

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0618613	(X3) Date Survey Completed 11/08/2024
Name of Provider or Supplier Eastern Plumas Health Care	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A proficiency testing desk review survey was performed on 11/8/2024, the laboratory was found not in compliance with the following CONDITION LEVE DEFICIENCIES D2016 - C.F.R. 493.803 Conditions: Successful participation [proficiency testing] and D6000 - C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; Laboratory Director.
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 the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and American Proficiency Institute (API) proficiency testing records (2024-1 and 2024-2), the laboratory failed to successfully participate in a</p>

	<p>proficiency testing program approved by HHS, for each specialty, subspecialty or test which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty General Immunology for the analytes - Infectious mononucleosis (INF MONO) and Rheumatoid factor (RA/RF). Refer to D2084.</p>
<p>D2084</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API proficiency testing report, the laboratory failed to achieve satisfactory performance in two out of three consecutive events for the analytes Inf Mono and RA/RF: The finding include: a. Inf Mono - 0% on the 2024 first event, Inf Mono - 0% on the 2024 second event; b. A review of the 2024 Inf Mono scores from API Proficiency Testing confirmed the above scores. c. RA/RF - 0% on the 2024 first event, RA/RF - 0% on the 2024 second event; b. A review of the 2024 RA/RF scores from API Proficiency Testing confirmed the above scores</p>
<p>D2085</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API proficiency testing report, the laboratory failed to achieve overall testing event for two consecutive testings or two of three consecutive testing events: The finding include: a. General Immunology 0% on the 2024 first event, General Immunology 0% on the 2024 second event, b. A review of the 2024 Inf Mono scores from API Proficiency Testing confirmed the above scores.</p>
<p>D2162</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API proficiency testing report, the laboratory failed to achieve satisfactory performance in two out of three</p>

	<p>consecutive events for the analytes ABO, ABO/RHO and D (RHO): The finding include: a. ABO - 0% on the 2024 first event, ABO - 0% on the 2024 second event; b. A review of the 2024 ABO scores from API Proficiency Testing confirmed the above scores; c. D (RHO) - 0% on the 2024 first event, D (RHO) - 0% on the 2024 second event; d. A review of the 2024 D (RHO) scores from API Proficiency Testing confirmed the above scores; e. ABO/RHO - 0% on the 2024 first event, ABO/RHO - 0% on the 2024 second event; f. A review of the 2024 ABO/RHO scores from API Proficiency Testing confirmed the above scores;</p>
<p>D2172</p>	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API proficiency testing report, the laboratory failed to achieve satisfactory performance in two out of three consecutive events for the analyte Antibody Detection: The finding include: a. Antibody Detection - 0% on the 2024 first event, Antibody Detection - 0% on the 2024 second event; b. A review of the 2024 Inf Mono scores from API Proficiency Testing confirmed the above scores.</p>
<p>D2181</p>	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API proficiency testing report, the laboratory failed to achieve satisfactory performance in two out of three consecutive events for the overall analyte Antibody Detection: The finding include: a. Antibody Detection - 0% on the 2024 first event, Antibody Detection - 0% on the 2024 second event; b. A review of the 2024 API Proficiency Testing Antibody Detection confirmed the above scores.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and API</p>

Proficiency Testing records for 2024-1 and 2024-2 events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a proficiency testing desk review of the CASPER 0155D report and API Proficiency Testing records for 2024-1 and 2024-2 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2084.