

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AB0007</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING: _____	(X3) DATE SURVEY COMPLETED  <b>10/09/2014</b>
--	---	--	---

NAME OF PROVIDER OR SUPPLIER  <b>HALLMARK WOMEN'S CLINIC</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>1919 GILLESPIE STREET FAYETTEVILLE, NC 28306</b>
--	--

✓  
02/05/2015  
CB3

(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 185	<p><b>.0314 CLEANING OF MATERIALS AND EQUIPMENT</b></p> <p>10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients.</p> <p>(b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use.</p> <p>This Rule is not met as evidenced by: Based on review of facility policy, autoclave testing log review, observation during tour and staff interview, the facility failed to control the risk of infection by failing to perform biological testing on the autoclave to ensure surgical instruments were sterile.</p> <p>The findings include:</p> <p>Review of the facility policy, "Attestation of Autoclave", not dated, revealed, "POLICY: In order to assure adequate sterilization of essential surgical equipment by the autoclave, testing with JM Attestation Indicators and incubator is required. Testing of the primary autoclave will be performed once each week and results of the test recorded in the quality control book (provided by the manufacturer of the testing kit) by the surgical technician and supervised by the clinic manager..."</p> <p>Observation during tour of the facility on 10/09/2014 revealed 2 autoclaves in the equipment processing room located between the two procedure rooms. Review of the autoclave testing log revealed the last documented Attest</p>	E 185		
-------	---	-------	--	--

Division of Health Service Regulation  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TIME  
*[Signature]*

(X6) DATE  
02/05/2015

Division of Health Service Regulation

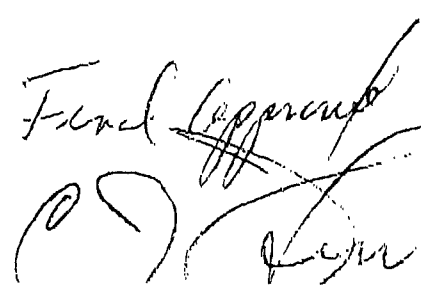
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AB0007</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/09/2014</b>
--	---	---	---

NAME OF PROVIDER OR SUPPLIER  <b>HALLMARK WOMEN'S CLINIC</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>1919 GILLESPIE STREET FAYETTEVILLE, NC 28306</b>
--	--

(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	<p>Continued From page 1</p> <p>performed once each week and results of the test recorded in the quality control book (provided by the manufacturer of the testing kit) by the surgical technician and supervised by the clinic manager...".</p> <p>Observation during tour of the facility on 10/09/2014 revealed 2 autoclaves in the equipment processing room located between the two procedure rooms. Review of the autoclave testing log revealed the last documented Attest (biological testing) was done on 03/22/2014 (6 months, 17 days ago). Observation of the Attest spore vials revealed the vials expired in November 2006 (7 years, 11 months ago).</p> <p>Interview on 10/09/2014 at 1000 with the surgical technician revealed the testing had not been done since 03/22/2014 because "we haven't done a lot of procedures". Interview revealed the autoclave is used weekly to sterilize surgical equipment.</p> <p>Interview on 10/09/2014 at 1015 with the facility administrator confirmed the autoclave had not been tested weekly per the facility's policy.</p> <p>NC00093287</p>	E 165		

## Incubator Monitoring Inspection- Control Testing

Date	Time in incubator	Date	Time Removed	Color Results	Initials
10/13/2014	10:40	10/15/2014	10:40	yellow	MJ
10/20/2014	10:40	10/22/2014	10:40	yellow	MJ
10/27/2014	10:40	10/28/2014	10:40	yellow	MJ
11/3/2014	10:40	11/5/2014	10:40	yellow	MJ
11/10/2014	10:30	11/12/2014	10:50	yellow	MJ
11/17/2014	10:30	11/19/2014	10:40	yellow	MJ
11/24/2014	10:40	11/26/2014	10:50	yellow	MJ
12/1/2014	10:30	12/3/2014	10:50	yellow	MJ
12/8/2014	10:30	12/10/2014	10:50	yellow	MJ
12/15/2014	10:40	12/17/2014	10:50	yellow	MJ
12/22/2014	10:30	12/24/2014	10:40	yellow	MJ
12/29/2014	10:30	12/31/2014	10:40	yellow	MJ
1/5/2015	10:00	1/7/2015	10:30	yellow	MJ
1/12/2015	10:00	1/14/2015	10:30	yellow	MJ
1/19/2015	10:00	1/21/2015	10:30	yellow	MJ
1/26/2014	10:00	1/28/2015	10:30	yellow	MJ
2/2/2015	10:00	2/4/2015	10:30	yellow	MJ
2/9/2015	10:00	2/11/2015	10:30	yellow	MJ
2/16/2015	10:00	2/18/2015	10:30	yellow	MJ

*Final Approval*  


## Autoclave Weekly Cleaning Log


(To be completed once each week on both autoclaves)

Date Cleaned	Autoclave	Time of Day Cleaning Completed	Initials
12/15/2014	Tuttnauer 2340M	9 am	MJ
12/15/2014	Ritter M9	9:15	MJ
12/22/2014	Tuttnauer 2340M	9 am	MJ
12/22/2014	Ritter M9	9:15 am	MJ
12/29/2014	Tuttnauer 2340M	9 am	MJ
12/29/2014	Ritter M9	9:15 am	MJ
01/05/2015	Tuttnauer 2340M	9:00 am	MJ
01/05/2015	Ritter M9	9:30 am	MJ
01/12/2015	Tuttnauer 2340M	9:30 am	MJ
01/12/2015	Ritter M9	9:00 am	MJ
01/19/2015	Tuttnauer 2340M	9 am	MJ
01/19/2015	Ritter M9	9:30 am	MJ
01/26/2015	Tuttnauer 2340M	9:30 am	MJ
01/26/2015	Ritter M9	9 am	MJ
02/02/2015	Tuttnauer 2340M	9 am	MJ
02/02/2015	Ritter M9	9:30	MJ
02/09/2015	Tuttnauer 2340M	9 am	MJ
02/09/2015	Ritter M9	9:30	MJ

## Autoclave Weekly Cleaning Log

(To be completed once each week on both autoclaves)

Date Cleaned	Autoclave	Time of Day Cleaning Completed	Initials
10/13/2014	Tuttnauer 2340M	9:30	mj
10/13/2014	Ritter M9	9:00 am	mj
10/20/2014	Tuttnauer 2340M	9:30	mj
10/20/2014	Ritter M9	9:00 am	mj
10/27/2014	Tuttnauer 2340M	9:30	mj
10/27/2014	Ritter M9	9:00 am	mj
11/3/2014	Tuttnauer 2340M	9:30	mj
11/3/2014	Ritter M9	9 am	mj
11/10/2014	Tuttnauer 2340M	9 am	mj
11/10/2014	Ritter M9	9:30 am	mj
11/17/2014	Tuttnauer 2340M	9 am	mj
11/17/2014	Ritter M9	10:30	mj
11/24/2014	Tuttnauer 2340M	9 am	mj
11/24/2014	Ritter M9	10:30	mj
12/1/2014	Tuttnauer 2340M	9 am	mj
12/1/2014	Ritter M9	10:00	mj
12/8/2014	Tuttnauer 2340M	9 am	mj
12/8/2014	Ritter M9	10:00	mj

*Final Approval*  


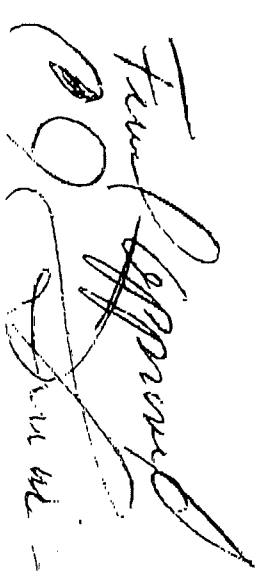
Lot 2015 - 2016  
 Ex 9. 2016

### Attest Biological Monitoring Inspection

Date	Sterilizer	Time Placed in Autoclave	Time Placed in Incubator	Date	BI Color	Initials
12/01/2014	Tuttnauer 2340M	9am	9:30	12/03/2014	Purple	MS
12/08/2014	Ritter M9	9am	9:30	12/10/2014	Purple	MS
12/15/2014	Tuttnauer 2340M	9:30	10:00	12/17/2014	Purple	MS
12/22/2014	Ritter M9	9:30	10:00	12/24/2014	Purple	MS
12/29/2014	Tuttnauer 2340M	9am	9:30	12/31/2014	Purple	MS
01/05/2015	Ritter M9	9am	9:30	01/07/2015	Purple	MS
01/12/2015	Tuttnauer 2340M	9am	9:30	01/14/2015	Purple	MS
01/19/2015	Ritter M9	9am	9:30	01/21/2015	Purple	MS
01/26/2015	Tuttnauer 2340M	9am	9:30	01/28/2015	Purple	MS
02/02/2015	Ritter M9	9am	9:30	02/04/2015	Purple	MS
02/09/2015	Tuttnauer 2340M	9am	9:30	02/11/2015	Purple	MS
02/16/2015	Ritter M9	9am	9:30	02/18/2015	Purple	MS
02/23/2015	Tuttnauer 2340M	9am	9:30	02/25/2015	Purple	MS
03/02/2015	Ritter M9	9am	9:30	03/04/2015	Purple	MS

Attest Biological Monitoring Inspection

Date	Sterilizer	Time Placed In Autoclave	Time Placed In Incubator	Date	BI Color	Initials
10/13/2014	Tuttnauer 2340M	10 am	10:40	10/15/2014	purple	MS
10/13/2014	Ritter M9	10 am	10:40	10/15/2014	purple	MS
10/20/2014	Tuttnauer 2340M	10 am	10:40	10/22/2014	purple	MS
10/20/2014	Ritter M9	10 am	10:40	10/22/2014	purple	MS
10/27/2014	Tuttnauer 2340M	10 am	10:40	10/29/2014	purple	MS
10/27/2014	Ritter M9	10 am	10:40	10/29/2014	purple	MS
11/3/2014	Tuttnauer 2340M	10 am	10:40	11/5/2014	purple	MS
11/3/2014	Ritter M9	10 am	10:40	11/5/2014	purple	MS
11/10/2014	Tuttnauer 2340M	10:30	10:50	11/12/2014	purple	MS
11/10/2014	Ritter M9	10:30	10:50	11/12/2014	purple	MS
11/17/2014	Tuttnauer 2340M	10:30	10:50	11/19/2014	purple	MS
11/17/2014	Ritter M9	10:00	10:40	11/19/2014	purple	MS
11/24/2014	Tuttnauer 2340M	10:30	10:40	11/26/2014	purple	MS
11/24/2014	Ritter M9	10:00	10:40	11/26/2014	purple	MS


  
 Frank Apperson

# Autoclave Cleaning Protocol

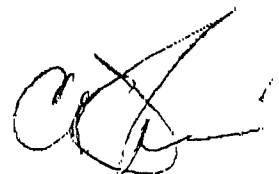
**WARNING:** The cleaning solution contains alkaline ingredients. Avoid contact with skin, clothing and eyes. In the event of contact, flush with water. If irritation continues, see M.D. DO NOT ingest.

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

## Autoclaves must be cleaned weekly

- 1.) Drain and refill the reservoir with clean distilled water.
- 2.) Add one ounce of Speed Clean to the inside of a cool chamber.
- 3.) Run one unwrapped cycle (shortest 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 and tray plate. Hand wash with water and Speed Clean using a soft cloth. Also wash the strainer mounted on the exhaust hole at the bottom of the chamber. Wipe out the inside of the chamber also using Speed Clean and a soft cloth. Be careful to NOT touch the heating element located inside on the back panel, towards the bottom. DO NOT use steel wool or brushes, they will damage the autoclave.
- 7.) Re-install components in the chamber. Make sure the tray is pushed to the back of the chamber.
- 8.) Run a full cycle with no solution, distilled water only.
- 9.) Drain water and refill with distilled water.

*Autoclave is now ready for use*



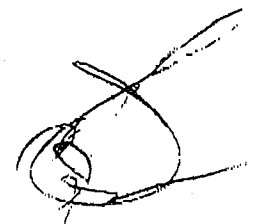


# Autoclave Testing Protocol

## Autoclaves must be tested weekly

- 1.) Grab a new Biological Indicator (BI) and write the following info on the sterilizing strip located on the indicator:
  - Machine being cleaned (brand)
  - Load #
  - Date
- 2.) Place (BI) inside of autoclave with first cleaning cycle.
- 3.) After BI has remained in autoclave for ONLY one cycle, remove BI and allow to cool before the vial is snapped/crushed
- 4.) Place vial in incubator and allow it to sit for at least 48 hours.
- 5.) After 48 hours, remove BI from incubator and log color on Autoclave Testing Log Spreadsheet. When running correctly, BI should turn purple/brown. If BI turns any other color except for purple/brown, bring results to the attention of Management.
- 6.) Discard BI appropriately
- 7.) Repeat weekly

*Autoclave is now ready for use*



# Incubator Testing Protocol

## Incubator control must be tested weekly

- 1.) Grab an unused Biological Indicator(BI) and snap/crush it. This breaks the glass ampule that is inside the plastic vial of the BI. *DO NOT run BI through autoclave for incubator testing protocol.*
- 2.) Place crushed vial inside incubator and let sit for at least 48 hours before reading results.
- 3.) After 48 hours read results. Results should be yellow. If BI turns any other color except for yellow, bring results to the attention of Management.
- 4.) Discard BI appropriately.
- 5.) Repeat weekly to insure incubator is working properly.

A handwritten signature in black ink, located in the bottom right corner of the page. The signature is stylized and appears to be a cursive name.

In Service  
Attest

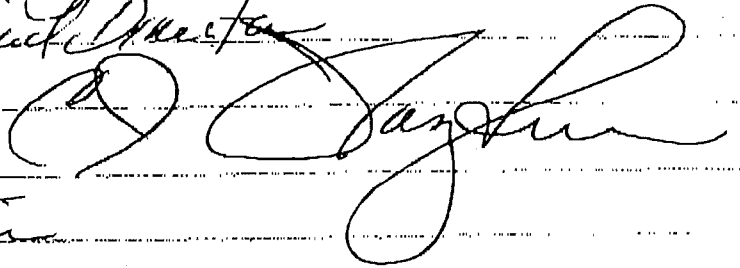
10/28/14

Stean Substation 3 m-

New System Arrived  
System Warmup Log - Checked for  
System Function - OK.

Will plan on System Check on  
Tuesday - with 48 hr warmup period  
and start of on Thursday weekly.  
Tubs to be read & K of K atrollog  
entered into log.

Medical Director



Manager

Mary Johnson  
J. Chalmers