

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2214836	(X3) Date Survey Completed 03/29/2023
Name of Provider or Supplier Prime Labs Llc	Street Address, City, State 10619 S Jordan Gateway Blvd Suite 125, South Jordan, 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 compliance team, the laboratory failed to achieve satisfactory performance scores for Glucose Non-Waived testing for two out of three events in 2022 and 2023. (2022, Event 3 and 2023, Event 1) See D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</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.

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 compliance team, the laboratory failed two out of three events in 2022 and 2023. (2022, Event 3 and 2023, Event 1) for Glucose (Non-Waived) Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 03/27/2022, at 12:47 PM, revealed the Glucose (Non-Waived) testing scores for 2022, Event 3 was 0% and 2023, Event 1 was 60%. 2. Email received from the compliance team on 03/29/2023, at 04:52 PM, confirmed two of three unsuccessful proficiency scores for Glucose (Non-Waived).