

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2019949	(X3) Date Survey Completed 04/24/2024
Name of Provider or Supplier Wellward Regenerative Medicine	Street Address, City, State 101 North Eagle Creek Drive, Lexington, KY	
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 recertification survey was conducted on 04/24/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of procedure manual, manufacturer's instructions, and confirmed in an interview with the Testing Personnel 1 (TP1), the laboratory failed to label fifteen (15) of twenty (20) in-use reagents with open and revised expiration dates. Findings Include: 1. Observed on 4/24/2024 at 10:35 AM, in the testing area, a sampling of two (2) open reagents stored in the refrigerator included: a. One (1) open bottle of Immunalysis EDDP Calibrator, Lot Number E51122 b. One (1) open bottle Immunalysis EDDP Low Urine Control, Lot Number E51599 The laboratory failed to label the bottles with open and revised expiration dates specified by the manufacturer. 2.Review of manufacturer instructions for a sampling of two (2) reagents titled " Storage and Stability" all stated as follows: Immunalysis EDDP Calibrator, EDDP Low Control Set: "The open vial stability is 60 days stored at 2-8C, not in excess of the expiration date on the label." 3. Review of the procedures manual titled, "V. Utilization, Expiration Dates ", page 40: Subpart b stated, "Date all reagents, etc. with the open day." Subpart c stated, "Date all reagents, etc. with the open expiration date." 3. In an interview on 4/24/2024, at 10:45 AM in the testing area, the TP1 was asked if open dates and expiration dates were placed on the</p>

reagents. The TP1 stated open dates and expiration dates were not placed on the vials. This confirmed the findings.

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 direct observation, review of manufacturer's instructions, procedure manual, and confirmed in an interview with the Laboratory Director (LD), the laboratory failed to follow the manufacturer's instructions for open vial expiration, utilizing 8 of 20 reagents past their expiration dates. Findings include: 1. Observed on 4/24/2024 at 10:50 AM, in the conference area, a word document list of open reagents with receive dates and open dates: a. EDDP Low Control, Lot E51599, b. EDDP High Control, Lot E51600, c. Multi- Level Control 1 Low, Lot E50773 d. Multi-Level Control 1 High, Lot E50772 e. Multi-Level Control 2 Low, Lot E51366, f. Multi-Level Control 2 High, Lot E51367 g. EDDP Calibrator, Lot E51122, h. Multi-Level 2 Calibrator, Lot E51584, Received date for reagents listed: 12/12/2023 Open date for reagents listed: 12/15/2023 Open vial stability expiration date for reagents listed: 2/15/2024 Total number of days still in use after reagents expired: 69 days Total volume of samples processed after 2/15/2024: 350 A sample of patients tested with expired reagents are as follows: a. Sample 100558, tested 2/16/2024 b. Sample 100599, tested 2/22/2024 2. Review of the manufacturer's instructions titled " Storage and Stability" stated as follows: Immunalysis EDDP Calibrator and Control Set: "The open vial stability is 60 days stored at 2-8C, not in excess of the expiration date on the label." Immunalysis Multi-Level Control and Calibrator Set: "Open Vial Stability is 60 days stored at 2-8C" 3. Review of procedure manual titled, "QC Storage and Stability", page 37, stated, " Samples will not be used past the expiration date specified by the manufacturer, including any applicable open-vial expiration dates." 4. In an interview on 4/24/2024, at 11 AM, the LD was asked if the open vials in the refrigerator were still being used for testing. LD stated that they were still in use. This confirmed the findings. Word Key: C = Degrees Celsius