Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0709026	11/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Center For Advanced Reproductive Services	2 Batterson Park Rd, Farmington, CT	

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
D0000	A proficiency testing desk review of the Center for Advanced Reproductive Services Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
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 record review of Proficiency Testing (PT) data report (Report 155D) and graded results from College of American Pathologist (CAP), the laboratory failed to obtain a satisfactory score for the regulated analyte Rubella in the subspecialty of General Immunology. The laboratory had unsatisfactory scores for Event 1 of 2023 and Event 2 of 2023.

D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(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 record review and staff interview with the laboratory director (LD), the laboratory failed to achieve a satisfactory score for the analyte #0235 (Rubella) in the subspecialty of General Immunology for 2 consecutive events resulting in unsuccessful performance. Findings include: 1. Record review on 11/22/2023 of the Centers for Medicare and Medicaid Services (CMS) 155D report revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores for 2 consecutive Proficiency Testing (PT) events in 2023 for Analyte #0235: Rubella, specifically Event #1: 0% and Event #2: 0%. 2. Record review on 11/22/2023 of the College of American Pathologist (CAP) 2023 Diagnostic Immunology PT Evaluation forms revealed the following for the regulated analyte, 'Rubella, Qual': a. "Test Method: Rubella Ab, qual, graded results with 'See Note 42'". b. "Legend: "Exception reason codes appearing in this evaluation: 42: No credit assigned due to absence of response". "Test Event Score %" "S-A 2023 0" "S-B 2023 0" c. "Current Event Performance Interpretations: Unsatisfactory". d. "Cumulative CLIA '88 Performance Interpretation: Unsuccessful". 3. Phone interview on 11/09/2023 at 2:45 PM with the LD confirmed the findings in Event 1 of 2023/S-A 2023. The LD further commented he/she was unaware of the recent failure and would investigate Event 2 of 2023/S-B 2023. 4. The laboratory performs 300 Rubella tests annually.
D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(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 record review and staff interview with the laboratory director (LD), the laboratory failed to achieve a satisfactory score for the analyte #0065: General Immunology for 2 consecutive events resulting in unsuccessful performance. Findings include: 1. Record review on 11/22/2023 of the Centers for Medicare and Medicaid Services (CMS) 155D report revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory scores for 2 consecutive Proficiency Testing (PT) events in 2023 for Analyte #0065: General Immunology, specifically Event #1: 50% and Event #2: 0%. 2. Record review on 11/22/2023 of the College of American Pathologist (CAP) 2023 Diagnostic Immunology PT Evaluation forms revealed the following scores for 'General Immunology': a. "Test Event Score %" "S-A 2023 50" "S-B 2023 0" b. "Current Event Performance Interpretation: Unsatisfactory". c. "Cumulative CLIA '88 Performance Interpretation: Unsuccessful". 3. Phone interview on 11/09/2023 at 2:45 PM with the LD confirmed the findings in Event 1/S-A 2023. The LD further commented he/she was unaware of the recent failure and would investigate Event 2 of 2023/S-B 2023.