

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2010821	<b>(X3) Date Survey Completed</b>  03/17/2025
<b>Name of Provider or Supplier</b>  Troyer Medical, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) package inserts, laboratory policy, surveyor observation and testing personnel (TP)interview 03/17/25, the laboratory failed to ensure quality control (QC) reagents were labeled with the open date and new expiration date after opening. Findings: Review of package inserts for Immunalysis Tetrahydrocannabinol (THC), Oxycodone (OXY) and Buprenorphine (BUP) Urine Quality Control Sets revealed "Storage, Stability and Handling...The opened bottles are stable for 60 days or the printed expiration date, whichever comes first.". Review of laboratory policy "Quality Control and Calibrations Procedure General Laboratory Policy" revealed "When opening reagents, controls, calibrators, and supplies affected by expiration dates, the container is to be labeled with the opening date (and time if relevant), the expiration date (and time if relevant), and initials of the individual opening it.". At approximately 1:00 p.m. surveyor observed the following 6 bottles of opened and in use Immunalysis QC reagent in the refrigerator door shelf with no open date or new expiration date on the label; 2 bottles of BUP Urine Control - Lot #E54866 and Lot #E54865. 2 bottles of OXY Urine Control - Lot #E55107 and Lot #E55106. 2 bottles of THC Urine Control - Lot #E55108 and Lot #E55109. Interview with TP #1 at approximately 1:00 p.m. confirmed the 6 bottles of QC reagent were opened, in use and not labeled with the open date and new expiration date.</p>