

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D2186874	<b>(X3) Date Survey Completed</b>  03/27/2025
<b>Name of Provider or Supplier</b>  Renest Recovery Support Services	<b>Street Address, City, State</b>  400 Ring Road Ste 155, Elizabethtown, KY	
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>D0000</b>	An initial survey was initiated on 03/27/2025 and concluded on 03/27/2025. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, facility policy review, and a manufacturer's instructions for use, the facility failed to discard 6 of 6 levels of quality control (QC) material when they had exceeded their open-vial stability expiration date. Findings included: A facility policy titled, "Toxicology Quality Control," last reviewed by the facility on 03/21/2024, revealed, "Once the controls are opened they are stable for 30 days." An undated Thermo Scientific package insert for the "MAS DOA Total Liquid Assayed Drugs of Abuse Control," revealed the section titled, "Storage and Stability," included, "Store DOA TOTAL at 2-8C [degrees Celsius]. Unopened vials are stable until the expiration date on the label. Once opened, vials of control are stable for 30 days when stored tightly capped at 2-8C." During an observation on 03/27/2025 at 12:00 PM, an examination of the QC materials in use for urine drug testing (UDS) revealed the vials were labeled with a hand-written open date of 01/09/2025. This was noted for 6 of 6 levels of ThermoFisher Drugs of Abuse Testing (DOAT) QC in use. The facility patient testing logs for the timeframe from 02/09/2025 through 03/26/2025, revealed 733 patients were tested when the QC materials were not stable according to the manufacturer's requirements. During an interview on 03/27/2025 at 12:15 PM, Testing Personnel (TP) #2 confirmed that the expired QC materials were the QC materials currently in use and the handwritten date on the vials indicated the</p>

date they had been put into use. TP #2 stated the controls had been in use since 01/09/2025. TP #2 stated it was her understanding that the QC materials could be used until the manufacturer's preprinted expiration date on the vials. During an interview on 03/27/2025 at 12:30 PM, the Technical Consultant (TC) stated that he was unaware of the manufacturer's open vial stability requirements.