

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2076047	(X3) Date Survey Completed 04/10/2025
Name of Provider or Supplier New Life Plastic Surgery	Street Address, City, State 8400 Sw 8th St, 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	An unannounced CLIA complaint survey with #2025001876 was conducted at NEW LIFE PLASTIC SURGERY from 04/02/2025 to 04/10/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D1000	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood - non-automated (3) Ovulation tests visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. (d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory was performing testing under their Certificate of Waiver that was not within the waived</p>

category at least since 2023. Findings include: 1-During the laboratory tour on 04/02/2025 at 10:30 AM the surveyor found that the laboratory had one box with a label that said: COT One STEP Cotinine Test Device Lot 0000867932 expiration 2026-04-16. 2-Review of the manufacturer package, revealed that the "COT One Step Cotinine Test Device (Urine) is a lateral flow Chromatographic immunoassay for the detection of Cotinine in human urine". The insert does not provide a classification of the test as waived; the Kit was manufactured in China for Alere San Diego. 3-A random sample of patients for 2025 revealed one patient tested on 02//21/2025 (positive result), one patient tested 03/11/2025 (negative result). 4-Review of Form CMS 116 signed by the new Laboratory Director on 04/07/2025 revealed that the laboratory had an annual volume of 1,000 tests. 5-During an interview on 04/10/2025 at 11:20 am, the Laboratory Manager confirmed that the laboratory was not aware that the test was not waived.

D1001

CERTIFICATE OF WAIVER TESTS
CFR(s): 493.15(e)

493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

This STANDARD is not met as evidenced by:
Based on laboratory tour, record review and staff interview, the laboratory failed to follow manufacturer's instructions for temperature monitoring for testing at least since April of 2023 through April 2025 for period reviewed. Findings included: 1- During laboratory tour approximately 10:15 AM observed that the laboratory did not maintain a record of temperature monitoring for the following testing: a. HCG Urine Pregnancy test b. Drug Abuse Test Cup Multi-drugs Test Panel with Adulterants c. COT ONE Step Cotinine Test 2- Review of the manufacturer instructions revealed the Storage and Stability for each laboratory test stated temperature ranges. a. HCG Urine Pregnancy test stated "Store as packaged in the sealed pouch at 36-86 F/2-30 C." b. Drug Abuse Test Cup Multi-drugs Test Panel with Adulterants stated "Store as packaged in the sealed pouch either at room temperature or refrigerated 2-30 C, 36-86 F." c. COT ONE Step Cotinine Test stated "Store as packaged in the sealed pouch either at room temperature or refrigerated 2-30 C." 3- During an interview on 04/02/2025 at approximately 11:35 AM, the laboratory Medical Assistant admitted that the laboratory did not record temperature for the testing performed. B Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions for "Mac Kesson Drug of Abuse Test Cups" of doing a confirmation test for positive tests at least since April 2023 through 2025. Findings included: 1-Review of Manufacturer Instructions For Use (MFU) revealed that on page 2 on Section "LIMITATIONS", said that "The One STEP Multi-Drug Screen Test Cup provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/mass spectrometry is the preferred confirmatory test." 2-Review of a patient with a Tetrahydrocannabinol (THC) positive test result on 03/11/2025, revealed that no further test was done for confirmation of the positive result. The surgery center proceeded with the surgery. 4- Review of Form CMS 116 signed by the new Laboratory Director on 04/07/2025 revealed that the laboratory had an annual volume of 1,000 tests 5-During an interview on 04/02/2025 at 11:30 am, the Laboratory Manager, confirmed that the

laboratory was not sending out positive results for confirmation and that the clinic did not keep record of patients with positive test results which ended with surgery cancellation.