

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AB0024	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/21/2016
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NAME OF PROVIDER OR SUPPLIER EASTOWNE OB-GYN AND INFERTILIT	STREET ADDRESS, CITY, STATE, ZIP CODE 180 PROVIDENCE RD #3 CHAPEL HILL, NC 27514
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(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
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E 123	.0206(3)(A) Elements and Equipment 10A NCAC 14E .0206 The physical plant shall provide equipment to carry out the functions of the clinic with the following minimum requirements: (3) Electrical Requirements (a) Procedure and recovery rooms, and paths of egress from these rooms to the outside shall have at a minimum, listed battery backup lighting units of one and one-half hour capability that will automatically provide at least five foot candles of illumination at the floor in the event of a utility or local lighting circuit failure. This Rule is not met as evidenced by: Based on observation and staff interview the facility failed to provide emergency back up lighting in the operating/procedure room in 1 of 1 procedure room. The finding included: Observation on June 21, 2016 at 1130 during facility tour revealed no emergency back up lighting present in the operating/procedure room. Interview with Staff #1 on June 21, 2016 at 1755 revealed there was no emergency back-up light in the operating room. Interview revealed, prior to the survey, the doctor would use his headlight as the back up light. Further interview revealed a contractor was called on June 21, 2016 to install a emergency back-up light in the operating/procedure room. The interview confirmed the observation finding.	E 123	To meet this standard an Emergency back up light has been. installed in Room 1. The light will be checked on a monthly basis to be sure it is working properly. This will be done by Medical Assistant and any problems to be reported to manage- ment.	<i>7/15/16</i>
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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E 127	Continued From page 1	E 127		
E 127	<p>.0206(4) Elements and Equipment</p> <p>10A NCAC 14E .0206 The physical plant shall provide equipment to carry out the functions of the clinic with the following minimum requirements: (4) Buildings systems and medical equipment shall have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure operation in compliance with manufacturer's instructions</p> <p>This Rule is not met as evidenced by: Based on observation and staff interview the facility failed to perform an annual preventive maintenance (PM) on an Ultrasound (U/S) machine in 1 of 2 U/S machines.</p> <p>The findings included:</p> <p>Observation on June 21, 2016 at 1130 during facility tour revealed an U/S machine in the procedure room. Observation revealed there was no sticker indicating PM had been performed.</p> <p>Interview with Staff #2 during tour revealed the U/S in the procedure room was new. Interview revealed the U/S machine was used on patients in the procedure room.</p> <p>Interview with Staff #2 on June 21, 2016 at 1640 revealed the U/S machine went into service on January 27, 2015. Interview revealed it should have had an annual PM with the other U/S on September 15, 2015. Interview revealed the U/S has not had an annual PM. Further interview revealed a message was left with the contractor to come onsite and perform the PM on June 21, 2016. The interview confirmed the observation</p>	E 127	<p>To meet this standard a preventive maintenance was conducted on the ultrasound machine in room 1 and no problems noted. This equipment will be added to the routine maintenance schedule done on a yearly basis.</p>	<p>6/24/16</p>

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E 127	Continued From page 2 finding.	E 127	To meet this standard the file of Employee # 3 has been updated to include this information regarding job description, pro-ficiency of duties. Updated information replaced in all employee files affected. All up-dated information is included. Management will oversee all employee files	7/18/16
E 146	.0306(A) Personnel Records 10A NCAC 14E .0306 (a) Personnel Records: (1) A record of each employee shall be maintained that includes the following: (A) employee's identification; (B) application for employment that includes education, training, experience and references; (C) resume of education and work experience; (D) verification of valid license (if required), education, training, and prior employment experience; and (E) verification of references. (2) Personnel records shall be confidential. (3) Notwithstanding the requirement found in Subparagraph (b)(2) of this Rule, representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records. This Rule is not met as evidenced by: Based on Personnel file review and staff interview the facility administrator failed to document training and competency for an employee in 1 of 1 medical assistants. (Staff # 3) The finding included: Review of personnel files on June 21, 2016 at 1600 revealed a job description for Staff #3, the medical assistant. Review revealed "Job Title: Medical Assistant, The Medical Assistant shall: 1. clean instruments, 2. wrap instruments in a sterile	E 146		

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E 146	Continued From page 3 fashion, 3. run sterilizer and empty sterilizer and put instruments away correctly ..." Further review revealed no documented training or competency for sterile processing of instruments and supplies. Interview on June 21, 2016 at 1630 with Staff #1 revealed Staff #3 was a Certified Medical Assistant. Interview revealed Staff #3 previously worked in hospital in the operating room. Interview revealed based on Staff #3's experience in the operating room, he was considered competent to perform his job. Further interview revealed Staff #1 did not document training and did not perform a competency assessment on Staff #3. The interview confirmed the review finding.	E 146		
E 156	.0310 Emergency Back-Up Services 10a NCAC 14E .0310 (a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to a nearby hospital when hospitalization becomes necessary. (b) The clinic shall have procedures, personnel, and suitable equipment to handle medical emergencies which may arise in connection with services provided by the clinic. (c) The clinic shall have a written agreement between the clinic and a hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule. (d) The clinic shall provide intervention for emergency situations. These provisions shall	E 156		

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E 156	<p>Continued From page 4</p> <p>include:</p> <ul style="list-style-type: none"> (1) basic cardio-pulmonary life support; (2) emergency protocols for: <ul style="list-style-type: none"> (A) administration of intravenous fluids; (B) establishing and maintaining airway support; (C) oxygen administration; (D) utilizing a bag-valve-mask resuscitator with oxygen reservoir; (E) utilizing a suction machine; and (F) utilizing an automated external defibrillator; (3) emergency lighting available in the procedure room as set forth in Rule .0206 of this Subchapter; and (4) ultrasound equipment. <p>This Rule is not met as evidenced by: Based on observation and staff interview the facility failed to provide emergency back up lighting in the operating/procedure room in 1 of 1 procedure room.</p> <p>The findings included:</p> <p>Observation on June 21, 2016 at 1130 during facility tour revealed no emergency back up lighting present in the operating/procedure room.</p> <p>Interview with Staff #1 on June 21, 2016 at 1755 revealed there was no emergency back-up light in the operating room. Interview revealed, prior to the survey, the doctor would use his headlight as the back up light. Further interview revealed a contractor was called on June 21, 2016 to install a emergency back-up light in the operating/procedure room. The interview</p>	E 156	<p>Emergency back up light has been installed in Room #1.</p>	7/15/16
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E 156	Continued From page 5 confirmed the observation finding.	E 156		
E 157	.0311(A) Surgical Services 10A-14E .0311(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms. The clinic shall establish procedures for infection control and universal precautions. This Rule is not met as evidenced by: Based on observation and staff interview, the facility staff failed to discard expired supplies in 3 of 5 areas toured. (procedure room, examination room and supply room) The findings included: Review revealed no policy for checking expiration dates on supplies. 1. Observation on June 21, 2016 at 1100 in the procedure/operating room revealed a cabinet with supplies. Observation revealed the cabinet had multiple bins with different sized curettes (tip used for suction during abortion procedure). Observation revealed the bins contained expired curettes with the following expiration (exp.) dates: curettes: six 13 mm (millimeter) straight curettes (exp. October 2012), one 13 mm straight curette (exp. March 2011), two 12 mm straight curettes (exp. October 2005), three 8 mm curettes (exp. August, 2013), one 8 mm straight curette (exp. April 2014), one 11 mm straight curette (exp. November 2011), One straight curette (exp.	E 157	To meet this standard, all expired curettes have been removed from the facility. All curettes were checked. A listing of vacuettes and hoses with expiration dates will be checked monthly. Monthly inventory will now include all expirable supplies and vacuettes. Inventory to be performed by Medical Assistant and Back-office Assistant.	6/21/16

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E 157	<p>Continued From page 6</p> <p>September 2008), eight 15 mm straight curettes (exp. June 2009), six 15 mm curettes (exp. September 2008) one 15 mm straight curette (exp. April 2012), two 10 mm straight curettes (exp. December 2012), thirteen 7 mm flexible curettes (exp. July 2013), six 6 mm straight curettes (exp. September 2013), thirteen 6 mm straight curettes (exp. July 2014) one 6 mm straight curette (exp. January 2012), two 9 mm straight curettes (exp July 2010), four 9 mm straight curettes (exp. November 2009), two 9 mm straight curettes (exp. December 2008), two 9 mm straight curettes (exp. September 2008), two 9 mm straight curettes (exp. December 2010), one 9 mm straight curette (exp. June 2010) and three 9 mm straight curettes (exp. May 2011). Further observation revealed a cart with a drawer holding supplies. Observation revealed the following supplies were expired: two finger cots [supply used to cover a single finger(exp. September 2010)] and one canal locator [instrument used to fine an opening (exp. February 2011)]. Observation revealed the bins contained curettes that had not expired.</p> <p>Interview with Staff #2 during tour revealed the supplies were expired. Inteview revealed the expired supplies would be discarded. The interview confirmed the observation finding.</p> <p>Interveiw with staff #1 on June 21, 2016 during the tour revealed the expiration dates were not checked. Interview revealed the expirations dates should have been checked by Staff #2. Interview revealed the supplies had expired and would be discarded. The interview confirmed the observation finding.</p> <p>2. Observation on June 21, 2016 at 1100 in the examination/recovery room revealed a cart with</p>	E 157		

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E 157	<p>Continued From page 7</p> <p>plastic bins containing supplies. Observation revealed multiple bins with different sized curettes. Observation revealed the cabinet contained expired curettes with the following expiration (exp.) dates: three 15 mm straight curettes (exp. June 2009), One 15 mm straight curette (exp. March 2009), one 15 mm straight curette (exp. April 2012), three 13 mm straight curette (exp March 2011), one 13 mm straight curette (exp. September 2012), One 14 mm straight curette (exp. July 2011), One 14 mm straight curette (exp. February 2012), four 11 mm straight curettes (exp May 2011), two 11 mm straight curettes (exp November 2011), One 11 mm straight curette (exp. January 2012), One 11 mm curved curette (exp. June 2013) and six 7 mm flexible curettes (exp. June 2013). Observation revealed the bins contained curettes that had not expired.</p> <p>Interview with Staff #2 during tour revealed the supplies were expired. Interview revealed the expired supplies would be discarded. The interview confirmed the observation finding.</p> <p>Interveiw with staff #1 on June 21, 2016 during the tour revealed the expiration dates were not checked. Interview revealed the expiration date should have been checked by Staff #2. Interview revealed the supplies had expired and would be discarded. The interview confirmed the observation finding.</p> <p>3. Observation on June 21, 2016 at 1100 in the supply room revealed a one gallon bottle of Cavicide Virucidal (cleaning solution) with and expiration date of September 2011 on the shelf containing supplies. Observation revealed a one gallon bottle of Formalin solution (preservative) with an expiration date of April 2014, and a 16</p>	E 157		
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E 157	<p>Continued From page 8</p> <p>ounce bottle of Autoclave Cleaner with and expiration date of March 31, 2011. Observation revealed Autoclave cleaner in the supply room that was not expired.</p> <p>Interview with Staff #2 on June 21, 2016 during tour revealed the facility no longer used Cavicide Virucidal for cleaning. Interview revealed the facility used canisters of germicidal (cleaner) disposable wipes to clean and disinfect the treatment area. Interview revealed the expired solutions would be discarded.</p> <p>Interveiw with staff #1 on June 21, 2016 during the tour revealed the expiration dates were not checked. Interview revealed the expiration date should have been checked by Staff #2. Interview revealed the supplies had expired and would be discarded. The interview confirmed the observation finding.</p>	E 157	<p>All expired fluids have been discarded. Current Auto-clave cleaner has no expiration date. This was verified with manufacturer. All others were discarded.</p>	6/21/16

EASTOWNE OB/GYN AND INFERTILITY
180 PROVIDENCE ROAD SUITE 3
CHAPEL HILL, NC 27514
TELEPHONE: 919-493-8466

MEDICAL ASSISTANT

The position of the Medical Asst. requires an individual who has proficiency in performing routine office procedures as well as those procedures covered under the CLIA guidelines. Some of this individual's duties will overlap with the support staff. Medical laboratory technicians, RNs, and LPNs are examples of qualified individuals who may perform this position. Other individuals may be trained according to CLIA regulations for non-waived testing. The responsibilities shall include but are not limited to the following:

- Using appropriate Universal Precautions
- Performing capillary and venous punctures to obtain adequate blood samples for testing
- Performing heights, weights, temperature and vital signs of patients with the knowledge of both manual and automated equipment
- Performing QC media testing and the recording of all results on the appropriate logs
- Performing urine testing to include urine pregnancy tests and urine chemical analysis
- Performing hemoglobins and Rh factor tests by use of capillary or venous punctures
- Operating the autoclave and the centrifuge
- Assisting with specimen processing for out-source testing; this includes using the appropriate method for the input of patients into the computer system, processing and preparing the specimen for transport (i.e. PAP smears)
- Inputting patient data into the electronic health record system
- Assisting the physician with routine exams and procedures
- Chaperoning patients as needed
- Performing other tests which may be ordered by the Medical Director

In addition, the Medical Asst. shall be responsible for the stocking and cleaning of the lab. All logs and cleaning schedules will be maintained according to CLIA/OSHA and state regulations. Some of these duties overlap and are shared with the back office medical staff in order that patients are seen in a timely and efficient manner. Other duties may be added as needed.

The Medical Asst. shall maintain 100% compliance with CLIA proficiency testing for the Rh factor.

Employee: _____ Date: _____

Eastowne OB-GYN and Infertility Representative: _____

EASTOWNE OB/GYN AND INFERTILITY
180 PROVIDENCE ROAD SUITE 3
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Back Office Medical Support Staff

The back office support staff shall be an individual who has been adequately trained to perform basic patient care and basic medical office responsibilities. This individual shall at least possess a high school diploma. Individuals who possess C.N.A, medical office assistant or other medical experience shall be qualified to assume this position. This individual shall be responsible for performing heights, weights, vital signs, basic machine operation/ maintenance and any other duty deemed necessary for the efficient operation of the medical phase of the patient's visit. The responsibilities of this position shall include but are not limited to the following:

Using appropriate Universal Precautions

Washing and wrapping of all instruments in a manner consistent with good practice and sterilization techniques

Cleaning the autoclave(s) monthly

Cleaning, disinfecting and stocking of all rooms

Cleaning the refrigerator and the microwave

Performing and recording the weights, heights and vital signs of the patients

Performing of laboratory testing within CLIA regulations and after appropriate training for said individual (UPT, HGB, RH, etc)

Assisting with specimen processing for out-source testing; this includes using the appropriate method for the input of patients into the computer system, processing and preparing the specimen for transport (i.e. PAP smears)

Inputting patient data into the electronic health record system

Directing patients and/or support persons to treatment rooms

These duties will be shared with the Medical Assistant in order that patients are seen in a timely and efficient manner. Other duties may be added as needed.

Employee: _____ Date: _____

Eastowne OB-GYN and Infertility Representative: _____

MEDICAL ASSISTANT/BACK OFFICE ASSISTANT

CHECK LIST

EMPLOYEE NAME: _____ DATE _____

The above named employee has been observed performing the following and found to be proficient in processing patients to be seen by the medical providers. This includes using all appropriate universal precautions and standard office procedures.

Task	Acceptable	Unacceptable
Proper identification of patient	_____	_____
Performing Vital Signs	_____	_____
Performing weight checks	_____	_____
Maintaining patient education information	_____	_____
Logging results onto patient logs	_____	_____
Transferring information to charts	_____	_____
Data input into the ERS as needed	_____	_____

Employee Signature: _____ Date: _____

Eastowne OB/GYN and Infertility Representative _____ Date: _____

07/15/2016

Cleaning of Instruments

All instruments shall be thoroughly cleaned of all cellular, blood and body secretions prior to being placed into the autoclave to be sterilized. Instruments shall be packaged and sterilized according to the operating instructions for the autoclave. The manual for the autoclave is located in room #1 in the drawer underneath the M11D autoclave. Once receiving the instruments into the scrub area, the instruments should process as indicated below. Instruments are received and processed on the soiled side of the lab and packaged on the clean side of the lab. Note: Processing of soiled

1. Prepare the washing solution using an approved detergent agent especially for the cleaning of the instruments.
2. Remove all debris from the instruments and rinse before adding the instruments to the cleaning solution.
3. Thoroughly remove any remaining debris with the use of brushes if needed. Rinse the instruments and place on a clean cloth to dry. Instruments may be covered with the towel to facilitate drying.
4. Before packaging the instrument, make sure the instruments are dry and all hinges move freely. Check the fittings on all other instruments to ensure there is no issue with the handles opening and closing properly.
5. Check the instruments to ensure that there are no cracks or breaks in the handles.
6. Prepare the clean side of the lab by wiping the counter with a disinfectant/antiseptic.
7. Assemble the packing supplies and autoclave trays.
8. Transfer the instruments inside the towel to avoid placing them on the counter.
9. Package the instrument using packing supplies. Instruments sets include sponge forceps and the tenaculum (which are packed together); regular speculums packed 3-4/pack and other miscellaneous items are packaged accordingly. As instruments are packaged, they are placed in the autoclave tray.
10. Once all instrument have been packaged and placed in the tray, the tray is taken to Room-1 where the autoclave(s) are located and processed according to the procedure for the operation of the autoclave.
11. A spore test is run on the first load of the machine for the week. The spore test is processed according to package instructions and read as directed. OK strips are packed and run with each load. The autoclaved strips are placed in a log book with the date, autoclave name, run number and items autoclaved.
12. Items are stored in room-1 and checked monthly. All items with an autoclave date of one year or greater are repackaged and autoclaved with the new date.

Cleaning and Sterilization of Instruments

Check list

EMPLOYEE NAME: _____ DATE _____

The above named employee has been observed performing the following and found to be proficient in cleaning and sterilizing the surgical instruments. This includes using all appropriate universal precautions.

Task	Acceptable	Unacceptable
Preparation of cleaning solution	_____	_____
Preparation of instruments	_____	_____
Packaging of instruments	_____	_____
Autoclave operation (both units)	_____	_____
Completion of all logs	_____	_____
Maintenance of autoclave(s)	_____	_____

Employee Signature: _____ Date: _____

Eastowne OB/GYN and Infertility Representative _____

Date: _____