Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0709026	05/20/2026
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
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to document corrective actions taken when the humidity levels were outside of the acceptable established range in the subspecialty of Endocrinology. Findings include: 1. Surveyor observation on 05/20/2026 at 9:25 AM of the laboratory revealed "Roche e 602 Serial Number 1600-11" instrument in use for Endocrinology testing. 2. Surveyor observation on 05/20/2026 at 12:10 PM of the laboratory 's "Roche e-602-Operating manual" revealed "32 to 85%" as the acceptable humidity range. 3. Record review on 05/20/2026 of the "Laboratory Temperature and Humidity Log" for the period of October 2024 through April 2026 revealed the following: a. Acceptable humidity range: 32 % - 85%. b. Humidity was out of range for a total of 227 days out of 331 days as follows: i. October through November of 2024: 33 of 61 days ii. January, February, March, April, October and November of 2025: 122 of 181 days iii. January, February and April of 2026: 72 of 89 days. c. Lack of documentation of corrective action when the humidity range was below the minimum cutoff range of 32%. 4. Staff interview on 05/20/2026 at 11:45 AM with the laboratory's General Supervisor (GS) confirmed the above findings. The GS further stated that there is an

	ongoing issue with humidity in the laboratory. 5. The laboratory performs approximately 78,300 tests annually in the subspecialty of Endocrinology.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to include the name and address of the laboratory performing the tests on final patient reports in the subspecialty of Endocrinology. Findings include: 1. Record review on 05/20/2026 of the laboratory's validation binder for the "Laboratory Information System" for patient medical records revealed the laboratory started using the new Laboratory Information System (LIS) since August 7, 2025. 2. Record review on 05/20/2026 of laboratory's LIS validation binder revealed the validation of new LIS system "CARS Endocrine IMS (intelligent Medical Software)" to verify final patient reports for the Farmington, Hartford and Branford locations. 3. Record review on 05/20/2026 of the "Patient Report" in the LIS- IMS binder revealed the following: a. Validation of patient final test reports of the new IMS for 3 locations: Farmington, Hartford and Branford. b. For each analyte results, "P" under the "Lab" section. c. Bottom of the report indicated," Performing Laboratory Information". "P", "Alison F. Bartolucci PhD/HCLD". d. Lack of documentation of the name and address of the laboratory on patient final test reports. 4. Record review on 05/23/2026 of the email communication from the laboratory dated 05/22/2026 revealed the laboratory had performed 32,596 endocrine tests since the new IMS (LIS) was implemented. 5. Staff interview on 05/20/2026 at 10:00 AM with the GS confirmed the findings in 3 above. The GS further commented that the verification of the name and address of the laboratory on the final patient report was missed during the validation of the new IMS-LIS.. 6. The laboratory performs 78,300 tests annually in the subspecialty of Endocrinology.