accepted 12/29/21 TW

PRINTED: 12/22/2021
FORM APPROVED

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C6301	A. BUILDING: _____ B. WING _____	12/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WEST ALABAMA WOMEN'S CENTER, INC	535 JACK WARNER PARKWAY, SUITE I TUSCALOOSA, AL 35404

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	INITIAL COMMENTS An onsite licensure survey was conducted on 12/14/21. West Alabama Women's Center was not in compliance with the Rules of Alabama State Board of Health, Chapter 420-5-1 Abortion or Reproductive Health Centers. The following deficiencies were cited and require a Plan of Correction.	L 000		
L 100	ALABAMA LICENSURE DEFICIENCIES THE FOLLOWING ARE LICENSURE DEFICIENCIES AND REQUIRE A PLAN OF CORRECTION. This Rule is not met as evidenced by: 420-5-1-.03 1. Patient Care. All patient care must be rendered in accordance with all applicable federal, state, and local laws, these ruses, and current standards of care, including all professional standards of practice... 8. Infection Control (b) Sterilization. Definitive written procedures governing sterilization techniques shall be developed...Procedures are to include: 5. Proper methods of preparation of items for sterilization (cleaning, wrapping and dating). 7. Use of sterilizer indicators. Based on review of policy and procedure, CDC (Center for Disease Control) Recommendations Guidance for Healthcare Providers Hand Hygiene, autoclave maintenance logs and	L 100		

Health Care Facilities
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Robin Marty

TITLE: Operations Director

(X6) DATE: 12/29/21

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C6301	A. BUILDING: _____ B. WING _____	12/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WEST ALABAMA WOMEN'S CENTER, INC	535 JACK WARNER PARKWAY, SUITE I TUSCALOOSA, AL 35404

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 100	Continued From page 1 Interviews It was determined the facility failed to ensure: a. Instruments used for abortions were inspected for damage, discarded and replaced when no longer safe for patient use. b. Dilution and preparation of concentrated enzymatic cleaning products were prepared at the recommended ratio. c. Biological spore testing strips were properly labeled with the autoclave identification. d. Biological spore test results were obtained from the outside testing service. e. Staff removed contaminated gloves and performed hand hygiene prior to obtaining clean supplies. These deficient practices had the potential to affect all patients served by the facility. Findings include: Facility Policy: Sterilization Protocol Updated 10/2021 Policy Statement: Sterilization is the process by which all forms of microorganisms are destroyed, including viruses, bacteria, fungi, and spores... Purpose: To ensure sterility of instruments and any other supplies processed in all steam sterilization cycles...	L 100		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C6301	A. BUILDING: _____ B. WING _____	12/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WEST ALABAMA WOMEN'S CENTER, INC	535 JACK WARNER PARKWAY, SUITE I TUSCALOOSA, AL 35404

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 100	Continued From page 2 Procedure: 1. Cleaning A. Once instruments are used, they are transported to the sterilization room to the Soiled Area. a. Don appropriate personal protective equipment (PPE)... ...e. Instruments are inspected for any damage. Damaged instruments are disposed of in the red bin... ...l. Instruments are rinsed and then placed in the Crosszyme liquid bath in the left sink. The instruments soak for at least 20 minutes. B. Once the 20 minutes of soaking in Crosszyme have been completed, remove the instruments, rinse under running water and place on drying racks to completely air dry in the Clean Area. Autoclave Maintenance III. Monthly Maintenance A. The autoclave should be flushed with distilled water, using appropriate cleaning fluids. In addition to the chemical indicator strips added to each package, a biological indicator for spores (spore testing) is performed every 40 service hours (60 cycles) for each autoclave. The test results are sent to an outside testing service. Source: CDC Website Topic: Hand Hygiene Recommendations Guidance for Healthcare Providers about Hand	L 100	On December 27, 2021, new instruments were purchased to ensure that all tools are undamaged and in best working order. Damaged instruments have been discarded. Current instruments will be inspected on a monthly basis by Clinic Administrator, who will order and replace inventory on a continuous and as needed basis. Instrument inspection examination added to Monthly Quality Assurance Checklist as "Check all sterilized instruments. All packages are checked to ensure no packages are torn, wet, or sterility compromised. Check instruments for damage and discard if necessary." Sterilization procedure updated on December 27, 2021 to include the following: "Prepare left side sink with solution of cleaner with a 10:1 ratio water to Crosszyme Ultrasonic Solution." and: "Also, hinged instruments are to be scrubbed, soaked, dried and autoclaved in the open position. Speculums are to be disassembled and their parts scrubbed, soaked and dried. They are only reassembled after complete drying prior to wrapping in kit for the autoclave." (See attached revised sterilization protocol). Sign placed in sink area on December 28, 2021 with reminder to properly ratio cleaner to water at 1:10 (see attached sign) Protocol updated on December 27, 2021 to ensure correct documentation of the autoclave serial number when submitting test strips for spore testing reports. (See attached protocol). Clinic Administrator is responsible for autoclave monthly maintenance and will sign off on the task on our Monthly Quality Assurance Checklist.	

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C6301	A. BUILDING: _____ B. WING _____	12/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WEST ALABAMA WOMEN'S CENTER, INC	535 JACK WARNER PARKWAY, SUITE I TUSCALOOSA, AL 35404

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 100	Continued From page 3 Hygiene... Updated: May 17, 2020 Hand Hygiene Guidance The Core Infection Prevention and Control Practices for Safe Care Delivery in All Healthcare Settings recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) include the following strong recommendations for hand hygiene in healthcare settings. Healthcare personnel should use an alcohol-based hand rub or wash with soap and water for the following clinical indications: After touching a patient or the patient's immediate environment. After contact with blood, body fluids, or contaminated surfaces. Immediately after glove removal. Healthcare facilities should: Require healthcare personnel to perform hand hygiene in accordance with Centers for Disease Control and Prevention (CDC) recommendations An observation and inspection of the sterilization area was conducted 12/14/21 from 10:10 AM to 11:25 AM with EI # 2, Sterilization Technician. EI # 2 was asked to describe the process for instrument cleaning and sterilization. EI # 2 stated the used kits are brought to the dirty sink and placed in the right sink, sprayed with an enzymatic foam spray and allowed to soak for 20 minutes; then rinsed and placed in the left sink. The left sink was filled approximately half full with a liquid solution. EI # 2 stated they use Crosszyme Ultrasonic Cleanser in the left sink - 1	L 100	On December 15, 2021, after ADHP visit, new signage was placed prominently in both the lab and sterilization areas (see sign attached) as reminder to staff about proper hygiene steps. New updated protocols for detailed hand hygiene added to policy manual section "Lab Safety and General Rules" on Dec. 28, 2021 (See attached). In order to reinforce the importance of hand hygiene throughout the clinic, all employees will be participating in a mandatory CDC training on January 11, 2022. https://www.cdc.gov/handhygiene/providers/training/index.html.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C6301	A. BUILDING: _____ B. WING _____	12/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WEST ALABAMA WOMEN'S CENTER, INC	535 JACK WARNER PARKWAY, SUITE I TUSCALOOSA, AL 35404

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 100	Continued From page 4 *cup of Crosszyme for 1/2 sink of water. Review of* Crosszyme container revealed a ration of 20:1 (20 parts water to 1 part cleaner) for regular cleaning and 10:1 (10 parts water to 1 part cleaner) for "heavy use". EI # 2 stated they use the "heavy use" concentration. When asked how she ensured the correct dilution was obtained EI # 2 stated she used a measuring cup and added 1 cup of cleanser to 1/2 sink of water. When asked how much water was added to the sink to make 1/2 sink full EI # 2 stated "I don't know." The surveyor asked EI # 2 to fill the empty right side sink with water to the 1/2 point using the measuring cup to determine how many cups of water were needed to obtain the correct dilution. It took 30 cups of water. EI # 2 confirmed the dilution she had been preparing was not a 10:1 ratio. When asked what happens after the 20 minute soak in Crosszyme solution, EI # 2 stated the instruments are rinsed and brought to the clean area to wrap. The surveyor asked if the instruments were allowed to air dry, EI # 2 stated "sometimes but I usually dry them with a paper towel." EI # 3, Medical Assistant, entered the sterilization area at 11:15 AM with the products of conception (POC) and a used instrument kit. EI # 3 placed the glass jar containing the POC on the counter top and handed the used instrument tray to EI # 2 for processing. EI # 3 then retrieved a clean glass jar from the countertop and a sterile instrument pack from the cabinet without *changing gloves and performing hand hygiene.* Inspection of a kit processed on 12/13/21 revealed 3 hinged instruments in the closed position; 1 sponge stick and 2 tenaculum forceps	L 100		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C6301	A. BUILDING: _____ B. WING _____	12/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WEST ALABAMA WOMEN'S CENTER, INC	535 JACK WARNER PARKWAY, SUITE I TUSCALOOSA, AL 35404

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 100	Continued From page 5 with rust. Inspection of a second kit processed on 12/13/21 revealed 3 hinged instruments in the closed position; a sponge stick with a crack at the hinge; 1 tenaculum with rust; and 1 needle extender with a black soot-like substance which, when wiped with a paper towel, came off onto the paper towel. There were 3 autoclaves in use at the facility. Review of the 2021 maintenance log book revealed spore-testing was documented as completed after each 60 cycles of operation and strips were mailed to an outside testing service. Results from the outside testing service was not included in the log book. Review of the direction on the box of biologic spore testing strips revealed the results would be available within 48 hours on the company website. The surveyor requested the spore-testing results from the outside testing service. Review of the spore-testing results provided by the facility revealed 6 of the 11 tests results provided, dated 6/1/21 to 12/3/21 failed to include the autoclave identification. There was no documentation that all 3 autoclaves were tested every 60 cycles by an outside testing service. An interview was conducted on 12/14/21 at 4:30 PM with EI # 1, Medical Director, who confirmed damaged instruments should be discarded, cleaning solution to be prepared with correct dilution ratio, spore-testing strips sent to outside testing service should be labeled properly and results obtained, and staff should discard contaminated gloves and perform hand hygiene prior to obtaining clean supplies.	L 100		