

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2161195	(X3) Date Survey Completed 08/18/2026
Name of Provider or Supplier Audubon Fertility	Street Address, City, State 4303 Magnolia Street, New Orleans, LA	
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 Validation survey was performed at Audubon Fertility, CLIA ID 19D2161195, on August 18, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer's instructions for use, and interview with personnel, the laboratory failed to document the open expiration date for endocrinology quality control materials. Findings: 1. Observation by surveyor during the laboratory tour on August 18, 2026 at 10:06 a.m. revealed the laboratory stored the following in use endocrinology quality control materials in the laboratory's refrigerator, did not label the controls with an open expiration date: a) PreciControl Tumor Marker 1, Lot 84581490, manufacturer's expiration date 6/30/2027 b) PreciControl Tumor Marker 2, Lot 84581590, manufacturer's expiration date 6/30/2027 2. Review of the manufacturer's package insert "PreciControl Tumor Marker" section "Storage and stability" revealed "Stability of the reconstituted control serum:" when stored " at 2-8 degrees Celsius" - "2 weeks." 3. In interview on August 18, 2026 at 1:21 p.m., the Technical Consultant confirmed the quality control materials identified above did not have the open expiration date documented.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation; review of the manufacturer's requirements, the laboratory's maintenance logs, and patient test records; and interview with personnel, the laboratory failed to perform maintenance every two (2) weeks on the Cobas e411 analyzer as required by the manufacturer for three (3) of forty-three (43) weeks reviewed. Findings: 1. Observation by surveyor revealed the laboratory utilized a Cobas e411 analyzer for endocrinology testing. 2. Review of the manufacturer's "Cobas e411 analyzer Maintenance Log" revealed the following required tasks "Every 2 Weeks": a) "Clean rinse stations" b) "Perform liquid flow cleaning" 3. Review of the laboratory's maintenance logs from December 17, 2024 through August 18, 2026 revealed the laboratory did not perform maintenance every two (2) weeks as follows: a) December 31, 2024 through January 14, 2025 - last performed December 17, 2024 b) September 23, 2025 through October 6, 2025 - last performed September 9, 2025 c) August 11, 2026 through August 18, 2026 - last performed July 28, 2026 4. Review of the laboratory's patient test records revealed the laboratory tested the following volume of patients when maintenance was not performed: a) December 31, 2024 through January 14, 2025: One hundred thirty (130) patients tested. b) September 23, 2025 through October 6, 2025 - Two hundred twelve (212) patients tested. c) August 11, 2026 through August 18, 2026 - Ninety-nine (99) patients tested. 5. In interview on August 18, 2026 at 11:59 a.m., the Technical Consultant confirmed maintenance was not performed as identified above.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory.

Findings: 1. The laboratory failed to document the open expiration date for endocrinology quality control materials. Refer to D5415. 2. The laboratory failed to perform maintenance every two (2) weeks on the Cobas e411 analyzer as required by the manufacturer for three (3) of forty-three (43) weeks reviewed. Refer to D5429.