Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2010821	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Troyer Medical, Inc	107 South Central Avenue, Landis, NC	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD) 8/25/22, the laboratory failed to retain all analytic systems records for at least two years. Findings: The laboratory failed to retain Easy RA calibration and maintenance records and laboratory refrigerator and room temperature records for approximately 8 months, from September of 2021 through May of 2022. Interview with the LD at approximately 1:30 p.m. confirmed the laboratory failed to retain calibration, maintenance, and temperature records from September of 2021 through May of 2022. The LD stated they were unable to locate the documentation and it might have been taken by a previous employee.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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 interview with the LD 8/25/22, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: During a tour of the laboratory approximately 12:15-12:30 p.m., the surveyor observed the following items

	in the laboratory's refrigerator, available for use: 1. 1 box GlucoTrol - AQ Level Low (1) and Level High (3) lot #18050010, expiration date 6/21; 2. 2 bottles Henry Schein, Inc. Urine Control Solution Level 1, lot #061033, expiration date 3/22; 3. 2 bottles Henry Schein, Inc. Urine Control Solution Level 2, lot #061034, expiration date 3/22; 4. 1 bottle Medica CREA-U CAL lot #21113, expiration date 4/23/22; 5. 1 box Verichem Urine Chemistry Standard Kit (Levels A, B, C, D, E) lot #G402206, expiration date 6/30/22. During interview at approximately 12:30 p.m., the LD stated she was unaware the expired supplies were in the laboratory's refrigerator.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of performance verification records for cocaine (COC) testing, review of analyzer performance records for the Easy RA toxicology analyzer, review of random patient test report and interview with LD 8/25/22, the laboratory test report was incorrect for the cut-off value established for COC testing. Findings: Review of performance verification records for COC revealed the laboratory had validated the testing for a cut-off value of 300 ng/mL (nanograms per milliliter). Review of analyzer performance records for the Easy RA toxicology analyzer revealed the cut-off value programmed in the analyzer to determine positive or negative results was 300 ng/mL. Review of random patient test report, patient identification number HF233283055, completed 8/12/22, revealed a cut-off value of 200 ng/mL for COC. Interview with LD at approximately 12:30 p.m. confirmed the test report had the incorrect cut-off value for COC testing and also confirmed the value should be 300 ng /mL.