

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0935406	(X3) Date Survey Completed 09/01/2026
Name of Provider or Supplier Center For Advanced Reproduct Medicine	Street Address, City, State 4 Ethel Road Suite 405a, Edison, NJ	
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	An on-site validation survey was completed on September 01, 2026 with the following standard level deficiencies cited.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's calibration verification records, and interview with the Laboratory Director (LD), the laboratory failed to perform calibration verification on the Roche Cobas e411 analyzer at least every 6 months for 1 of 2 years (2025). Findings Included: 1) During a laboratory tour on 9/1 /2026 at 11:55 AM, one Roche Cobas e411 analyzer (Serial Number 1463-10) was observed in use. 2) Review of the laboratory's calibration verification records revealed

'Validate LGC Maine Standards' S1 verifier testing on the Roche Cobas e411 missed in 2025. Only S2 verifier testing was performed. 3) In an interview on 9/01/2026 at 10:37 AM, the LD confirmed S1 and S2 verifier testing (Calibration Verification) are performed on March 1 and September 1 of each year, and that S1 was missed in 2025.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on direct observation, review of quality control (QC) records, laboratory test records, written laboratory policies and procedures, and confirmed in an interview with the Laboratory Director (LD), the laboratory failed to take corrective action since the last acceptable test run after QC failures on the Roche Cobas e411 analyzer for 4 of 59 testing days (Random review from May 1 to June 30, 2026). Findings Included: 1) During a laboratory tour on 9/1/2026 at 11:55 AM, one Roche Cobas e411 analyzer (Serial Number 1463-10) was observed in use. 2) Review of the QC records revealed the following QC failure dates with subsequent recalibrations, for which a patient evaluation since the last acceptable test run was not performed: a) 5/29/2026, Analyte: Prolactin (PRL) 1 Patient test run on 5/28/2026, Specimen ID(s): 260528028 b) 6/6/2026, Analyte: Progesterone (P4) 29 Patient tests run on 6/5/2026, Specimen ID(s): 260605001, 260605002, 260605003, 260605004, 260605005 ... c) 6/23/2026, Analyte: Estradiol (E2) 7 Patient tests run on 6/22/2026, Specimen ID(s): 260622001, 260622002, 260622003, 260622004, 260622005 ... d) 6/29/2026, Analyte: Estradiol (E2) 7 Patient tests run on 6/28/2026, Specimen ID(s): 260628001, 260628002, 260628003, 260628004, 260628005 ... 3) Review of the laboratory's policies and procedures titled 'Advanced Reproductive Medicine IVF Laboratory Standard Operating Procedure Quality Management, Assurance and Improvement' stated the following on page 13 of 15: "Quality Control Results - For each incident where the quality control results are not within defined limits, remedial actions must be documented and corrective actions identified according to the requirements...An Incident Report should be filed if patient samples are adversely affected". 4) In an interview on 9/1/2026 at 11:56 AM, the LD confirmed the laboratory did not perform patient evaluation to the last acceptable test run after QC failures with subsequent recalibrations performed.