

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D0949748	<b>(X3) Date Survey Completed</b>  10/21/2025
<b>Name of Provider or Supplier</b>  Cny Fertility, Pllc	<b>Street Address, City, State</b>  265 S Parkside Dr, Colorado Springs, CO	
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>D0000</b>	The following condition level deficiencies were found to be out of compliance: 42 C.F.R. 493.803 Condition: Successful Participation [proficiency testing];
<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 a review of proficiency testing evaluation reports from the PT provider, College of American Pathologists (CAP), and an interview with the Technical Supervisor during the survey, the laboratory failed to achieve satisfactory performance scores for the College of American Pathologists (CAP) proficiency testing for Prolactin for two consecutive proficiency testing events (event 1 in 2025 and event 2 in 2025), see D2096.</p>

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

(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 review of proficiency testing evaluation reports from the PT provider, College of American Pathologists (CAP), and an interview with the Technical Supervisor during the survey, the laboratory failed to achieve a satisfactory score for Prolactin in two consecutive testing events, Event 1 in 2025, and Event 2 in 2025. Findings include: 1. A review of the PT evaluation report during the survey from the PT provider, CAP, on October 21, 2025, at approximately 12:00 PM, revealed the CAP PT results for the Prolactin analyte was 0% in Event 1 of 2025, and was 20% for event 2 of 2025. 2. An interview with the Technical Supervisor on October 21, 2025, at approximately 12:30 PM confirmed that the CAP PT results for the Prolactin analyte was 0% in Event 1 of 2025, and was 20% for event 2 of 2025.