

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D1046309	(X3) Date Survey Completed 05/21/2024
Name of Provider or Supplier Healthy Futures Co, Pllc	Street Address, City, State 1634 N Downing St, Denver, 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	<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 (PT) performance and email communications with the back office supervisor and laboratory director, the laboratory failed to achieve satisfactory performance scores for the American Proficiency Institute (API) PT for ABO/RHO for two out of three PT events, (event 2 in 2023 and event 3 in 2023), and RHO for two out of three PT events, (event 2 in 2023 and event 3 in 2023). See D2153.</p>
D2153	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p>

Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

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 back office supervisor, and the laboratory director, the laboratory failed to achieve a satisfactory score for ABO/RHO for event 2 in 2023, and event 3 in 2023, and failed to achieve a satisfactory score for RHO for event 2 in 2023, and event 3 in 2023.

Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 5/10/2024, at 1:32 PM, revealed the API PT results for ABO/RHO testing scores for event 2 in 2023 was 0%, and 40% for event 3 in 2023. 2. A review of the CMS-155 Individual Laboratory Profile on 5/10/2024, at 1:32 PM, revealed the API PT results for RHO testing scores for event 2 in 2023 was 0% and 40% for event 3 in 2023. 3. An email with the laboratory's back office supervisor on 5/10/2024, at 3:12 PM, confirmed the laboratory failed to achieve satisfactory PT test performance for ABO/RHO, and RHO. 4. An email with the laboratory director on 5/17/2024, at 10:08 AM, confirmed the laboratory failed to achieve satisfactory PT test performance for ABO/RHO, and RHO.