

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2210862	(X3) Date Survey Completed 09/30/2024
Name of Provider or Supplier Reproductive Specialists Of The Carolinas	Street Address, City, State 1918 Randolph Road, Suite 410, Charlotte, NC	
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 desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 CAP (College of American Pathologists) proficiency testing results 9/30/24, the laboratory failed to achieve satisfactory performance for Serum hCG (human chorionic gonadotropin), and failed to achieve overall test event scores of satisfactory for Endocrinology on two consecutive test events, resulting in unsuccessful participation in proficiency testing. Findings: See the deficiencies cited at D2107 and D2108.</p>
D2107	ENDOCRINOLOGY

CFR(s): 493.843(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 desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 CAP proficiency testing results 9/30/24, the laboratory failed to achieve satisfactory performance for Serum hCG on two consecutive test events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS Casper reports 153D and 155D and 2023 CAP proficiency testing results revealed the laboratory received a score of 20% for Serum hCG on the CAP K-C 2023 Ligand-General event. 2. Desk review of CMS Casper reports 153D and 155D and 2024 CAP proficiency testing results revealed the laboratory received a score of 40% for Serum hCG on the CAP K-A 2024 Ligand-General event.

D2108

ENDOCRINOLOGY

CFR(s): 493.843(g)

Failure to achieve an overall testing event score of satisfactory performance for 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 desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 CAP proficiency testing results 9/30/24, the laboratory failed to achieve an overall test event score of satisfactory performance for Endocrinology on two consecutive test events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS Casper reports 153D and 155D and 2023 CAP proficiency testing results revealed the laboratory received a score of 20% for Serum hCG, resulting in an overall score of 60% for Endocrinology on the CAP K-C 2023 Ligand-General event. 2. Desk review of CMS Casper reports 153D and 155D and 2024 CAP proficiency testing results revealed the laboratory received a score of 40% for Serum hCG, resulting in an overall score of 70% for Endocrinology on the CAP K-A 2024 Ligand-General event.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 CAP proficiency testing results 9/30/24, the laboratory director failed to provide overall management and direction to ensure successful proficiency testing participation. Findings: See the deficiency cited at D6089.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on desk review of CMS Casper reports 153D and 155D 9/23/24 and desk review of 2023 and 2024 CAP proficiency testing results 9/30/24, the laboratory director failed to ensure successful participation in proficiency testing as required in Subpart H. Findings: See the deficiencies cited at D2107 and D2108.