

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D1094000	<b>(X3) Date Survey Completed</b>  09/16/2021
<b>Name of Provider or Supplier</b>  Ogden Clinic Utah Hematology Oncology Layton	<b>Street Address, City, State</b>  2132 North 1700 West #301, Layton, UT	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 American Proficiency Institute (API) performance summary review and confirmation from laboratory supervisor on 9/15/2021, the laboratory failed to achieve successful participation in two of three consecutive events for Platelet Count testing performance. See D2130.</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on American Proficiency Institute (API) performance summary review and confirmation by laboratory supervisor on 09/15/2021, the laboratory failed to achieve satisfactory performance in two out of three consecutive testing events for Platelet Count. Findings include: 1. API summary report included documentation that the laboratory failed two out of three consecutive testing events for Platelet Count (0% for third testing event of 2020 and 60% for second testing event of 2021). 2. Laboratory supervisor confirmed via email on 09/15/2021 that API testing samples were not tested before the closing date of the third testing event of 2020 and therefore results were not submitted to API. 3. Laboratory supervisor confirmed via email on 09/15/2021 that the laboratory failed the Platelet Count for the second API testing event of 2021.