

[78C 245.023]

Texas Department of State Health Services

FORM APPROVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140000	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	DATE SURVEY COMPLETED C 06/24/2014
--	--	--	--

NAME OF PROVIDER OR SUPPLIER
WHOLE WOMANS HEALTH OF FORT WORTH, LLC

STREET ADDRESS, CITY, STATE, ZIP CODE
**3256 LACKLAND ROAD
FORT WORTH, TX 76116**

(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
A 00C	<p>The last date on site was 4/16/14. The survey findings were discussed with the facility's representatives during a telephone exit conference on 6/24/14 at 2:50 PM. The facility was provided an opportunity to respond to the survey findings and to provide evidence of compliance with regulations surveyed. No evidence was provided. Deficiencies were cited.</p>	A 000	<p>REVIEWED AUG 06 2014 by: <u>mw</u></p> <p>RECEIVED JUL 08 2014 By: <u>W</u></p>	
A 283		A 283		

SOD - State Facility Laboratory

STATE FORM

E TITLE CORPORATE VICE PRESIDENT (X6) DATE 07/03/14

0459 KO9911

[HSC 245.023]

PRINTED: 08/20/2014
FORM APPROVED

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140000	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	DATE SURVEY COMPLETED C 6/24/2014
--	--	--	---

NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF FORT WORTH, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3258 LACKLAND ROAD FORT WORTH, TX 76116
--	---

(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
A 283		A 283		08/01/14 08/01/14 08/01/14 08/01/14

[HSC 245.023]

REVISED: 06/23/2014
FORM APPROVED

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140000	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	DATE SURVEY COMPLETED C 06/24/2014
--	--	--	--

NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF FORT WORTH, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3256 LACKLAND ROAD FORT WORTH, TX 76116
--	---

(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
A 283		A 283		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140000	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	DATE SURVEY COMPLETED C 06/24/2014
--	--	--	--

NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF FORT WORTH, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3258 LACKLAND ROAD FORT WORTH, TX 76116
--	---

(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
A 326	Continued From page 4 In OR #2, 3 tenaculums, 2 sopers and 3 forceps were observed in the sterilized package in the closed position. Personnel #2 was present and confirmed the findings. The April 2013 "Procedure for Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" policy required, "...All instruments to be sterilized will be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature. All ratches and hinges will be open during sterilization and any sharp tips will be covered in gauze..."	A 326		
A 328	139.49(d)(5)(D)(ii) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (5) Equipment and sterilization procedures. (D) Packaging. (ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave. This Requirement is not met as evidenced by: Based on observation, instrument review and interview, the facility failed to ensure items were labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave, in that, 14 of 14 sterile instruments were observed with incomplete labeling to ensure safe patient use. Findings Included:	A 328	The Clinic Administrator will be responsible for ensuring all infection control standards are met. A sterilization appendix has been created and incorporated into the training procedure for packaging and sterilizing in order to ensure all necessary tracking is documented on the pack as well as the sterilization log (see attached). An in service will be conducted for the staff in order to train them on the proper packaging, labeling and sterilization tracking procedure. The Clinic Administrator will monitor compliance with this practice by conducting the monthly EOC checklist mentioned on correction A233.	08/01/14

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140000	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	DATE SURVEY COMPLETED C 06/24/2014
--	--	--	--

NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF FORT WORTH, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3256 LACKLAND ROAD FORT WORTH, TX 76116
--	---

(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
A 328	<p>Continued From page 5</p> <p>During a tour on 3/27/14 at 9:55 AM with Personnel #2, the sterilized supplies were observed in Operating Room (OR) #1, "Clean Pathology" and OR #2.</p> <p>In OR #1, 2 tenaculums were observed in the sterilized package not labeled with the year, the time of sterilization, the sterilizing load number, and the autoclave. The 2 sophers were observed in the sterilized package not labeled with the time of sterilization, the sterilizing load number, and the autoclave.</p> <p>In "Clean Pathology," 2 tenaculums were observed in the sterilized package not labeled with the year, the time of sterilization, the sterilizing load number, and the autoclave.</p> <p>In OR #2, 3 tenaculums and 2 sophers were observed in the sterilized package not labeled with the time of sterilization, the sterilizing load number, and the autoclave. The 3 forceps were observed in the sterilized package not labeled with the time of sterilization, the sterilizing load number, and the autoclave.</p> <p>Personnel #2 was present and confirmed the findings.</p>	A 328		
A 498	<p>139.60(i) State and Federal Requirements</p> <p>(i) A licensed abortion facility shall not use adulterated or misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431.111. Misbranded drugs or devices are described in Health and Safety Code, §431.112.</p>	A 498	<p>Whole Woman's Health of Fort Worth does not use adulterated drugs or devices. The syringes mentioned in this report are clean syringes purchased through a legitimate medical supplies company. These syringes are noncritical items §139.49(d)(4)(c) Noncritical items include items that come in contact with intact skin. Clean supplies and instruments are utilized while performing noninvasive clean procedures such as abortion procedures where no incision is made.</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140000	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	DATE SURVEY COMPLETED C 08/24/2014
--	--	--	--

NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF FORT WORTH, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3256 LACKLAND ROAD FORT WORTH, TX 76118
--	---

(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
A 498	<p>Continued From page 6</p> <p>This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to ensure adulterated devices were not available for patient use, in that, 27 of 27 syringes were observed on 3/27/14 in the "Clean Pathology" room, out of their sterile packaging, in an open to air basket and labeled "1% lidocaine 3/28/14" or "1% lidocaine 3/29/14."</p> <p>Findings Included:</p> <p>During a tour on 3/27/14 at 10:30 AM with Personnel #3, syringes were observed in the "Clean Pathology" room in baskets.</p> <p>There were 13 - 20 milliliter (ml) syringes observed in a white basket next to the sterilizer that had a handwritten label which reflected, "1% lidocaine 3/28/14."</p> <p>There were 14 - 20 milliliter (ml) syringes observed in a black basket next to the sterilizer that had a handwritten label which reflected, "1% lidocaine 3/29/14."</p> <p>Personnel #3 was present and confirmed the findings.</p> <p>During an interview on 3/27/14 at 10:30 AM, Personnel #3 was asked why the syringes were open and stored in a basket. Personnel #3 stated Personnel #5 had prepared the syringes prior to the procedures to save time. Personnel #3 was asked if this was okay. Personnel #3 said no.</p> <p>The March 2011 "Procedure for Surgical Assistant" policy required, "Open the instrument pack using sterile technique...Drop needles and</p>	A 498	<p>The Clinic Administrator will conduct a staff training to ensure surgical assist personnel understands the procedure for sterile technique and utilizes sterile supplies when following the sterile technique procedure.</p> <p>The Clinic Administrator will monitor the accuracy of this process by conducting random monthly traces (see trace attached) during surgical procedures.</p>	

Texas Department of State Health Services

PRINTED: 06/25/2014
FORM APPROVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140000	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(3) DATE SURVEY COMPLETED C 06/24/2014
--	--	--	--

NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF FORT WORTH, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3256 LACKLAND ROAD FORT WORTH, TX 78116
--	---

(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
A 498	Continued From page 7 syringes onto the open pack using sterile technique..."	A 498		