

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0283602	(X3) Date Survey Completed 03/16/2022
Name of Provider or Supplier Goodman Neil F Md Pa	Street Address, City, State 4675 Ponce De Leon Blvd Ste 204, Miami, 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	A recertification survey conducted on 03/16-24/2022 found the clinical laboratory GOODMAN NEIL F MD PA not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to label controls currently in use with the new expiration date. Findings include: - During the laboratory tour on 03/16/2022 at 10:00 AM, the surveyor observed that the laboratory had in use Alere (Trademark) Human Chorionic Gonadotropin Hormone (hCG) Positive (lot CCO1327) and Negative (lot N00198) controls with no open date and no new expiration date registered. Photographic evidence collected. - Review of the package insert for the controls in the section for Storage & Stability revealed that: When stored refrigerated (2-8 C), the unopened controls are stable until the expiration date. Once opened, the controls are stable at refrigerated storage temperatures for 90 days from the date of opening or until the expiration date, whichever comes first. - Review of patients log revealed that the controls first use was 01/05/2022. During an interview on 03/16/2022 at 11:30 AM, the Testing Personnel A, confirmed that controls in use were not label as described above.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to ensure the immersion oil was not expired prior to patient testing from 01/11/2020 to 03/16/2022. Findings include: -During the laboratory tour on 03/16/2022 at 10:05 AM, the surveyor observed that the laboratory had in use immersion oil (lot 7347) used for semen microscopic analysis with an expiration date of 01/10/2020. Photographic evidence collected. -According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/15/2022, the laboratory had an estimate annual test volume of 387 semen analysis tests per year. During an interview on 03/16/2022 at 11:30 AM, Testing Personnel A, confirmed that the immersion oil in use was expired.