

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2004180	(X3) Date Survey Completed 04/24/2024
Name of Provider or Supplier Grace Health Clinic Laboratory	Street Address, City, State 3191 South Vaughn Way, Aurora, CO	
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director, the laboratory failed to achieve satisfactory performance scores for the American Proficiency Institute (API) PT for Chloride for two out of three PT events, (event 3 in 2023 and event 1 in 2024). See D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

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 a routine desk review of the CMS-155 report for Proficiency Testing (PT), American Proficiency Institute (API) reports, and email communication with the laboratory director, the laboratory failed to achieve a satisfactory score for Chloride for event 3 in 2023 and event 1 in 2024. Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 4/10/2024, at 11:21 AM, revealed the API PT results for Chloride testing scores for event 3 in 2023 was 0%, and 40% for event 1 in 2024. 2. An email with the laboratory director on 4/11/2024, at 10:21 AM, confirmed the laboratory failed to achieve satisfactory test performance for Chloride.