STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	56788 S	A. BUILDING: _____ B. WING _____	12/10/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD	6511 W 41ST STREET SIOUX FALLS, SD 57106

(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
S 000	Compliance Statement Surveyor: 25107 A licensure survey for compliance with the Administrative Rules of South Dakota, Article 44:67, Abortion Facilities, was conducted from 12/9/14 to 12/10/14. Planned Parenthood was found not in compliance with the following requirement: S150.	S 000	The Sioux Falls clinic process changed on 12/10/14 as the surveyor was in the clinic. We are currently running an unprocessed control as well as the processed indicator and inspecting them at 24 hours to look for the unprocessed control to turn yellow as a positive result and the processed ampule to turn purple as the negative result. We run a control each day the sterilizer is ran per the manufacturer's instructions. We have ordered a new incubator and incubator supplies from 3M. They are both expected to arrive sometime in Mid January. At that time we will be trained by a representative from 3M on the use of the new incubator. We will also start the following process at that time. Sterilization Control Process for Sioux Falls – January 2015 An Attest UNPROCESSED control indicator will be ran each day that the sterilizer is ran. Mark top of indicator with the letter "C" to indicate this is the control. Close, crack and tap and place in 6th spot in Auto-Reader. The result should come up as a (+) underneath the indicator. 1) You will place one "challenge tray" (this is a pseudo tray) which must have an Attest indicator INSIDE the wrapping along with an "OK" strip. Place it on a shelf in the sterilizer as normal. This may be done at the same time you are running other AB trays and instruments.	1/28/15
S 150	44:67:01:01 Physical Environment Each abortion facility shall comply with all applicable physical environment standards in chapter 44:04:02. This Administrative Rules of South Dakota is not met as evidenced by: Surveyor: 25107 Based on record review, interview, and instructions for use review, the provider failed to follow the manufacturer's instructions for the use for Attest biological monitoring. The provider had not tested a control biological (a biological that had not been sterilized) to ensure the spore viability, the capability of the media to promote growth, and confirm the incubator was functioning properly. Findings include: 1. Record review and interview on 12/10/14 at 10:30 a.m. with the registered nurse who oversaw the operation of the steam sterilizer revealed: *The facility was using an Attest biological monitoring system once a week to monitor the effectiveness of the steam sterilizer. *The biological indicator would have been incubated and visually checked for a color change to verify no bacteria grew. *They had not tested a control biological to ensure the spore viability, the capability of the media to promote growth, and confirm the	S 150		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Andrea Adams — TITLE: Clinic Manager — (X6) DATE: 12/29/14

South Dakota Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	56788 S	A. BUILDING: _____ B. WING _____	12/10/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD	6511 W 41ST STREET SIOUX FALLS, SD 57106

(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
S 150	Continued From page 1 incubator was functioning properly. Review of the manufacturer's instructions for use for the Attest biological monitoring system revealed: *Use of a control - Incubate a non-processed, activated Attest indicator at the same time as the sterilized activated Attest indicator. *A control ensures spore viability, demonstrates the capability of the media to promote growth, and confirms the incubator was functioning properly.	S 150	2) Run the load as normal. 3) When load is complete you will open the "challenge tray" and remove the Attest indicator and let cool for 10 minutes. 4) When indicator has cooled you will need to" Push, Crack and Tap" 1. Make sure the top is pushed down,2. Crack the indicator by using the special area on the Auto-Reader device. Do NOT crack it by hand 3 Gently tap the indicator several times on a hard surface(NOT ON THE AUTO-READER) so the purple media wets the spore strip at the bottom of the vial, before placing into the Auto-Reader. 5) Place each indicator into a spot in the Auto-Reader and DOCUMENT on log sheet ALL information needed. 6) Results will be ready in 3 hours. Document results on log sheet. 7) A NEGATIVE (-) result indicates a SUCCESSFUL load- A POSITIVE (+) result indicates a load FAILURE-STOP and seek assistance from the Clinic Manager. 8) Rewrap "challenge trays" and remember to place an indicator inside the tray before wrapping In the event of a failed test the Clinic Manager will follow instructions as outlined in the 3M user manual. The Sterilizer Control logs will be monitored by the Clinic Manager. They will be audited quarterly for the first year and then yearly after. The Clinic Manager will report to the Quality Assurance Director. The QA Director will report to CQRM (Compliance Quality Risk Management) Committee after every report, quarterly for the first year and annually after that. These reports will be reflected in the CQRM meeting minutes.	