

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0701320	(X3) Date Survey Completed 01/03/2023
Name of Provider or Supplier Valley Obstetrics & Gynecology, Provo	Street Address, City, State 585 North 500 West, Provo, UT	
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
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 a routine desk review of the CMS-155 report for proficiency testing performance and email from the laboratory director, the laboratory failed to achieve satisfactory performance scores for Total Bilirubin testing for two out of three events in 2021 and 2022. (2021, Event 3 and 2022, Event 2) See D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

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

This STANDARD is not met as evidenced by:

Based on review of proficiency testing scores from the American Proficiency Institute (API) and email communications with the laboratory director, the laboratory failed to achieve a score of 80% for Total Bilirubin testing for two out of three events in 2021 and 2022. (2021, Event 3 and 2022, Event 2) Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 12/27/2022, at 5:17 PM, revealed the Total Bilirubin testing scores for 2021, Event 3 was 40% and 2022, Event 2 was 40%. 2. Email received from the laboratory director on 01/03/2023, at 05:14 PM, confirmed two of three unsuccessful proficiency scores for Total Bilirubin testing due to sample handling.