

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2166308	(X3) Date Survey Completed 07/22/2026
Name of Provider or Supplier Brown Fertility Associates Pa	Street Address, City, State 2200 Fowler Grove Blvd Suite #260, Winter Garden, FL	
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 announced CLIA validation survey was conducted at Brown Fertility Associates PA on 7/22/26. The laboratory was surveyed under 42 CFR, Part 493 CLIA requirements. Standard deficiency was cited as follows:
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on interview, and record review, the laboratory failed to accurately transcribe the ordering physician's name for three of three final patient reports, (patient #1, patient #2 and patient #3). Findings Include: 1. Review of Semen Analysis Worksheets revealed the following: a. Patient #1 Semen Analysis Report indicated semen analysis was tested on 5/04/26 and ordering physician had a physician name written. b. Patient #2 Semen Analysis Report indicated semen analysis was tested on 6 /02/26 and ordering physician name was written as self. c. Patient #3 Semen Analysis Report indicated semen analysis was tested on 6/03/26 and ordering physician name was written as the patient's name. 2. Review of Final Patient reports revealed the following: a. Patient #1 Semen Analysis final report on 5/04/26 listed ordering physician as the clinic's name. b. Patient #2 Semen Analysis final report on 6/02/26 listed ordering physician as self. c. Patient #3 Semen Analysis final report on 6/03/26

listed ordering physician as self. 3. Review of the laboratory's policy, Review of Results [written as seen} signed by the Laboratory Director on 2/10/20 read, "Transcribe all test results performed in-house onto facility reporting forms or utilize chartable reports per analyzer. Ensure that all pertinent information, including patient name, sex, birth date, ordering physician, date and time of draw phlebotomist initials and date and time of report with initials of staff performing test are recorded on result forms. C. Test Reports test reports will contain the following elements: ii Ordering provider name." On 7/22/26 at 1:37 PM, the Operations Manager and Administrator Coordinator confirmed the physician's name was not accurately transcribed as the ordering physician for patient #1, patient #2 and patient #3 in three final patient reports.