STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C5101	A. BUILDING _____ B. WING _____	C 07/18/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BEACON WOMEN'S CENTER	**1011 MONTICELLO COURT MONTGOMERY, AL 36117**

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L 000	INITIAL COMMENTS An onsite complaint survey was conducted at Beacon Women's Center 06/12/08 through 07/18/08 to investigate Complaint # AL00016270. The following deficiencies were written on the survey conducted at the facility on 08/03/2006 and are cited again on this survey: Administration Patient Care - Operative Procedures Pharmaceutical Services Physical Environment- Preventive Maintenance Infection Control	L 000		
L 100	ALABAMA LICENSURE DEFICIENCIES THE FOLLOWING ARE LICENSURE DEFICIENCIES AND REQUIRE A PLAN OF CORRECTION. This Rule is not met as evidenced by: 420-5-1-.02(1)(a) Administration. Governing Authority. (a) Responsibility. The governing authority is the person or persons responsible for the management, control, and operation of the facility, including the appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the facility is organized, equipped, staffed and administered in a manner to provide adequate care for each patient admitted.	L 100		

Health Care Facilities

TITLE (X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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L 100	Continued From page 1 Based on observations, record reviews, and interviews the facility's Governing Authority failed to ensure: 1. The clinic was properly staffed to provide safe quality patient care. 2. The clinic maintained accurate documentation of medication counts. 3. The clinic was following policies and procedures related to the administration of medications to known patients with allergies. 4. The physician documented in the medical record patient services rendered. 5. The physician was documenting the viability prior to completing procedures. 6. Complete and accurate documentation of the administration of medications given to patients. 7. The Registered Nurse (RN) administered medications per the physician's order. 8. The Code of Alabama Title 26 Chapter 23A was followed. 9. The facility was not stocked with out of date supplies available for patient use. 10. The clinic had a quality improvement program. 11. All instruments were sterilized prior to use. 12. Fire drills were conducted and documented. 13. Maintenance of the clinic laboratory to meet the diagnostic needs of patients served. 14. The Speed Clave Sterilizer was maintained per agency policy. 15. Non-functioning patient equipment was removed from service. Refer to: 420-5-1-.03 (5)(a) 420-5-1-.03(4) 420-5-1-.03(7)(b) 420-5-1-.03(4)(f)(3) 420-5-1-.03(4)(f)(5)	L 100		

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L 100	Continued From page 2 420-5-1-.03(7)(e) 420-5-1-.04(5)(d) 420-5-1-.02(1)(a) 420-5-1-.02(3) 420-5-1-.03(7)(c) 420-5-1-.03(8)(b) 420-5-1-.02(6)(b) 420-5-1-.03(4)(d)(3)(4) 420-5-1-.03(4)(d)(4) 420-5-1-.04(5)(b)(2)(c) ********* 420-5-1-.03(5)(a) Operative Procedures Only physicians duly licensed in the state of Alabama, shall order diagnostic work or medications or perform abortions. Based on review of patient # 68's medical record, it was determined the physician failed to document a physical examination, failed to document the procedure, failed to document who performed the procedure, and failed to document the termination of the pregnancy. Documentation on the recovery room record revealed the date of the procedure was 6/12/08. ******** 420-5-1-.03(4) Operative Procedures (c) Before a physician performs an abortion, the physician shall examine the fetus by use of ultrasound and by such other techniques as to produce a reasonably accurate method of determining the gestational age and viability of the fetus. After such examination, the physician shall enter into the patient's medical record the	L 100		

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L 100	Continued From page 3 test or examinations performed, and his findings regarding viability. This regulation is not met as evidenced by: Based on a review of medical records, it was determined, the physician failed to enter into the patient's medical record his findings regarding viability in 3 of 68 charts reviewed. Findings include: 1. Patient # 8, Patient # 14 and Patient # 68 had no viability documented by the physician. Patient # 68 had an ultrasound in the record, but it could not be determined who performed the ultrasound since there was no signature of the physician present on the form. ******** 420-5-1-.03(7)(b) Pharmaceutical Services. Administering, Dispensing, and Prescribing Drugs and Medicines. Only physicians and properly credentialed nurse practitioners and physician assistants may prescribe or order medications. Nurse practitioners and physician assistants may prescribe only those medications described in their individual collaborative agreements. Except for standing orders as permitted below, medications shall be prescribed for patients of the facility after an appropriate medical evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered nurse, licensed practical nurse, or a pharmacist. Oral and telephone orders shall be immediately documented in writing by the individual receiving the order. Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the State Board of	L 100		

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L 100	Continued From page 4 Medical Examiners and the State Board of Pharmacy. Based on review of the patient records, it was determined in 66 of 68 patient records reviewed the physician failed to order the route for drugs to be administered. Also, the Registered Nurse (RN) failed to document the route the medications were given in 66 of 68 records, and failed to give the correct medications in 6 of 68 records. Findings include: According to Potter and Perry, Fundamentals of Nursing, 6th Edition Copyright 2005, Mosby, Inc. "A medication order is required for any medication to be administered by a nurse...If the medication order is incomplete, the nurse should inform the prescriber and ensure completeness before carrying out any medication order." "A medication order is incomplete unless it has the following parts: client's full name, date that the order is written, medication name, dose, route of administration, time and frequency of administration, and signature of physician, nurse practitioner, or physician assistant." The medications that were given included Versed, Aleve and Valium. The medication Versed may be administered orally, intramuscularly, or intravenously according to the Mosby's Nursing Drug Reference book 21st Edition 2008. The medication Valium may be administered orally, intramuscularly, rectally or intravenously according to the Mosby's Nursing Drug	L 100		

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L 100	Continued From page 5 Reference book 21st Edition 2008. The medication Aleve may be administered orally or rectally according to the Mosby's Nursing Drug Reference book 21st Edition 2008. The physician failed to order the route for the drugs to be administered for the following patients: #1, #2, #3, #4, #5, #6, #8, #9, #10, #11, # 12, #13, #14, #15, #16, #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, #27, #29, #30, #31, #32, #33, #34, #35, #36, #37, #38, #39, #40, #41, #42, #43, #44, #45, #46, #47, #48, #49, #50, #51, #52, #53, #54, #55, #56, #57, #58, #59, #60, #61, #62, #63, #64, #65, #66, #67 and #68. The registered nurse (RN) failed to give the correct medications in the following patients: 1. Patient #2 with a date of the procedure 1/3/08 had a preoperative order for Valium 10 mg. The nurse documented Valium 10 mg and Aleve 220 mg were administered at 4:30 P.M. 2. Patient #8 with a date of the procedure 1/31/08 had a preoperative order for Valium 10 mg. The nurse documented Valium 10 mg and Aleve 220 mg were administered at 4:35 P.M. 3. Patient #11 with a date of the procedure 12/19/07 had a preoperative order for Valium 10 mg. The nurse documented Valium 10 mg and Aleve 220 mg were administered at 4:30 P.M. 4. Patient #12 with a date of the procedure 5/7/08 had a preoperative order for Valium 10 mg. The nurse documented Valium 10 mg and Aleve 220 mg were administered at 3:45 P.M.	L 100		

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L 100	Continued From page 6 5. Patient #16 with a date of the procedure 1/3/08 had a preoperative order for Valium 10 mg and Aleve 220 mg. The nurse documented Valium 10 mg only with no documentation the Aleve was given. The Valium was given at 3:00 P.M. 6. Patient #22 with a date of the procedure 2/19/08 had a preoperative order for Valium 10 mg. The nurse documented Valium 10 mg and Aleve 220 mg were administered at 5:10 P.M. 7. The physician failed to provide orders for pre operative medications for patient # 59 on 6/12/08 and the RN administered Valium 10 mg and Aleve 220 mg without an order. ********** 420-5-1-.03(7)(b) Pharmaceutical Services. Administering, Dispensing, and Prescribing Drugs and Medicines. Only physicians and properly credentialed nurse practitioners and physician assistants may prescribe or order medications. Nurse practitioners and physician assistants may prescribe only those medications described in their individual collaborative agreements. Except for standing orders as permitted below, medications shall be prescribed for patients of the facility after an appropriate medical evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered nurse, licensed practical nurse, or a pharmacist. Oral and telephone orders shall be immediately documented in writing by the individual receiving the order. Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the State Board of Medical Examiners and the State Board of Pharmacy.	L 100		

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L 100	Continued From page 7 Based on a review of medical records of patients who received the morning after pill, there was no documentation by the nurse in 21 of 21 records that the medication was administered by a licensed nurse. There was no physician's order for the morning after pill, and no standing order. Based on a review of 25 Recovery Room Record sheets dated 6/19/08, it was determined the clinic nurse failed to sign any of the 25 sheets, and failed to initial that medications were given when there was times beside the medication indicating the medications had been given in 15 of the 25 records. ********** 420-5-1-.03(4)(f)(3)Ultrasound The physician who is to perform the abortion or the referring physician is required to perform an ultrasound before the abortion. The woman has the right to review the ultrasound before an abortion. The woman shall complete a required form to acknowledge that she either saw the ultrasound image or that she was offered the opportunity and rejected it. (6)(i) The patient shall complete and sign the form in Appendix A to these rules. Code of Alabama Title 26 Chapter 23A. The Woman's Right to Know Act 26-23A-4 Except in the case of a medical emergency, no abortion shall be performed or induced without the voluntary and informed consent of the woman	L 100		

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L 100	Continued From page 8 upon whom the abortion is to be performed or induced. (4) The physician who is to perform the abortion or the referring physician is required to perform an ultrasound on the unborn child before the abortion. The woman has the right to review the ultrasound before an abortion. The woman shall complete a required form to acknowledge that she either saw the ultrasound image of her unborn child or that she was offered the opportunity and rejected it. 26-23A-6 (c) The Department of Public Health shall develop a signature form for verifying that she has received the complete information as described in Section 26-23A-4, was offered the opportunity of viewing the video and ultrasound image of her unborn child, and provides her informed consent for an abortion on her unborn child. Based on a review of records and interview, it was determined the clinic failed to follow the laws of the State of Alabama, Department of Public Health regarding documentation on Appendix A, whether the patient chose to view the ultrasound or rejected the opportunity to view it in 39 of 68 records reviewed. Findings include: The following records did not have a signature of the patient regarding whether she viewed the ultrasound, or refused the opportunity to view it: Patient #29, #30, #31, #32, #33, #35, #36, #37, #38, #39, #40, #41, #42, #43, #44, #45, #46, #47, #48, #49, #50, #51, #52, #53, #54, #55, #56, #57,	L 100		

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L 100	Continued From page 9 #58, #59, #60, #61, #62, #63, #64, #65, #66, #67 and #68. An interview was conducted 06/16/08 at 3:00 PM with the Administrator and RN for the clinic. She was asked, " When are the patients offered the opportunity to see the ultrasound? " She said that the day they come in for the procedure. She was then asked, " When do you get the form signed and who is responsible for getting it signed? " She said that the day of the procedure, medical assistant who's in the room. She could not give an answer why they were not signed. ******** 420-5-1-.03(4)(f)(5) Any need for anti-Rh immune globulin therapy, and if she is Rh negative, the likely consequences of refusing such therapy and the cost of the therapy. Based on record reviews, it was determined the clinic failed to document the amount of the Rhogam dose in 1 of 11 patients who tested Rh negative. Findings include: Taber's Cyclopedic Medical Dictionary, 20th Edition Copyright 2001 by F.A. Davis reads, "A pregnant woman who is Rh- (negative) may become sensitized by entry of red blood cells from an Rh+ (positive) fetus into the maternal circulation after abortion, ectopic pregnancy, or delivery. In subsequent pregnancies, if the fetus is Rh+ (positive), Rh antibodies produced in maternal blood may cross the placenta and destroy fetal	L 100		

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L 100	Continued From page 10 cells, causing erythroblastosis fetalis." 1. Patient # 38 visited the clinic on 6/3/08. Documentation in the record revealed the patient tested Rh negative. The patient returned to the clinic for an abortion procedure on 6/14/08. Documentation in the medical record by the RN revealed an injection of Rhogam was given at 12:10 P.M., however, no dose of the medication Rhogam was documented. ********* 420-5-1-.03(7)(e) Pharmaceutical Records Records shall be kept of all stock controlled substance giving an account of all items received and administered. Records shall be kept in a manner which allows accurate reconciliation. Based on review of narcotic counts and invoices of received drugs, observation, and interview, it was determined the facility failed to account for all controlled medications and was unable to reconcile the stock of controlled drugs. Findings include: 1. A review of the clinic drug order sheets revealed, 100 tablets of Valium 10 mg (milligram) were ordered on 1/3/08, 200 tablets of Valium 10 mg were ordered on 1/22/08, 100 tablets of Valium 10 mg were ordered on 2/7/08, and 200 tablets of Valium 10 mg were ordered on 3/18/08. 2. A review of the clinic drug log revealed 100 Valium 10 mg tabs were added to stock on 1/3/08, 2/9/08, 3/27/08, and on 5/1/08. This review revealed no accountability for 2 bottles	L 100		

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L 100	Continued From page 11 (200 tablets) of Valium 10 mg. 3. A review of the clinic drug order sheets revealed Nalbuphine (Nubain) 10 mg/ml (milliliter) 10 ml vial was ordered and received on 4/10/08. A clinic form titled "Narcotic Discrepancy Form" dated 5/22/08 was reviewed and revealed the medication was documented as missing. The form was signed by the medical director and the clinic administrator. The form was not completed until the Executive Director did an audit 05/22/08 and identified the missing Nubain. An interview with the clinic administrator on 6/16/08 at 3:00 P.M. revealed he/she was unaware of any missing Valium. ********* 420-5-1-.04(5)(d) Supplies Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. Each facility shall examine all stored medications and supplies no less frequently than once a month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The facility shall maintain a log recording each such examination, and a description of each item or group of items removed from inventory and the reason for such removal. Based on observation and interview, it was determined the facility failed to remove from inventory, supplies which had expired and failed to document routine monthly examination of supplies and medications to check expiration	L 100		

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L 100	Continued From page 12 dates. Findings include: During a tour of the facility on 06/12/08 at 9:00 AM the surveyor observed the following items in procedure room # 1: Chromic Gut suture 2-0 Expired 01/05 Introcan catheter 20 gauge 1 1/4 inch needle expired 07/05 14 Plastic suction tips expired 04/07 4 Synevac vacuum curettes 10mm (millimeter) expired 02/08 6 vacuum curettes 16mm expired 10/07 52 vacuum curettes 16mm expired 10/07 9 vacuum curettes 16mm expired 01/08 5 vacuum curettes 16mm expired 02/08. There was no documentation the supplies had been reviewed for expiration dates. During a tour of the facility on 06/12/08 at 9:30 AM the surveyor observed in the Recovery Room the Emergency drugs with 2 ampules of Tigan expired 05/08. An inventory sheet was attached to the emergency drugs and it was documented that the Tigan was to expire May 2008. The Registered Nurse was asked regarding the drugs not being removed and stated she had just had not gotten around to it. ********** 420-5-1-.02(1)(a) Responsibility. The governing authority is the person or persons responsible for the management, control, and operation of the facility, including the appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the facility is	L 100		

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L 100	Continued From page 13 organized, equipped, staffed and administered in a manner to provide adequate care for each patient admitted. Based on observation and interview, it was determined the governing body failed to assure the facility was adequately staffed on a procedure day to provide safe and organized care to the patient's. Findings include: Upon arrival to the facility on 6/12/08, the surveyors were informed that five employees had been terminated from employment of the facility on 6/9/08, leaving only three employees to perform all the job functions, even on procedure days. The facility runs two procedure rooms, the pre operative room, the sterilizer room and the recovery room on all procedure days. In a letter to the owner of the clinic from the Executive Director dated 05/28/2008, it was stated the clinic needed immediate attention, needed a full time Director of Nursing (DON) and an Administrator; the current Administrator was not capable of running the clinic. In an interview on 06/12/08 at 2:00 PM with the Executive Director, she reported the termination of 5 of the 8 current clinic staff had been done, this included the Administrator and all of the full time Technicians. From 05/28/2008 forward no action plan had been put in place to ensure adequate staff was available for appropriate and safe patient care. There was no evidence that the Governing Body had initiated any measures to omit and/or decrease the number of	L 100		

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BEACON WOMEN'S CENTER	1011 MONTICELLO COURT MONTGOMERY, AL 36117

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L 100	Continued From page 14 procedures performed at the clinic due to the recent staff changes. The clinic did 14 follow-up visits on 06/12/08 and 16 abortion procedures. The administrator called another clinic in the area for assistance with the procedures in order to provide patient care. ********** 420-5-1-.02(3) Governing Authority There shall be a facility-wide quality improvement program to evaluate patient care and facility services. The program shall be on-going, have statistical summaries and a written plan of implementation. Based on a review of the quality improvement plan and an interview, it was determined the facility did not have a quality improvement program. A review of requested and provided information revealed the only quality improvement that was in the facility consisted of 17 chart audits dated 5/16/08 done by a medical assistant who was no longer employed by the clinic since 6/9/08. An interview with the Executive Director on 6/12/08 verified that was all the quality improvement that was available for review by the surveyors. **** 420-5-1-.03(7)(c)Standing Orders When permitted by a policy of the facility reduced	L 100		

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L 100	Continued From page 15 to writing and approved by the facility's current medical director, limited standing orders may be directed to a nurse practitioner, physician assistant, registered professional nurse or licensed practical nurse. All post-operative complications must be immediately referred to a qualified registered nurse, nurse practitioner, physician assistant, or physician, in accordance with the requirements for post-operative policies and procedures specified in accordance in section 420-5-1-.03(6)(d). Standing orders may not be used to prescribe controlled substances or abortifacient medications. Prescriptions or medication orders called or faxed to a pharmacy pursuant to a standing order shall be immediately documented by the nurse practitioner, physician assistant, registered professional nurse or licensed practical nurse, in the same manner required for oral or telephone orders. All oral orders, telephone orders, and records of prescriptions called or faxed pursuant to standing orders shall be verified by the prescribing physician's signature within 48 hours. Such verification may be undertaken by fax. Drugs and medications may not be dispensed except by or under the direct supervision of a physician or pharmacist. Facility Policy dated 9/22/06 Standing orders for post TAB (Therapeutic Abortion) problems E. Allergic reaction to Doxycycline: 1. Patient is to discontinue taking Tetracycline or Doxycycline. 2. A prescription is called in for an alternative antibiotic according to the physician's	L 100		

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L 100	Continued From page 16 instructions. Based on record review and review of the clinic infection control book, it was determined the clinic failed to follow the medical director's approved standing order for 1 of 1 post TAB patient who was allergic to Doxycycline (Tetracycline). Findings include: Patient # 14 was seen at the clinic for a procedure on 2/9/08. A review of the patients history and physical revealed the patient was allergic to Tetracycline. According to the discharge information the patient was given Doxycycline (contains tetracycline) 100 mg capsules to take 1 (one) capsule (100mg) twice a day for 5 (five) days. On review of the clinics infection control book it was noted the patient called the clinic on 2/12/08 with complaints of allergic symptoms and mild fever. The nurse advised the patient to stop the Doxycycline but there was no documentation the physician had been contacted, and no alternate antibiotic was provided. ********** 420-5-1-.03(8)(b) Infection Control Sterilization. Definitive written procedures governing sterilization techniques shall be developed. All equipment must be sterilized either by pressurized steam sterilization or gas sterilization. Procedures are to include: 1. Technique to be used for a particular instrument or group of instruments. Based on a report received by the complaintent	L 100		

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L 100	Continued From page 17 and an interview, it was determined the clinic failed to sterilize all instruments prior to use in 1 of 2 second trimester patients treated 06/12/08. The clinic failed to use a sterile speculum in 1 of 2 patients assisted by a second medical assistant on loan from another clinic in the area. Findings include: 1. Patient # 67 with a gestational age of 15.3 weeks had her procedure on 6/12/08 which started at 5:07 P.M. and ended at 5:12 P.M. During the procedure a 45 Pratt dilator was used in the termination procedure. The estimated blood loss was 75ccs. The patient arrived in the recovery room at 5:25 PM. 2. Patient # 66 with a gestational age of 15.3 weeks had her procedure on 6/12/08 which started at 5:26 P.M. and ended at 5:30 P.M. During the procedure a 45 Pratt dilator was used in the termination procedure. The estimated blood loss was 100ccs. The patient arrived in the recovery room at 5: 41 PM. An interview was conducted by telephone on 6/17/08 at 12:45 P.M. with the medical assistant who worked the sterilization/ autoclave room the day of procedures 06/12/08. Medical assistant # 1 was asked about her observations during the cleaning and sterilizing process on 06/12/08. She stated that a dilator was used, a 41-45 for a 16 weeker (16 weeks gestation) and it was sterile but then the assistant from the procedure room brought it to the sterilizer room and told her to wash it they needed to use it again. She said she told them it needs to be sterilized. The girl told her to wash it and put it in the basket to dry. She came back in	L 100		

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L 100	Continued From page 18 and picked it up with gauze and took it to the procedure room. The assistant was asked which room did she take it to? The response was, the room closest to the sterilizer room, only one room was being used because the suction machine in the other room wasn't working. The documented fact that the procedures followed by one minute between cases does not allow time to adequately clean the room and to sterilize the instruments. The assistant reporting this incident was on loan from another clinic in the area due to a staffing shortage at this clinic. Medical assistant # 2 was interviewed in person on 06/17/08 at 12:50 PM. This assistant started out assisting in the procedure room on 06/12/08. Medical assistant # 2 was asked about her observations in the procedure room. She stated she saw a patient approximately 14 weeks. The doctor said that the speculum wasn't big enough and he opened the drawer at the end of table and just pulled one out an used it. It was not wrapped so it was not sterile. She told them right then she just wanted to be a runner and not work in the rooms. Medical assistant # 2 was asked which room this happened in and she said, only one room was working. One of the suction machines wasn't working. It wouldn't suck. On 06/16/08 the surveyor did observe in procedure room # 2 that the exam table drawer contained different sizes of speculums laying in the drawer. The instruments were not wrapped and not packaged in a manner to keep them aseptic or clean.	L 100		
L 200	ALABAMA LICENSURE DEFICIENCIES	L 200		

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L 200	Continued From page 19 This Rule is not met as evidenced by: 420-5-1-.02 (6)(b) Administration. (6) Fire Evacuation Plan. (b) Fire Drills. Fire drills shall be conducted at least semi-annually for the staff and written observations of the effectiveness of these rehearsals shall be filed and kept at least three years. Based on an interview with the clinic administrator on 6/13/08 at 2:00 P.M., it was determined there was no documentation of a fire drill being conducted within the past year. ******** 420-5-1-.03 (4)(d)(3)(4) Patient Care. (d) Laboratory Tests. If the above tests are performed by the facility, the facility's laboratory personnel shall meet any requirements which are in effect and which apply to the facility under Rules promulgated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Act Amendments of 1988. If the tests are referred, they shall be referred to a hospital, to a pathologist certified, or deemed Board eligible by the American Board of Pathology, who is currently licensed to practice medicine in Alabama, or who holds an equivalent license in another state, or to an independent clinical laboratory. If the tests are sent to an independent clinical laboratory in Alabama, such laboratory must be licensed by the State to perform clinical and anatomical work. If the tests are referred to a laboratory outside the State, the laboratory	L 200		

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L 200	Continued From page 20 must hold an interstate license or letter or exemption under the 1988 Clinical Laboratory Improvement Act (CLIA). When specimens are collected on premises, a record must be maintained to reflect the apparent condition of the specimen, time and date collected, and name of the patient. All personnel collecting specimens shall be adequately and appropriately trained and, where otherwise required by law shall be licensed, and their personnel files shall reflect such training and licensure. Based on interviews with testing personnel and direct observation of urine pregnancy,(non-waived)procedure, and microhematocrit, (waived), lab procedures, it was determined that the technical consultant, also serving as the Laboratory Director, had not provided adequate technical and scientific oversight to detect the following: 1. The surveyor asked both lab testing personnel what the hematocrit quality control (QC) "crosscheck"was at the bottom of the QC records. They said they did not know what QC crosscheck meant even though they were signing and dating as having done this check on a daily basis. 2. The laboratory's hematocrit procedure had a reference source from Wintrobe, 1933 and not the Triac manufacturer Operator's Manual copyright @ 1981. 3. The laboratory testing personnel was observed, by the surveyor, performing a non-waived urine pregnancy test incorrectly, not following the laboratory's policy allowing 2 minutes for the reaction to occur before reading and reporting the results. This employee stated	L 200		

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L 200	Continued From page 21 that she did not use the timer, but rather estimated the two minute timeframe. The laboratory's technical consultant, also serving as the Laboratory Director, failed to provide technical and scientific oversight to detect laboratory errors, implement corrective actions, monitor , and evaluate corrective action plans to ensure that these problems did not recur. The findings are: 1. Laboratory personnel were performing hematocrit procedures and checking off under quality control as having performed the "crosscheck" daily, however when asked what the check mark indicated, neither of the two testing personnel could answer. 2. Annual competency evaluations for the two lab testing personnel had not been performed and documented by the Technical Consultant, also serving as the Laboratory Director. 3. Maintenance records for the Triac Centrifuge had not been maintained to ensure that the motor brushes had been inspected for proper length and function, and replaced on an as needed bases as required by the manufacturer. 4. The lab's hematocrit procedure was taken from a hematology textbook, Wintrobe, 1933, which is outdated, and not the manufacturer's procedure for the Triac Centrifuge, which has been approved by CDC and FDA as a waived test procedure. The Laboratory Director had not ensured that a	L 200		

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L 200	Continued From page 22 procedure or manufacturer's manual was available for the Triac Centrifuge. The findings are as follows: 1. Laboratory testing personnel and the center's administrator was asked about a procedure manual for the Triac Centrifuge. They replied that they were not aware of one. The administrator stated that the instrument was so old that she was not sure if a they could get a manual or replacement parts for the centrifuge. 2. Quality control procedures were not available for review. 3. Quality assessment program was not available for review. The Laboratory Director had failed to ensure that policies and procedures were available and staff inserviced on the preanalytical, analytical, and postanalytical phases of laboratory testing. The findings are as follows: 1. Based on observation by the surveyor, laboratory personnel failed to appropriately instruct patients on the proper collection and labeling of urine samples. A patient came into the lab, while testing personnel was out obtaining some copies for the survey, and told the surveyor that she had written her name on the specimen cup and asked where she should leave it, the specimen. She told the surveyor she had not been asked to write her name on the cup, but thought she should do that so it wouldn't get mixed up with somebody else's specimen.	L 200		

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L 200	Continued From page 23 2. The surveyor observed two unlabeled urine specimens setting on the counter for urine pregnancy test to be done. The lab testing personnel picked up one of the sample and stated to the surveyor that she was going to ask the patient to recollect the sample. The patient, when asked to recollect the specimen, told the lab personnel that her urine had a paper towel wrapped around it so she could tell which of the samples was hers. The testing personnel told her that she could not use that and ask her to collect another one. However, there was another unlabeled specimen on the counter with a urine pregnancy test to be done. The Laboratory Director had not conducted the annual personnel competency evaluations on two of two laboratory testing personnel. The previous evaluation was signed and dated by the Laboratory Director in April 2007. All lab testing personnel should demonstrate that they can perform all testing operations reliably and report accurate lab results. One lab testing personnel was observed estimating the 2 minutes reaction time for urine pregnancy testing, rather than utilizing a timer for an accurate time measurement. The laboratory did not have a written quality control procedure for testing personnel to reference. The quality control log indicated with a checkmark that a "crosscheck" is done daily for the hematocrits. When asked what a "crosscheck" was and how it was done, both testing personnel said they did not know, but marked it as being done.	L 200		

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L 200	Continued From page 24 Based on an interview with testing personnel and on a review of the CMS OSCAR 155 report, it was determined that the lab had failed proficiency testing for urine pregnancy for Event #2, 2008. There was no documentation available to verify that the Laboratory Director had reviewed and implemented corrective actions to ensure that the failure did not reoccur. The Laboratory Director had failed to observe laboratory testing personnel modifying the urine pregnancy test procedures. This modification of the test procedure could render the lab results inaccurate. The finding is as follows: 1. Based on an interview with testing personnel and on direct observation of the Wampole Urine Pregnancy Test, nonwaived procedure, it was determined that lab personnel was not following the manufacturer's and the facility's instruction to allow 2 minutes for the reaction to occur. 2. Testing personnel stated that she estimated the 2 minutes and did not time the reaction with a timer. 3. The lab had scored a 60% failing score on Proficiency Testing Event #2, 2008 for urine pregnancy tests. The Laboratory Director, also serving as the Technical Consultant, failed to provide direction and technical oversight for the four laboratory procedures conducted in this center as evidenced by the following:	L 200		

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L 200	Continued From page 25 1 The microhematocrit instrument was outdated, not functioning properly, and not providing the quality lab results required for patient care. 2. Laboratory personnel failed to follow the urine pregnancy test procedure, nonwaived, and laboratory policy to ensure accurate and reliable results. 3. Proficiency Testing results, worksheets, and attestation statements were not retained for the CLIA required two year record retention period. The laboratory had received a score of 60% on the nonwaived Wampole pregnancy test for Event #2, 2008, however, no documentation was available to verify that the Laboratory Director had either reviewed or taken corrective action for this failure. 4. The laboratory failed to have a written quality control or a quality assessment program established and maintained to assure the quality of laboratory services provided 5. Testing personnel had not had an annual competency evaluation as of date of the survey in 2008, previous evaluation conducted by the Laboratory Director was April 2007. 6. Policies and procedures for the preanalytical, analytical, and postanalytical phases of testing had not been established and reviewed with testing personnel. 7. Testing personnel did not have a procedure manual for the Triac Centrifuge for the microhematocrit procedure. Based on an interview with laboratory testing	L 200		

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L 200	Continued From page 26 personnel, review of patient test results and quality control check, it was determined that manufacturer required maintenance on the Triac Centrifuge had not been performed to assure that the centrifuge was providing accurate hematocrit results. The findings are as follows: 1. The microhematocrit instrument was outdated not functioning properly. A review of 47 days of patient hematocrit results revealed 20 days having patient hematocrit results of 47-58%, abnormally high. 2. The lab failed to have available an instrumentation manual for the Triac Centrifuge to reference and to perform maintenance in accordance with the manufacturer's instructions. 3. The center's administrator stated that she was not aware of a instrument manual for the centrifuge and that the instrument was old and probably needed replacing. 4. The Laboratory Director had failed to identify the instrument malfunction and the unusual number of high patient hematocrits Based on an interview with testing personnel, direct observation of the test procedure, and facility's hematocrit procedure, the laboratory testing personnel failed to follow the lab's current hematocrit policy and the manufacturer operator's instructions when performing the microhematocrit test procedure, a waived test, on the Triac Centrifuge. The findings include:	L 200		

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L 200	Continued From page 27 1. The laboratory hematocrit policy states to fill 2 capillary tubes with blood and centrifuge for 3 minutes, read, and record results. The surveyor observed testing personnel fill one capillary tube, centrifuge, read and record the result as 41%. Forty seven days of patient test results were reviewed and none of the patient hematocrits had been run in duplicate and recorded as stated in the laboratory's policy. 2. The laboratory's hematocrit policy states that the machine, (Triac Centrifuge) is calibrated once a month, and the maximum packing speeds are checked once a month. However, the maintenance stickers, performed by an outside equipment maintenance company, indicated that these checks were done on an annual bases, rather than monthly as stated in the policy. The manufacturer state that the motor brushes should be inspected every six months, but the laboratory had no documentation from the maintenance company to verify the proper length, functionality, and replacement of the brushes as needed on the Triac Centrifuge. 3. The laboratory's hematocrit procedure stated that the normal range is 34-48%. However, the manufacturer's stated normal range is 37-47% .Based on a review of 420 patient hematocrit results from April 15 through June 14, 2008, it was determined that an abnormally high number of patients had hematocrit values ranging from 47-58%. Levey Jennings graphs plotted by the surveyor demonstrated a bias to the high side of the mean, 38% Hematocrit value, for 42% of patient results, also 42% of patient results were found to be above the mean , while only 16% were found to be below the mean , with only two patients having a hematocrit result of 30 %.	L 200		

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L 200	Continued From page 28 4. The laboratory's two testing personnel and the center's administrator was asked if the lab had a Triac Centrifuge instruction manual or a manufacturer's procedure for proper maintenance instructions; they stated they did not. The administrator said that the instrument was old and probably needed to be replaced. 5. The lab's hematocrit procedure was referenced to an older laboratory hematology reference book, Wintrobe, Macroscopic examination of the blood, Am. J. Med Sci, 185:58, 1933. However, the manufacturer operator's manual, obtained by the surveyor, for the Triac Centrifuge model number 0200 has a copyright@ 1981, which is a more current and is the microhematocrit waived test procedure and the methodology approved by CDC and FDA. Based on a review of personnel and proficiency testing records, it was determined that the laboratory had failed to maintain an effective mechanism to evaluate and monitor all general laboratory systems. The findings include: 1. Documentation was not available to assure that annual competency evaluations had been performed by the technical consultant (also serving as the laboratory director) on the two testing personnel. The last employee competency evaluations for the two current testing personnel were signed and dated by the Laboratory Director on 4/26/2007. 2. Corrective actions had not been taken and documented for the following unacceptable proficiency testing results: Event #2, 2008- Urine Pregnancy (60%).	L 200		

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	C5101	A. BUILDING _____ B. WING _____	C 07/18/2008

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L 200	Continued From page 29 3. Proficiency testing worksheets and attestation statements had not been retained for Event # 2, 2007, Event #3, 2007, Event #1, 2008, and Event #2, 2008. 4. Since the laboratory failed to retain worksheets and attestation statements, the surveyor could not determine if proficiency testing had been rotated among the two testing personnel. 5. No quarterly assessment reviews were available to verify whether the laboratory had identified and/or implemented corrective actions to address the above noted problems. 6. This is a repeat deficiency cited on the CLIA recertification survey 4/25/2007. The laboratory had submitted an acceptable plan of corrections with an effective date of 4/26/2007, which stated that violations would be corrected and monitored by the Laboratory Director and the center's Executive Director. The plan of correction also stated that any deviations will be reported to the Governing Body for further action. 420-5-1-.03 (4)(d)(4) Each abortion and reproductive health center must develop and retain on file a written quality assurance plan governing the performance of all laboratory procedures performed on-premises. Facilities will be subject to unannounced inspections by the Department of Public Health to determine that on-premises laboratory procedures are being correctly and accurately performed. Findings include: Based on review of the quality control log and an interview the laboratory failed to have written	L 200		

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L 200	Continued From page 30 quality control or quality assessment program established and maintained to assure the quality of laboratory services provided The laboratory did not have a written quality control procedure for testing personnel to reference. The quality control log indicated with a checkmark that a "crosscheck" is done daily for the hematocrits. When asked what a "crosscheck" was and how it was done, both testing personnel said they did not know, but marked it as being done. The laboratory failed to have a quality assessment program to identify instrument malfunction, instrument maintenance requirements, proficiency testing reviews, personnel evaluations and other systems in place to identify problems, implement corrective actions, monitor, and evaluate the effectiveness of the corrections to ensure the problem does not reoccur. ******** 420-5-1-.04(5)(b)(2)(c) Physical Environment. 2. Autoclave: All autoclaves must be tested and maintained at least annually by a trained, qualified technician in accordance with the manufacturer's recommendations, except that necessary routine weekly cleaning, maintenance, and inspection may be performed by properly trained clinic staff or a trained, qualified technician in accordance with the manufacturer's recommendations. Dated chemical indicators shall be used with every load to ensure sterilization. Biological indicator testing must be performed every 40 service-hours, and the results of the biological indicator testing must be	L 200		

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L 200	Continued From page 31 logged. Based on an interview, observation and review of the policy and cleaning log the facility failed to assure the Speed Clave Sterilizer received daily, weekly and monthly maintenance. This affected all patients who received procedures at the facility. Findings include: On 06/12/08 at 8:34 AM initial tour of the facility revealed a Speed Clave Sterilizer located in the equipment cleaning area. Posted on the wall above the Speed Clave Sterilizer was a document titled "Autoclave Maintenance" which read, "In order to keep our autoclave in good working condition, the following needs to be completed daily, weekly and monthly:..." There were directions listed for completing daily, weekly and monthly cleaning. A review of the weekly autoclave cleaning log book revealed the Speed Clave Sterilizer had not been cleaned the week of 06/08/08. On 06/12/08 at 4:38 P.M. a staff member, from another clinic, was observed to use the Speed Clave Sterilizer to sterilize a package of used equipment. On 06/16/08 at 1:13 P.M. a staff member, who is employed full time with the clinic, was asked how often the cleaning is done on the autoclave and responded, "As far as I know we only do the autoclave weekly. We don't do the daily or monthly. I've been doing the autoclave lately." There was no documentation of the Speed Clave Sterilizer being cleaned daily or monthly in the	L 200		

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L 200	Continued From page 32 facility. In addition, there was no documentation of biological indicator testing being performed every 40 service-hours. (c) The facility must maintain a record for all equipment containing the following information: manufacturer, make, and model of the equipment; date of purchase of the equipment; any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to service; date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by clinic personnel; the names and qualifications of the company and technician performing the tests, maintenance, or repairs; and the results of any tests, maintenance, or repairs. In addition, all manufacturer literature and information must be maintained in this record. If any of this information is not available for equipment purchased prior to October 2006, the fact of the missing information shall be noted in the equipment record, and, if there is no record of proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired. Based on observation and interviews the facility failed to remove from service one of two suction machines used for patient procedures that was not functioning properly. Findings include: On initial tour of the facility on 06/12/08 at 8:34 A.M. in each patient treatment room there was a	L 200		

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L 200	Continued From page 33 suction machine with a label showing the last inspection date of the equipment was completed 06/08. On 06/12/08 the facility was scheduled to perform 16 abortion procedures. An invoice from the medical equipment inspection company dated 06/02/08 was reviewed on 06/16/08. The invoice listed only one suction machine was inspected. On 06/17/08 at 12:45 P.M. Medical Assistant # 1 was interviewed by phone and stated only one suction machine was working on 06/12/08. On 06/17/08 at 12:50 P.M. Medical Assistant # 2 was interviewed and stated only one room was working, one of the suction machines was not working. It would not suck. On 06/18/08 at 2:19 P.M. the Medical Technician (MT) who completed the equipment inspections in June 2008 was interviewed by phone. The MT was asked how many suction machines were checked during his June 2008 visit and he stated, "There was one that was broke down and I told Ms. (former Administrator's name) to replace it. (The machine) needs a new pump head...I worked on it, but couldn't get parts (needed) to fix (the) suction machine. I looked at it but didn't certify it." There was no documentation the suction machine was taken out of service and the suction machine was not labeled to alert staff the machine was not working.	L 200		