</b> 05/08/2024
<b>Name of Provider or Supplier</b> Eastern Plumas Health Care	<b>Street Address, City, State</b> 500 E 1st Ave, Portola, CA	
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>D5815</b>	<p>TEST REPORT CFR(s): 493.1291(h)</p> <p>When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory's policies, review of patient test records randomly selected from 8/9/2022 to 5/2/2024, and interview with the technical supervisor (TS); it was determined that the laboratory failed to have a policy for turn-around time (TAT) for all tests performed in the laboratory. 1. The laboratory failed to provide TAT of testing for four (5) out of four (5) randomly chosen patients at the time of the survey (May 8, 2024). The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory TS on May 8, 2024, at approximately 2:00 p.m. affirmed that the laboratory did not have a TAT policy to notify any delay on testing to the physician. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/6/2024, stated that the laboratory performs 155,081 tests annually for which a TAT policy was not available.</p>
<b>D6106</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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> <p>This STANDARD is not met as evidenced by: The laboratory director is cited herein on the lack of laboratory's written policies. Based on the surveyor's review of laboratory records and interview with the</p>

laboratory technical supervisor (TS); it was determined that the laboratory director failed to ensure that an approved, signed, and dated policy manual ( policies on all the phases of laboratory testing including: specimen rejection criteria, documents retention policy, panic values, labelling of reagents, proficiency testing policy, validation and verification policy, etc.) is available to all personnel responsible for any aspect of the testing process. See D5815.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's records of personnel training, competency evaluation, laboratory policies and procedures, random patient testing records, and interview with the laboratory 's technical supervisor (TS); the laboratory failed to provide records showing that the laboratory director (LD) has authorized, delegated, and approved lab personnel of any responsibilities and duties in writing. The findings include: 1. The laboratory did not have any records of written delegation and authorization of responsibilities and duties by the LD for the laboratory's technical supervisor/general supervisor. In addition, the responsibilities of the technical supervisor/general supervisor, and testing personnel (TP) were not specified in writing. 2. On May 8, 2024, at approximately 1:00 p.m. the TS affirmed that the LD did not assign, delegated, and authorized in writing duties and responsibilities to the laboratory personnel including the TS and TP. 3. The laboratory testing declaration form, signed by the LD on 5/6/2024 stated that the laboratory performs 155,081 tests annually.