| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 07D0709026 | 11/19/2025 |
| **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 1998. |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review of the 'CASPER Report 155D' from 'Centers for Medicare and Medicaid Services (CMS)' and the proficiency testing evaluation report from the College of American Pathologist (CAP), the laboratory failed to successfully perform proficiency testing (PT) for the regulated analytes: rubella for event 3, 2024 and event 2, 2025 as well as hepatitis B surface antigen for event 2 and 3, 2025. Refer to D2084. |

**D2084**

GENERAL IMMUNOLOGY
CFR(s): 493.837(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 record review and staff interview, the laboratory failed to achieve satisfactory performance for two out of three consecutive proficiency testing (PT) events for rubella, for event 3, 2024 and event 2, 2025 as well as for hepatitis B surface antigen for event 2 and 3, 2025 in the specialty of diagnostic immunology. Findings include: 1. Record review on 11/10/2025 of the 'CASPER Report 155D' from 'Centers for Medicare and Medicaid Services (CMS)' revealed the laboratory failed to achieve satisfactory scores for the following analytes: a. 'Analyte Number: 0145 - HBS AG' i. '2025, Event 2 - Score: 0*' ii. '2025, Event 3 - Score: 0*' b. 'Analyte Number: 0235 - Rubella' i. '2024, Event 3 - Score: 0*' ii. '2025, Event 2 - Score: 0*' 2. Record review on 11/18/2025 of the College of American Pathologist (CAP) "VM-B 2025 Viral markers (VM1) revealed the following: a. 'Exception Reason Codes appearing in this evaluation: [40] = Results for this kit were not submitted'. b. 'Proficiency: 2025, Event: 2' c. 'Regulated Analyte: HBsAg' d. 'Test Event: VM-B' e. 'Score: 0/5, Percentage: 0%' f. 'Current Event Performance Interpretation: Unsatisfactory' g. Corrective Actions documented by the laboratory: i. 'CARS discontinued this test, no longer perform on site as of 04/06/2025'. ii. 'CAP aware'. iii. 'Reviewed and approved by the Laboratory director on 08/22/2025' 3. Record review on 11/18/2025 of CAP's "VM-C 2025 Viral markers (VM1) revealed the following: a. 'Exception Reason Codes appearing in this evaluation: [40] = Results for this kit were not submitted'. b. 'Proficiency: 2025, Event: 3' c. 'Regulated Analyte: HBsAg' d. 'Test Event: VM-C' e. 'Score: 0/5, Percentage: 0%' f. 'Current Event Performance Interpretation: Unsatisfactory' g. Corrective Actions documented by the laboratory: i. 'CAP notified in August that We no longer perform these tests' ii. 'Upon further investigation the technician/laboratory director designee should have entered the exception code which was not done and therefore the results were processed as unsatisfactory and reported to DPH' iii. 'The tests and PT have officially been removed, and the exception code will be used for the remainder of 2025' iv. 'Reviewed and approved by the Laboratory director on 11/17/2025' 4. Record review on 11/18/2025 of CAP's "S-C 2024 Diagnostic Immunology (RUB) revealed the following: a. 'Exception Reason Codes appearing in this evaluation: [40] = Results for this kit were not submitted'. b. 'Proficiency: 2024, Event: 3' c. 'Regulated Analyte: Rubella, Qual' d. 'Test Event: S-C' e. 'Score: 0/5, Percentage: 0%' f. 'Current Event Performance Interpretation: Unsatisfactory' g. Corrective Actions documented by the laboratory: i. 'Incident Report for Missing PT Entry' i. 'Occurrence: Proficiency testing results were not officially submitted' ii. 'PT shipment/due date schedule printed and posted in both labs for viewing' iii. 'PT assignment written on Endocrine lab with ship date, due date, and testing personnel for visibility' iv. 'PT result entry added as a meeting request to weekly Microsoft Outlook calendar every Friday (for director and designee)' v. 'Bin created in designee's office for PT event requiring entry/submission' vi. 'Reviewed and approved by the Laboratory director on 12/30/2024' 5. Record review on 11/18/2025 of CAP's "S-B 2025 Diagnostic Immunology (RUB) revealed the following: a. 'Exception Reason Codes appearing in this evaluation: [40] = Results for this kit were not submitted'. b. 'Proficiency: 2025, Event: 2' c. 'Regulated Analyte: Rubella, Qual' d. 'Test Event: S-B' e. 'Score: 0/5, Percentage: 0%' f. 'Current Event

| | |
|---|---|
| | Performance Interpretation: Unsatisfactory' g. Corrective Actions documented by the laboratory: i. 'Stopped performing rubella testing on site as of 4/8/2025' ii. 'Failed to enter proper exception code on PT results therefore received unsatisfactory results' iii. 'Will you use proper exception code for remainder of 2025 and PT test menu has been updated for 2026' iv. 'Reviewed and approved by the Laboratory director on 11/17 /2025' 6. Record review on 11/17/2025 of the laboratory test order roster revealed last rubella IgG AB and hepatitis B Surface AG testing was completed on 04/03/2025. 7. Telephone interview on 11/17/2025 at 02:20 PM with the laboratory's technical supervisor (TS) confirmed the above findings. The TS further commented that the laboratory no longer performs HBsAg and Rubella testing and therefore did not submit the proficiency testing results and was unaware that an exception code must have been used instead. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review of the 'CASPER Report 155D' from 'Centers for Medicare and Medicaid Services (CMS)' and the proficiency testing (PT) evaluation report from the College of American Pathologist (CAP), the laboratory director failed to ensure effective remedial action was instituted in response to unsatisfactory PT scores for rubella, event 2, 2025 as well as hepatitis B surface antigen, event 3, 2025 in the specialty of diagnostics immunology. Refer to D2084. |