STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0055	A. BUILDING: _____ B. WING _____	11/03/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A PREFERRED WOMENS' HEALTH CEN	3320 LATROBE DRIVE CHARLOTTE, NC 28211

12/7/21 DM

(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
E 165	.0314 Cleaning of Materials and Equipment 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on observation, policy and protocol review, autoclave log review, and staff interview, the facility staff failed to maintain clean equipment between patient use by failing to perform weekly autoclave spore testing for 4 of 5 weeks reviewed and weekly autoclave cleaning for 3 of 5 weeks reviewed. The findings included: Observation on 11/03/2021 at 1210 during a facility tour revealed the sterilizer room with one autoclave machine (machine used to kill bacteria on equipment or tools) and one biological monitoring system (system used to ensure the autoclave machine is functioning properly) on the counter. Observation revealed a tray of instruments wrapped in blue sterilization paper and white indicator tape next to the autoclave machine. Observation revealed the "Daily Autoclave Use Log" was located to the left of the autoclave machine. Observation revealed the "3M Attest Biological Indicator Log" was located in the cabinet above the autoclave machine. Review on 11/03/2021 of the facility protocol,	E 165	We thank NC DHHS for their time and feedback. In regards to the deficiency cited (identified by 10A-14E .0314 (a) and (b) Cleaning of Materials and Equipment), we provide the following response: Administration acknowledges the error of clinical staff and the insufficient following of internal protocols regarding cleaning of materials and equipment. In terms of corrective action, we propose the following action plan: - On 11/04/2021, after state visit was performed, the executive director reviewed with staff all expectations for autoclave use, including weekly cleaning and spore testing. APWHC protocol states that spore testing is to be performed every Monday. APWHC protocol states that autoclave testing should be performed weekly. Protocols are attached for DHHS review. - On 11/22/2021, a staff inservice will be performed by clinic management to review autoclave use policy and to review and implement corrective oversight review.	11/22/21

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: EXECUTIVE DIRECTOR | (X6) DATE: 11/18/21

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0055	A. BUILDING: _____ B. WING _____	11/03/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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E 165	Continued From page 1
	"(Named facility) 3M BI(Biological Indicator) Autoclave Weekly Spore Test Protocol" dated 10/19/2016, revealed, "Effective immediately, (Named facility) will resume in-house weekly spore testing using the 3M Attest 1262 Biological Indicator for steam sterilizers. The testing will continue to be performed on Monday following the manufacturers instructions, examined after 8, 12, and 24 hours for any color change if possible, with final results read 48 hours after initial incubation. All testing information and results will be recorded in the 3M 1266 Attest Logbook, and kept in the autoclave room..."
	
	Review on 11/03/2021 of the facility protocol, "Autoclave Cleaning Protocol" dated 01/2006, revealed, "The autoclaves are to be cleaned weekly."
	
	Review on 11/03/2021 of the "3M Attest Biological Indicator Log" failed to reveal documentation of weekly spore testing for the following Mondays: 10/11/2021, 10/18/2021, 10/25/2021, and 11/01/2021.
	
	Review on 11/03/2021 of the "(Named facility) Daily Autoclave Use Log" failed to reveal documentation of weekly cleaning for the following weeks: 10/11/2021 through 10/17/2021, 10/18/2021 through 10/24/2021, and 10/25/2021 through 10/31/2021.
	
	Interview on 11/03/2021 at 1210 with Clinic Staff #1 revealed she had not performed the weekly spore testing on 11/01/2021. Interview revealed the autoclave cleaning and spore testing should be performed each week on Mondays.
	
	Interview on 11/03/2021 at 1800 with the Executive Director revealed the expectation of
		E 165	- Beginning on 11/22/2021, corrective oversight review will begin. This review will be performed by the clinic manager or a member of APWHC administration (director of patient care, director of operations, or executive director); this review is to ensure adherence to the infection control program.
			  - Spot checks will include review of autoclave spore test log, autoclave run log, and any other applicable supporting documentation of autoclave use.
			  - At least 1 spot check will be conducted each week at a random time; the results of these will be documented for review (see attached log as template).
			  - If a spot check is failed, the staff member assigned to autoclave testing for that incident will be subject to disciplinary action and will undergo retraining; a second spore test and cleaning cycle must be completed and documented in the event of a failed spot check.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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E 165	Continued From page 2 clinic staff was to perform autoclave cleaning and spore testing weekly on Mondays. Interview revealed the testing had not been performed due to recent staff turnover. Interview revealed the facility staff were working on a plan to ensure the autoclave equipment was cleaned and tested per facility protocol.	E 165		

APWHC SPOT CHECK AUDIT
AUTOCLAVE USE (CLEANING/SPORE TEST)

Date/Time	Staff Member Assigned	Was spore testing completed & documented?	Was machine cleaning completed & documented?	Additional Notes	Initials of observer
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		
		[ ] yes [ ] no	[ ] yes [ ] no		

APWHC - EXHIBIT A

Autoclave Cleaning Protocol

WARNING: The cleaning solution contains. alkaline ingredients.
Avoid contact with skin, clothing, and eyes.
In case of contact, flush with water. If irritation continues, see physician.
DO NOT take internally.

Equipment Needed: Gloves, protective goggles, apron, cleaning solution, distilled water.

The autoclaves are to be cleaned weekly.

1. Drain and refill the reservoir with clean distilled water.
2. Add one ounce of Speed-Clean to a cool chamber.
3. Run one cycle at 270-degrees for 6 minutes.
4. Instruments should **NOT** be sterilized while cleaning the autoclave.
5. Drain the reservoir and allow the autoclave to cool.
6. Remove the trays, tray rack, tray plate. Wash with water and detergent using soft cloth. Also wash the strainer mounted on the exhaust hole at the bottom of the chamber.
7. Wipe out the inside of the chamber using a soft cloth being careful not to damage the heater element or the temperature and level sensors. Do not use steel wool or brushes, they will damage the chamber.
8. Wipe off the tray and reinstall into the chamber. Make sure the tray is pushed all the way to the back of the chamber.
9. Put a few drops of oil on the 2 door pins and door tightening bolts.
10. Refill with clean distilled water. The autoclave is now ready for use.

*Wipe outside of the autoclaves and the door gasket **daily** with soft cloth.*

APWHC - Exhibit B

APWHC 3M BI Autoclave Weekly Spore Test Protocol Change 10.19.16

Effective immediately, APWHC will resume in-house weekly spore testing using the 3M Attest 1262 Biological Indicator testing for steam sterilizers. The testing will continue to be performed on Monday following the manufacturer's instructions, examined after 8, 12, and 24 hours for any color change if possible, with final results read 48 hours after initial incubation. All testing information and results will be recorded in the 3M 1266 Attest Logbook, and kept in the autoclave room. All testing information logs from Mesa and ATS will be kept on site as well.

Please review the following 3M Attest Biological Indicator Technical Profile booklet, the testing protocol usage poster, and 3M Biological Indicator package insert with applicable staff, have each employee demonstrate understanding, and post a copy of the 3M instructions in the autoclave room for reference.

In the event of a positive spore test:

1) Remove the sterilizer that produced the positive spore test from service
2) Repeat a spore test on the affected machine immediately and review sterilization operating procedures with staff to determine whether operator error could be responsible.
    a) If the test remains positive, the use of the affected autoclave must be discontinued until it is serviced and repaired.
        i) If possible, items from suspect loads dating back to the last negative BI test should be recalled, rewrapped, and resterilized
    b) Once repaired, perform 3 spore tests in consecutive empty-chamber sterilization cycles.
    c) If all 3 biological tests pass, the autoclave may be put back in service.

This testing protocol will be monitored at least quarterly and as needed through QA checks. Please contact Rachel or Danielle (ext 1105) with any questions.

Please have all staff sign and date once all policies have been reviewed and testing protocol demonstrated. ***Place a copy of the package insert in the MSDS notebook up front***

APWHC- EXHIBIT C