

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		DATE(S) OF INSPECTION 5/27/2026-6/4/2026* FEI NUMBER 1074265	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Edward Payton, Executive Director			
FIRM NAME Lt Col Luke Weather Jr Veterans Affairs Medical Center (113)		STREET ADDRESS 116 N Pauline St	
CITY, STATE, ZIP CODE, COUNTRY Memphis, TN 38104-2193		TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted. Specifically, On 5/27/2026, the operator was observed conducting aseptic manipulations in which the movement of first air in the ISO 5 LAFH (b)(4) was blocked during the aseptic production of the following sterile drug products: - Sodium Phosphate 15mmol in Dextrose 5% 100mL, Order ID: naphos052726, BUD 06/06/2026 - Cefepime 2g, Order ID: cefepime2052726, BUD: 06/11/2026 The operator's hand placement was observed blocking the bag port and needle, and vial stopper and needle. The operator's hands were positioned in a manner that obstructed the unidirectional "first air" between the HEPA filter and the critical work surface. On 5/28/2026, the operator was observed conducting aseptic manipulations in which the movement of first air in the ISO 5 LAFH (b)(4) was blocked during the aseptic production of the following sterile drug products: - Daptomycin (Cubicin) 750 mg/NS 50 mL, Order ID: 84305997, BUD: 05/30/2026			
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- Cefepime/Sodium Chloride 0.9% 50 mL, Batch: 052826FS1, BUD: 06/12/2026 - Bumetanide 3 mg in Dextrose 5% 50 mL, Order ID: 84299952, BUD: 05/29/2026 - Acyclovir 600 mg in Sodium Chloride 0.9% 250 mL, Order ID: 84301319, BUD: 05/29/2026 - Iron Dextran 975 mg in Sodium Chloride 0.9%, Order ID: 84301224, BUD: 05/28/2026 The operator's hand placement was observed blocking the bag port and needle, and vial stopper and needle. The operator's hands were positioned in a manner that obstructed the unidirectional "first air" between the HEPA filter and the critical work surface.			
OBSERVATION 2 Personnel performed aseptic manipulations with exposed hair or skin. Specifically, On 5/27/2026, during the aseptic production of the following drug product: - Ondansetron 8 mg, Dexamethasone 12 mg in Sodium Chloride 0.9% 50mL Order ID: 83618268, BUD 5/27/2026 I observed your operator's head and face enter the ISO 5 LAFH located in the non-hazardous Oncology suite without adequate protective gowning. The skin surrounding the operator's forehead and eyes was visibly exposed and unprotected by appropriate gowning at the time of the aseptic manipulation. On 05/29/2026 during the aseptic production of the following drug products: - Romiplostim 500 mcg/3 mL Syringe, Order ID: 83919777, BUD 5/29/2026 - Ipilimumab (Yervoy) 50 mg in Sodium Chloride 0.9% 100 mL, Order ID: 84304960, BUD 5/29/2026 - Nivolumab 180 mg in Sodium Chloride 0.9% 82 mL, Order ID: 84304861, BUD 5/29/2026			
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Methylprednisolone Sodium Succinate 1,000 mg in Sodium Chloride 0.9% 250 mL, Order ID: 84314922, BUD 5/29/2026 I observed your operator's head and face enter the ISO 5 LAFH located in the non-hazardous Oncology suite without adequate protective gowning. The skin surrounding the operator's forehead and eyes was visibly exposed and unprotected by appropriate gowning at the time of the aseptic manipulation.			
OBSERVATION 3 Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow. Specifically, On 06/02/2026, during aseptic production operations, an operator was observed moving quickly within ISO 5 LAFH (b)(4) while performing aseptic manipulations. At the time of the observation, the operator had an exposed, filled syringe of sterile drug product in hand. Rapid personnel movement within the ISO 5 critical zone is likely to disrupt unidirectional (first air) airflow, thereby compromising the sterile air barrier protecting exposed drug products and critical sites from potential microbial and particulate contamination. The following drug products were being aseptically produced at the time of this observation: - Daptomycin 750 mg in Sodium Chloride 0.9% 50 mL, BUD 06/04/2026, Order ID: 84305998 - Sodium Bicarbonate 8.4% 150 mEq in Dextrose 5% 1000 mL, BUD: 06/03/2026, Order ID: 84327268			
OBSERVATION 4 Lack of disinfection of supplies at each transition from areas of lower quality air to areas of higher quality air.			
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Specifically, On 5/28/2026, during the aseptic production of the following drug products: - Daptomycin (Cubicin) 750 mg/NS 50 mL, Order ID: 84305997, BUD: 05/30/2026 - Cefepime/Sodium Chloride 0.9% 50 mL, Batch: 052826FS1, BUD: 06/12/2026 - Bumetanide 3 mg in Dextrose 5% 50 mL, Order ID: 84299952, BUD: 05/29/2026 - Acyclovir 600 mg in Sodium Chloride 0.9% 250 mL, Order ID: 84301319, BUD: 05/29/2026 - Iron Dextran 975 mg in Sodium Chloride 0.9%, Order ID: 84301224, BUD: 05/28/2026 The following deficiencies were observed: - I observed an operator retrieving needles from a shelf beneath the ISO 5 LAFH (b)(4), located in the ISO 7 In-Patient Pharmacy Suite, and placing them directly onto the working surface of the ISO 5 LAFH without performing any disinfection step. - I observed an operator retrieving multiple components and supplies from a white bin located outside of the ISO 5 environment. The operator cradled the items in their arms while wearing a non-sterile gown and then placed them directly into the ISO 5 LAFH (b)(4) located in the ISO 7 In-Patient Pharmacy Suite, without performing any disinfection step.			
OBSERVATION 5 Smoke studies were inadequately performed under dynamic conditions. Specifically, your firm failed to adequately perform smoke studies under dynamic conditions to demonstrate unidirectional airflow, simulate aseptic production, simulate worst-case conditions			
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including all components, materials, and equipment present during actual or routine aseptic operations, and an adequate air quality environment within your ISO 5 critical areas. The following deficiencies were observed: 1. Turbulent air was noted in the following videos • Oncology BSC - Dynamic.mp4 (b)(4) • LAFW (b)(4) - Dynamic.mp4 (b)(4) • LAFW (b)(4) - Dynamic.mp4 (b)(4) 2. Inadequate Smoke Volume: Insufficient smoke was used, limiting the ability to adequately visualize airflow patterns, during dynamic smoke studies conducted for the following: • Modular – LAFW (b)(4) • Modular – LAFW (b)(4) • LAFW (b)(4) – Dynamic • LAFW (b)(4) – Dynamic • BSC (b)(4) Dynamic 3. Failure to Simulate Routine Aseptic Operations: The smoke studies do not simulate all aseptic operations, interventions, and manipulations performed during routine manufacturing activities. This deficiency was observed in the following videos: • LAFW (b)(4) - Dynamic.mp4 • LAFW (b)(4) - Dynamic.mp4 • BSC (b)(4) - Dynamic.mp4 • Oncology LAFW - Dynamic.mp4 • Oncology BSC - Dynamic.mp4			
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4. The dynamic smoke study video for BSC (b)(4) - Dynamic.mp4 does not capture the entire work area. The equipment producing the smoke is cut off within the video frame. 5. In the following videos, the smoke study failed to capture all critical steps of the production process, as aseptic simulation was initiated prior to the introduction of smoke, thereby preventing visualization of airflow during critical manipulations. - LAFW (b)(4) - Dynamic.mp4 - LAFW (b)(4) - Dynamic.mp4 - BSC (b)(4) - Dynamic.mp4			
OBSERVATION 6 Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area. Specifically, your operator failed to disinfect the (b)(4) machine between aseptic production operations. For example: On 5/27/2026, during the aseptic production of the following drug products, the operator failed to disinfect the (b)(4) machine between aseptic production operations: - Sodium Phosphate 15mmol in Dextrose 5% 100mL, Order ID: naphos052726, BUD 06/06/2026 - Cefepime 2g, Order ID: cefepime2052726, BUD: 06/11/2026 On 5/28/2026, during the aseptic production of the following drug products, the operator failed to disinfect the (b)(4) machine between aseptic production operations: - Daptomycin (Cubicin) 750 mg in Sodium Chloride 0.9% 50 mL, Order ID: 84305997, BUD: 05/30/2026			
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- Cefepime in Sodium Chloride 0.9% 50 mL, Batch: 052826FS1, BUD: 06/12/2026 - Bumetanide 3 mg in Dextrose 5% 50 mL, Order ID: 84299952, BUD: 05/29/2026 - Acyclovir 600 mg in Sodium Chloride 0.9% 250 mL, Order ID: 84301319, BUD: 05/29/2026 - Iron Dextran 975 mg in Sodium Chloride 0.9%, Order ID: 84301224, BUD: 05/28/2026 On 5/29/2026, during the aseptic production of the following drug products, the operator failed to disinfect the Omnicell IVX machine between aseptic production operations: - Romiplostim 500 mcg/3 mL Syringe, Order ID: 83919777, BUD 5/29/2026 - Ipilimumab (Yervoy) 50 mg in Sodium Chloride 0.9% 100 mL, Order ID: 84304960, BUD 5/29/2026 - Nivolumab 180 mg in Sodium Chloride 0.9% 82 mL, Order ID: 84304861, BUD 5/29/2026 - Methylprednisolone Sodium Succinate 1,000 mg in Sodium Chloride 0.9% 250 mL, Order ID: 84314922, BUD 5/29/2026			
OBSERVATION 7 Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces. Specifically, observations include, but are not limited to, the following: - Peeling and Chipped Paint – Non-Hazardous Oncology Pharmacy SCA- Peeling and chipped paint was observed on both side of the door frame and surrounding walls of the non-hazardous Oncology Pharmacy Segregated Compounding Area (SCA). This room contains an ISO 5 classified LAFH used to produce sterile drug products. - Protruding Sprinkler Head – In-Patient Pharmacy ISO 7 Classified Cleanroom (Hazardous)- A protruding sprinkler head was observed in the ceiling of the In-Patient Pharmacy ISO 7 classified cleanroom used to produce sterile hazardous drugs. The sprinkler head is located directly above the ISO 5 classified LAFH. The sprinkler head is not on a routine cleaning schedule and the date of last			
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cleaning is unknown. - Protruding Sprinkler Head – In-Patient Pharmacy ISO 7 Classified Cleanroom (Non-Hazardous)- A protruding sprinkler head was observed in the ceiling of the In-Patient Pharmacy ISO 7 classified cleanroom used to produce sterile non-hazardous drugs. The sprinkler head is located in the ceiling between ISO 5 classified LAFH (b)(4) and LAFH (b)(4) - Protruding Sprinkler Head – Oncology Pharmacy SCA (Hazardous)- A protruding sprinkler head was observed in the ceiling of the Oncology Pharmacy Segregated Compounding Area (SCA) used to produce sterile hazardous drugs. The sprinkler head is located in the ceiling adjacent to the ISO 5 classified BSC. The sprinkler heads observed are not on a routine cleaning schedule and the date of last cleaning is unknown.							
OBSERVATION 8 Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions. Specifically, your firm's media fill protocol does not closely simulate the manipulations, container/closure configurations, or fill volumes used during actual production operations. For example, - During actual production, operators use syringe(s) to admix drug product into prefilled bags, sometimes changing the (b)(4) between each product addition. However, during media fill simulations, the operator aliquot (b)(4) of media and transfer it between (b)(4) bags (b)(4) dispensing into (b)(4) vials for incubation. - During media fill simulations, operators dispense approximately (b)(4) of media into (b)(4) vials for incubation which does not represent final fill volume of your firm's sterile drug products. However, during actual production operations, operators fill prefilled bags (ranging from (b)(4)) or syringes.							
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> EMPLOYEE(S) SIGNATURE Demario L Walls, Investigator </td> <td style="width: 40%; border: none; text-align: center;"> DATE ISSUED 6/4/2026 </td> </tr> <tr> <td style="border: none; vertical-align: bottom;"> Demario L Walls Investigator Signed By: DEMARIO L WALLS - Date Signed: 06-04-2026 14:46:32 </td> <td style="border: none;"></td> </tr> </table>		EMPLOYEE(S) SIGNATURE Demario L Walls, Investigator	DATE ISSUED 6/4/2026	Demario L Walls Investigator Signed By: DEMARIO L WALLS - Date Signed: 06-04-2026 14:46:32	
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OBSERVATION 9 Materials were exposed to lower than ISO 5 quality air. Specifically, on 5/28/2026, I observed sterile wipes stored on a counter across from ISO 5 LAFH (b)(4) within the ISO 7 classified cleanroom. The wipes were opened and exposed to ISO 7 air quality and were subsequently used to clean and disinfect the surfaces of the ISO 5 LAFH. According to staff, the wipes are stored in the ISO 7 environment until contents are fully depleted. Drug products aseptically produced on 5/28/2026 include but are not limited to - Daptomycin (Cubicin) 750 mg/NS 50 mL, Order ID: 84305997, BUD: 05/30/2026 - Cefepime/Sodium Chloride 0.9% 50 mL, Batch: 052826FS1, BUD: 06/12/2026 - Bumetanide 3 mg in Dextrose 5% 50 mL, Order ID: 84299952, BUD: 05/29/2026 - Acyclovir 600 mg in Sodium Chloride 0.9% 250 mL, Order ID: 84301319, BUD: 05/29/2026 - Iron Dextran 975 mg in Sodium Chloride 0.9%, Order ID: 84301224, BUD: 05/28/2026 On 5/29/2026, I observed sterile wipes stored in a cart adjacent to the ISO 5 LAFH in segregated compounding area (SCA) in the Oncology Pharmacy Suite. The wipes were opened and exposed to unclassified air and were subsequently used to clean and disinfect the surfaces of the ISO 5 LAFH. According to staff, the wipes are stored in the SCA until contents are fully depleted. Drug products aseptically produced on 5/29/2026 include but are not limited to - Romiplostim 500 mcg/3 mL Syringe, Order ID: 83919777, BUD 5/29/2026			
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*DATES OF INSPECTION 5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri), 6/01/2026(Mon), 6/02/2026(Tue), 6/03/2026(Wed), 6/04/2026(Thu)		
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."