

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0058598	(X3) Date Survey Completed 12/09/2021
Name of Provider or Supplier Humboldt General Hospital Laboratory	Street Address, City, State 118 E Haskell St, Winnemucca, NV	
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	This Statement of Deficiencies was generated as a result of the CLIA proficiency testing desk review, conducted off-site for your laboratory on 12/09/2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 desk review of federal database CASPER Reports 153D and 155D and the American Association of Bioanalysts (AAB) proficiency testing (PT) evaluation</p>

	<p>forms, on 12/09/2021, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two consecutive testing events for the second and third testing events of 2021 with a score of 60% and 80%, respectively, resulted in unsuccessful proficiency testing performance for compatibility testing. Findings include: The laboratory failed to maintain successful participation with the AAB PT program shown by the unsuccessful performance for compatibility testing in the second and third testing events of 2021. Refer to D2181.</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 desk review of federal database CASPER Reports 153D and 155D and AAB PT evaluation forms, the laboratory did not perform successfully in a proficiency testing program. Findings include: 1. The laboratory failed to maintain successful participation with the AAB PT program shown by the unsuccessful performance for compatibility testing in two consecutive testing events, the second and third testing events of 2021. 2. CASPER Report 155D and the AAB PT evaluation both reported scores of 60% for the second testing event of 2021 and a score of 80% for the third testing event of 2021.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on desk review of federal database CASPER Reports 153D and 155D and AAB PT evaluation forms, the Condition: Laboratories Performing High Complexity Testing; Laboratory Director was not met. The laboratory director failed to provide overall management and direction in accordance with CFR 493.1445 of this subpart. Findings include: The laboratory director failed to ensure that the laboratory successfully participated in a PT program, approved by CMS; as described in subpart 1 of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. Refer to D6089.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on desk review of federal database CASPER Reports 153D and 155D and AAB PT evaluation forms, the laboratory did not successfully participate in a proficiency testing program. Findings include: 1. The laboratory failed to maintain successful participation with the AAB PT program shown by the unsuccessful performance for compatibility testing in the second and third testing events of 2021. 2. CASPER Report 155D and the AAB PT evaluation both reported scores of 60% for the second testing events of 2021 and 80% for the third testing event o 2021.