Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D2301589	**(X3) Date Survey Completed** 03/25/2025
Name of Provider or Supplier Therapeutic Life Choices	**Street Address, City, State** 1728 S Carson Ave, Tulsa, OK	

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	The initial survey was performed on 03/25/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant, and quality assurance manager at the conclusion of the survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of procedure manuals and interview with the laboratory director and technical consultant, the laboratory failed to ensure two of two procedure manuals had been approved, signed, and dated by the laboratory director. Findings include: (1) A review of two procedure manuals identified no evidence they had been signed and dated as approved by the laboratory director as follows: (a) The manual titled "Therapeutic Life Choices QA Procedures" (b) The manual titled, "Laboratory General Policies and Procedures" (2) The manuals were reviewed with the the laboratory director and technical consultant. Both stated on 03/25/2025 at 12:15 pm, the manuals had not been signed and dated as approved by the laboratory director.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for

	the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and technical consultant, the laboratory failed to ensure the performance specification data had been evaluated prior to implementing the new test system for one of one new test methods introduced into the laboratory in June 2024. Findings include: (1) On 03/25/2025 at 11:45 am, the technical consultant stated the laboratory began using the Viva-Pro E analyzer to perform patient Urine Drug Screen (Amphetamines, Barbiturate, Benzodiazepines, Buprenorphine, Cannabinoid, Cocaine Metabolites, Methadone, Opiates, Oxycodone, and Phencyclidine) testing on 06/04/2024; (2) A review of the performance specification records for the analyzer identified no evidence the data had been signed and dated as approved by the laboratory prior to putting into use for patient testing; (3) Interview with the laboratory director and technical consultant on 03/26/2025 at 02:56 pm confirmed there was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use.
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 a review of records, manufacturer's instructions, and interview with the laboratory director and technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for the Viva Pro-E analyzer during the review period of July 2024 through February 2025. Findings include: (1) On 03/25/2025 at 11:45 am, the technical consultant stated the laboratory began using the Viva-Pro E analyzer to perform patient Urine Drug Screen (Amphetamines, Barbiturate, Benzodiazepines, Buprenorphine, Cannabinoid, Cocaine Metabolites, Methadone, Opiates, Oxycodone, and Phencyclidine) testing on 06/04/2024; (2) A review of the "Viva-ProE Quick Reference Guide" identified the following manufacturer's maintenance requirements: (a) Weekly (i) Rinse the Probes (b) Monthly (i) Clean Waste and Trated Water Containers (ii) Fill the Cooling Fluid (iii) Clean Exterior of the Analyzer (iv) Clean Reagent Rotor Compartment (c) Quarterly (i) Replace the Drying Block (3) Maintenance records from July 2024 through February 2025 were requested. Interview with the laboratory director and technical consultant on 03/25/2025 at 04:25 pm confirmed that, although maintenance procedures had been performed during the review period, they had not been documented as performed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by:

	Based on a review of records and interview with the laboratory director and technical consultant, the laboratory failed to perform a negative and positive control material one of ten days of patient Urine Drug Screen testing reviewed. Findings include: (1) On 03/25/2025 at 11:45 am, the technical consultant stated the laboratory began using the Viva-Pro E analyzer to perform patient Urine Drug Screen (Amphetamines, Barbiturate, Benzodiazepines, Buprenorphine, Cannabinoid, Cocaine Metabolites, Methadone, Opiates, Oxycodone, and Phencyclidine) testing on 06/04/2024; (2) A review of QC (Quality Control) and patient testing records for testing performed in October 2024 and February 2025 identified negative and positive QC materials had not been documented as performed each day of patient testing for one of ten days. The specific day of patient testing was 02/04/2025; (3) The records were reviewed with the laboratory director and technical consultant. Both stated on 03/25/2025 at 04:15 pm, negative and positive QC materials had not been documented as performed.