

**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 04/08/2026-04/16/2026*
	FEI NUMBER 1073935

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Randall W. Weaver, Deputy Chief of Staff Montgomery

FIRM NAME Central Alabama Veterans Health Care System - West Campus	STREET ADDRESS 215 Perry Hill Rd
CITY, STATE, ZIP CODE, COUNTRY Montgomery, AL 36109-3725	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**

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,

- A. The media fill instructions in section 8(k) of SOP 119-19-12 require compounders use the (b) (4) Validation (b)(4) which contains (b) (4), and (b) (4). The (b) (4) during media fill does not closely simulate the (b)(4) consecutive drug product vials I saw (b) (4) during routine compounding of Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL compounded sterile product (CSP), barcode 719803357553V28, on 04/10/26.
- B. Compounders use a new syringe for every vial and ampule during media fill. I watched a compounder using the same syringe to (b) (4) (b)(4) vials during routine compounding of Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803357553V28, on 04/10/26.
- C. Your firm did not incubate all intact media fill units. A technician completed initial (b) (4) gowning competency (glove) qualification, media fill, and post-media fill surface sampling on about 10/30/25. Compounding personnel explained four of the (b)(4) pre-compounding fingertip samples, the post-compounding fingertip samples, and the post-compounding surface sample were dropped and subsequently discarded on an unspecified date. The intact media fill unit and (b)(4) fingertip samples did not fall and were kept. Your firm sent the (b)(4) intact fingertip samples from 10/30/25 to the contract laboratory with all the samples and media bag collected during a repeat media fill on about 11/24/25. There is no justification for not sending the original media fill bag from 10/30/25 to the contract laboratory for incubation, especially when your firm sent the intact fingertip samples from that same day. The media fill bag was held in an inadequately calibrated (b) (4) incubator for an unknown period before it was discarded.

OBSERVATION 2

Smoke studies were inadequately performed under dynamic conditions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L Hunt, Senior CSO	Nicholas L Hunt Senior CSO Signed By: Nicholas L. Hunt -G Date Signed: 04-16-2026 13:20:28 X	DATE ISSUED 04/16/2026

**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 04/08/2026-04/16/2026*
	FEI NUMBER 1073935

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Randall W. Weaver, Deputy Chief of Staff Montgomery

FIRM NAME Central Alabama Veterans Health Care System - West Campus	STREET ADDRESS 215 Perry Hill Rd
CITY, STATE, ZIP CODE, COUNTRY Montgomery, AL 36109-3725	TYPE ESTABLISHMENT INSPECTED producer of sterile drug products

Specifically, the most recent smoke study video available to review for your (b) (4) ISO 5 compounding aseptic (b) (4) is dated 07/20/25. It did not contain enough information to verify airflow was suitable for aseptic compounding.

- There was not enough smoke to visualize airflow in the direct compounding area of the ISO 5 (b) (4). An approximately one-inch diameter stream of smoke was jetted directly onto the critical sites of the simulated CSP and (b) (4) from less than one foot away.
- There was no smoke introduced throughout the ISO 5 (b) (4) to determine if there was turbulent flow or dead spots.
- The two vials and one syringe used to simulate dynamic conditions during the smoke study were not representative of routine operations I observed, or the highest complexity operation used to produce CSPs. Items inside the ISO 5 (b) (4) during routine compounding of Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803357553V28, on 04/10/26 included: a (b) (4) bin used to hold materials, about (b) (4) drug product vials, saline bag, syringe, needle, pair of sterile gloves, bottle of sterile (b) (4) hanging from an IV bar, and a pack of sterile wipes.
- The study did not introduce smoke or verify recovery time of unidirectional airflow inside the ISO 5 (b) (4) attached to the ISO 5 (b) (4). I watched the compounder move materials from the unclassified SCA into the ISO 5 (b) (4) and then immediately move the items into the ISO 5 (b) (4) during production of Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL compounded sterile product (CSP), barcode 719803357553V28, on 04/10/26.
- The (b) (4) sliding door between the ISO 5 (b) (4) and ISO 5 (b) (4) was not evaluated during the smoke study for potential airflow disruption when compounders open it and (b) (4) into the (b) (4).
- The smoke study did not evaluate opening the (b) (4) outer door that connects to the unclassified SCA.

OBSERVATION 3

Use of non-sterile disinfecting agents in the ISO 5 area.

Specifically,

- I watched a compounder wipe the (b) (4) bin and all materials needed to produce Category 1 compounded sterile products (CSPs) with nonsterile (b) (4) in the unclassified SCA, move these items into the ISO 5 (b) (4) and then move the items into the ISO 5 (b) (4) (b) (4) without wiping them with a sterile disinfectant or sterile (b) (4). Category 1 CSPs produced with these materials include:
 - Iron Sucrose 200 mg/Sodium Chloride 0.9% 100 mL CSP, barcode 73513V15, on 04/09/26
- I watched a compounder disinfect all surfaces in the ISO 5 (b) (4) and unclassified segregated compounding area (SCA) with nonsterile (b) (4) production and (b) (4) during the day per the approved procedure SOP 119-19-12. CSPs produced in the (b) (4) include:
 - Iron Sucrose 200 mg/Sodium Chloride 0.9% 100 mL CSP, barcode 73513V15, on 04/09/26
 - Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803357553V28, on 04/10/26
 - Briumvi (ublituximab-xiiv) 450 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803356510V10, on 04/10/26

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L Hunt, Senior CSO	Nicholas L Hunt Senior CSO Signed By: Nicholas L. Hunt -G Date Signed: 04-16-2026 13:20:20 X	DATE ISSUED 04/16/2026

**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 04/08/2026-04/16/2026*
	FEI NUMBER 1073935

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Randall W. Weaver, Deputy Chief of Staff Montgomery

FIRM NAME Central Alabama Veterans Health Care System - West Campus	STREET ADDRESS 215 Perry Hill Rd
CITY, STATE, ZIP CODE, COUNTRY Montgomery, AL 36109-3725	TYPE ESTABLISHMENT INSPECTED producer of sterile drug products

OBSERVATION 4

Lack of disinfection of supplies at each transition from areas of lower quality air to areas of higher quality air.

Specifically,

- A. The (b) (4) bin, drug product vials, unopened syringes and needles, pack of sterile wipes, pack of sterile gloves, and other materials wiped with (b) (4) remained in the unclassified SCA about (b) (4) before they were placed into the ISO 5 (b) (4) to the ISO 5 (b) (4) on the (b) (4) ISO 5 (b) (4). The compounder did not sanitize the items again before introducing them into the ISO 5 (b) (4) to produce one Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803357553V28, on 04/10/26.
- B. The bottom of the (b) (4) bin containing items for the Remicade CSP directly contacted items when the compounder placed it on top of the bin containing sanitized material for a Briumvi CSP. The compounder did not sanitize the items again before introducing them into the ISO 5 (b) (4) (b) (4) to produce one Briumvi (ublituximab-xiyy) 450 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803356510V10, on 04/10/26.

OBSERVATION 5

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically, there was visible residue on the walls and direct compounding area in the ISO 5 (b) (4) and ISO 5 (b) (4) on the (b) (4) during production of sterile products. CSPs produced in the (b) (4) include:

- Iron Sucrose 200 mg/Sodium Chloride 0.9% 100 mL CSP, barcode 73513V15, on 04/09/26
- Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803357553V28, on 04/10/26
- Briumvi (ublituximab-xiyy) 450 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803356510V10, on 04/10/26

OBSERVATION 6

Inadequate routine environmental monitoring in the ISO 5 area.

Specifically,

- A. Environmental monitoring (EM) and Media Fill records from the previous six months document your firm regularly kept media fill, gloved fingertip and thumb (GFT), and surface EM microbiology samples for multiple weeks, and in one instance more than one month, before sending them to the contract laboratory for incubation and testing. Personnel store the samples in a (b) (4) incubator that is not monitored or calibrated at that temperature range. There is inadequate justification to delay initiating incubation. The required incubation scheme for GFT and EM samples per SOP 119-19-12 starts with (b) (4) incubation before transfer to (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L Hunt, Senior CSO	Nicholas L Hunt Senior CSO Signed By: Nicholas L. Hunt -G Date Signed: 04-16-2026 13:20:28 X _____	DATE ISSUED 04/16/2026

**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 04/08/2026-04/16/2026*
	FEI NUMBER 1073935

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Randall W. Weaver, Deputy Chief of Staff Montgomery

FIRM NAME Central Alabama Veterans Health Care System - West Campus	STREET ADDRESS 215 Perry Hill Rd
CITY, STATE, ZIP CODE, COUNTRY Montgomery, AL 36109-3725	TYPE ESTABLISHMENT INSPECTED producer of sterile drug products

B.I observed one tray of (b) (4) (b) (4) stored in its (b) (4) tray exposed to the light in your inpatient pharmacy. The manufacturer Directions for Use instruct users to protect the (b) (4) from light. Compounders use these (b) (4) for GFT sampling and surface sampling the direct compounding area inside the ISO 5 (b) (4) and (b) (4) in the (b) (4) ISO 5 (b) (4)

OBSERVATION 7

No measurement of room pressure differentials was observed during operations to demonstrate proper airflow.

Specifically, your firm does not adequately monitor differential pressure in the (b) (4) ISO 5 (b) (4). The (b) (4) standard configuration has Minihelic gauges for the (b) (4) and (b) (4) that are not connected to an audible alarm or alarm indicator light on the (b) (4) control panel. Additionally, personnel do not document differential pressure readings from either Minihelic gauge at least (b) (4) on days of compounding. CSPs I saw produced inside the (b) (4)

- Iron Sucrose 200 mg/Sodium Chloride 0.9% 100 mL CSP, barcode 73513V15, on 04/09/26
- Remicade (infliximab) 750 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803357553V28, on 04/10/26
- Briumvi (ublituximab-xiyy) 450 mg/Sodium Chloride 0.9% 250 mL CSP, barcode 719803356510V10, on 04/10/26

OBSERVATION 8

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically, your unclassified segregated compounding area (SCA) established within the inpatient pharmacy contains surfaces that are not easily disinfected, impervious, free from damage, or are particle generating. The SCA does not have specific physical boundaries but is defined as a (b) (4) buffer zone around the (b) (4) ISO 5 (b) (4). The SCA contains a cracked drop ceiling tile which potentially allows the intrusion of air from the plenum, an exposed sprinkler head, an air supply vent, an approximate 1-inch hole in the drywall, textured mineral fiber drop ceiling tiles, (b) (4) small incubators, and (b) (4) oral solid dose counting machines. These surfaces could compromise the ISO 5 environment, particularly when the (b) (4) door is opened during cleaning, maintenance, or compounding activities. The SCA floor and ceiling are not included in the (b) (4) or (b) (4) cleaning and disinfection logs.

***DATES OF INSPECTION**

4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L Hunt, Senior CSO	Nicholas L Hunt Senior CSO Signed By: Nicholas L. Hunt -G Date Signed: 04-16-2026 13:20:28 X	DATE ISSUED 04/16/2026

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."