

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2107297	(X3) Date Survey Completed 09/10/2026
Name of Provider or Supplier Solstice Counseling Services, Inc	Street Address, City, State 300 Birmingham Road, Pemberton, NJ	
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 conducted on September 10, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's written policies and procedures, review of the laboratory's test records, and interview with the Technical Consultant (TC), the laboratory failed to establish and follow written policies and procedures of conditions for specimen transportation for 2 of 2 years (2025 and 2026). Findings Included: 1) The laboratory could not provide written policies and procedures of conditions for specimen transportation (e.g. temperature) for urine toxicology samples sent from outside satellite facilities for testing. 2) Review of test records on 9/10/2026 revealed the following urine samples sent, processed, and run at the laboratory from surrounding satellite facilities: a. Cherry Hill - 23 urine samples b. Woodbury - 47 urine samples 3) Review of the laboratory's test volume revealed approximately 80,000 urine toxicology tests run annually. 4) In an interview on 9/10/2026 at 11:30 AM, the TC confirmed the laboratory failed to establish policies established for specimen transportation conditions.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, review of the laboratory's temperature records and interview with the Technical Consultant (TC), the laboratory failed to define room temperatures in accordance with manufacturer's instructions for 2 of 2 years (2025 and 2026). Findings Included: 1) During a tour of the laboratory on 9/10/2026 at 11:00AM, one Thermo Scientific CEDIA Buprenorphine Assay reagent (Lot Number 75559255) was observed stored in the refrigerator available for use. 2) Review of the manufacturer's package insert from Thermo Scientific titled 'CEDIA Buprenorphine Assay REF 10015658' stated the following on page 1 of 3: "Cap bottle 2 and let stand approximately 5 minutes at room temperature (15 to 25 degrees Celsius). Mix again. Record the reconstitutions date on the bottle label. Place the bottle directly into the reagent compartment of the analyzer or into refrigerated storage (2 to 8 degrees Celsius) and let stand 30 minutes before use". 3) Review of the laboratory's temperature records in 2025 and 2026 revealed an acceptable laboratory room temperature range of 18 to 30 degrees Celsius. The laboratory's acceptable upper temperature threshold exceeded the manufacturer's requirements. 4) In an interview on 9/10/2026 at 11:30 AM, the TC confirmed the laboratory's acceptable room temperature range was not defined in accordance with manufacturer's instructions.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on direct observation, review of the laboratory's Quality Control (QC) records, written policies and procedures, and interview with the Technical Consultant (TC), the laboratory failed to take corrective action of evaluating patients since the last acceptable test run after QC failures on the Thermo Fisher Scientific Indiko Plus Analyzer for 3 of 52 testing days (Random review from May 1 to June 30, 2026). Findings Included: 1) During a laboratory tour on 9/10/2026 at 11:00AM, one Indiko Plus Analyzer was observed in use. 2) Review of the laboratory QC records from May 1 to June 30, 2026, revealed QC failures with subsequent recalibrations performed on the following dates, with no patient evaluations to the last acceptable QC performed as corrective action: a. 5/20/2026, Failed Analyte: Fentanyl 5 Patients run on 5/19

/2026 (MRNs: 012474, 013960, 013236, 014299, 014416 b. 6/2/2026, Failed Analyte: PCP 5 Patients run on 6/1/2026 (MRNs: 002192, 009049, 014214, 013327, 013579 c. 6/10/2026, Failed Analyte: Fentanyl 5 Patient run on 6/9/2026 (MRNs: 014538, 014229, 011994, 014474, 014083) 3) Review of the laboratory's written policy titled 'Solstice Counseling Services Toxicology Quality Control' stated the following on page 3 of 4: 12. The laboratory technician will review the QC daily and evaluate and correct QC results that are not within acceptable range. The technician is to document corrective action taken in the log book ... 13. Daily evaluations will be made by the laboratory general supervisor to insure that the instrument is functioning properly ... B. Action to take if QC is out of range: 1. Recheck/rerun control once 2. Open a fresh bottle of control 3. Repeat using new reagent 4. Recalibrate the instrument 5. Notify the supervisor and suspend testing as directed by the supervisor until problem is resolved ..." The policy did not contain procedures on corrective actions of performing patient evaluations since the last acceptable test run after QC failures requiring recalibration. 4) In an interview on 9/10/2026 at 11:30 AM, the TC confirmed the findings the laboratory failed to perform corrective actions for QC failures requiring recalibration, including conducting patient evaluations to the last acceptable test run.