Hope Medical Group for Women

Lab Procedures

Section XII of Standard Operating Procedures

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A. General Guidelines

Laboratory testing and staffing at Hope Medical Group for Women will fall within the guidelines of moderate complexity as established by the Clinical Laboratory Improvement Amendment.[1]

B. Personnel Requirements

Personnel responsible for laboratory are linked to the complexity of testing. While four different job descriptions are defined, please note a single individual may perform up to all four jobs. For moderate complexity labs they include:

Laboratory Director:

- Responsible for the overall management and direction of the laboratory but does not have to be on-site at all times.
- Broad range of experience and education acceptable. For example, a physician with 1 year of experience directing/supervising a non-waived laboratory or 20 CMEs in laboratory practice would qualify, as would a person with a bachelor's degree and 2 years laboratory training/experience plus 2 years supervisory experience in non-waived testing.
- The director could, depending on education and experience, qualify for all other positions

Technical Consultant:

- Responsible for the technical and scientific oversight of the testing.
- Minimum requirement a bachelor's degree with 2 years laboratory training or experience in non-waived testing

Clinical Consultant:

- Provides clinical consultation.
- Minimum requirement a doctoral degree with board certification

Testing personnel:

- Responsible for specimen processing, test performance and reporting test results.
- Minimum requirement is a high school diploma or equivalent and training for the testing performed testing.

C. Responsibilities of Lab Director, Technical Consultant and Clinical Consultant:

[1] http://wwwn.cdc.gov/clia/moderate.aspx

- Responsible for overall operation and administration of the lab, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately, and proficiently to ensure compliance with applicable regulations
- Annually evaluates and documents the performance of all testing personnel
- Serves as Laboratory Director, Clinical Consultant and Technical Consultant
- Ensure that lab personnel have ready access to onsite, telephone or electronic consultation as needed
- Ensure that testing systems are developed and used for each test performed in the lab, and that the testing systems assess all aspects of test performance, including pre-analytic, analytic and post-analytic phases of testing.
- Ensure the physical plant and environmental conditions of the lab are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical and biological hazards
- Ensure:
    1. Test methodologies selected have the capability of providing the quality of results required for patient care
    2. Verification procedures used are adequate to determine the accuracy, precision and other pertinent performance characteristics of the method
    3. Laboratory personnel are performing the test methods as required for accurate and reliable results
- Ensure:
    1. The lab is enrolled in a HHS approved proficiency testing program
    2. The proficiency testing samples are tested as required under subpart H of CLIA regulations
    3. Test results are returned within the time frame established by the testing program
    4. All testing reports are reviewed and signed in a timely manner to identify any problems requiring corrective action
    5. An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system
- Ensure all necessary remedial actions are taken and documented whenever significant deviations from the lab's established performance specifications are identified and patient test results are reported only when the system is functioning properly
- Ensure reports of test results include pertinent information required for interpretation

- Ensure consultation is available to the lab's clients on matters relating to the quality of test results reported and their interpretation concerning specific patient conditions
- Employ a sufficient number of lab personnel with the appropriate education and either experience or training to provide appropriate consultations, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities
- Ensure prior to testing patient specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated they can perform all testing operations reliably to provide and report accurate results
- Ensure policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical and post-analytical phases of testing to ensure they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.
- Ensure an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Procedures and changes in procedures must be approved, signed and dated by the Lab Director prior to implementation of procedures.
- Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the pre-analytic, analytic and post-analytic phases of testing that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.
- Reports to the clinic owner/ administrator
- Supervises all lab personnel
- Interpersonal relations

  1) Direct contact with patients, physicians, lab personnel and administrator

  2) Direct contact with Lab Corp, consulting committee (governing board), hospitals and other health care providers. May have direct contact with state surveyors/ inspectors.
- Level of difficulty is moderate to high. Acts independently subject to policies set forth by board
- Impact of error is significant. Could jeopardize a patient's health. Could damage relationships between other health care providers and clinic. Could result in deficiencies as established by state or CLIA surveyors.

- ***Qualifications***:

  1) Must meet the qualification requirements for moderate complexity testing listed in section I of HCFA-114.

2) Must have more than one year of experience directing and supervising moderate complexity lab testing.

3) Ability to provide technical and scientific oversight of of all tests performed in the lab.

4) Experience in each of the specialties of tests performed is required.

5) Ability to serve as liaison between laboratory and its clients in reporting and interpreting results.

- Minimum Education:

  Must be an MD, DO or board certified doctoral level scientist.

THE ABOVE STATEMENTS ARE INTENDED TO DESCRIBE THE GENERAL NATURE AND LEVEL OF WORK PERFORMED IN THIS POSITION. THEY ARE NOT TO BE CONSTRUED AS AN EXHAUSTIVE LIST OF ALL JOBS PERFORMED BY LAB DIRECTOR/CLINICAL CONSULTANT/TECHNICAL SUPERVISOR.

D. Responsibilities of Lab Testing Personnel:

- Upon hire, updates/changes to procedure/policy, and at least annually read and review lab manual
- Process all ordered laboratory tests or obtain specimens to be sent out
- Maintain lab, keep it stocked, clean and orderly
- Check inventory of supplies and Inform Director or Administrator of needed supplies
- Properly discard all expired testing supplies and reagents
- Analyze lab requisitions for accuracy
- Accurately record lab findings in appropriate places on patient charts
- Inform Lab Director and Administrator of malfunctioning equipment or need for new equipment
- Maintain acceptable level of knowledge regarding current lab tests and equipment
- Perform miscellaneous projects as requested by Lab Director
- Perform proficiency tests as required by CLIA
- Follow the laboratory's procedure for specimen handling and processing, test analysis, reporting and maintaining records of patient test results

- Maintain records that demonstrate proficiency testing samples are tested in the same manner as patient samples
- Adhere to lab's quality control policies, document alt quality control activities, instrument and procedural calibrations and maintenance performed
- Follow lab's established corrective action policies and procedures whenever test systems are not within the lab's established acceptable levels of performance
- Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the Lab Director and Administrator
- Document all corrective actions taken when test systems deviate from the lab's established performance specifications
- Reports to the Lab Director and Administratbr
- Direct observation by Lab Director
- Has direct contact with patients, significant contact with physicians including Lab Director and regular contact with Administrator
- Has direct contact with state/CLIA surveyors and some degree of contact with outside labs
- Level of difficulty is moderate
    1) Acts with considerable independence, subject to policies set by Lab Director and board
- Impact of error is significant
    1) Could jeopardize a patient's health. Could damage relationship between patients and clinic. Could result in fines or deficiencies as established by state or CLIA.
- Significant physical demands such as standing for long periods of time is often required
- Flexibility in hours and days of work is required

- *Qualifications*:
    1) Well informed about various lab tests and their limitations, technical information.
    2) Understands and observes a professional code of ethics based on respect for patient's privacy and autonomy.
    3) Demonstrates the ability to function as a team member and an independent professional in a health care setting.
    4) Flexible and functions well under pressure.
    5) Average or above average written and verbal communication skills.

6) Well groomed appearance, pleasant personality, courteous manner and professional demeanor.

- Minimum education:

1) High school diploma or equivalent and training for the testing performed.

2) LSBME license.

Staff members who are performing Rh-typing (or any and all tests that are covered by CLIA) must have two personnel files. One file is kept in the personnel files in the front office and a copy of this file is kept the doctor's office in the credenza solely for CLIA record keeping.

Lab personnel files should contain the following:

- An application
- Copy of degree
- A license from the state of Louisiana (LSBME)
- An Evaluation of Lab Personnel signed by the Medical Director for new employee
- Evidence of "independent" testing results which must occur three times a year. If the employee is unavailable during proficiency testing, an annual review signed by the lab director can be substituted.
- Signed statement of understanding regarding "universal" precautions
- Signed statement from the lab personnel that he/ she has received the CLIA Lab management manual and protocol
- A "New Employee Checkout Sheet"

E. Lab Requirements

Every day "CLIA" covered lab tests are run temperatures, lot numbers expiration and required maintenance are checked and documented. In addition, (Rh typing) the laboratory technician is required to check and document on the appropriate log the following:

1. The temperature of the lab refrigerator. The temperature should remain between 2-8 degrees C.
2. The temperature of the incubator range 36-38 degrees C.
3. Anti-D type, lot and expiration date
4. Rh control type, lot, expiration date and control results
5. Saline solution lot and expiration date

6. All reagents lot and expiration
7. Any deviation reported
8. Signature of lab technician.

F. Proficiency Testing

Policy:

1) PT Participation

Laboratory participates in a HHS approved proficiency testing program.

2) Alternative Assessment

If PT is not available, participation in an ungraded/educational PT program or split sample testing analysis with another laboratory, or split samples with an established in-house method, assayed materials, clinical validation by chart review, or other suitable and documented means.

3) PT Integration Routine Workload

All PT samples are integrated within the routine laboratory workload. All PT samples are analyzed by personnel who routinely test patient samples on a rotation basis. All PT samples are analyzed using the same method as for patient samples.

4) Interlaboratory Communication

Interlaboratory communication about PT samples are strictly prohibited until after the deadline for submission of data to the proficiency testing provider.

5) PT Referral

Referral of PT specimens to another laboratory or acceptance of PT specimen from another laboratory is strictly prohibited. In instances which samples would be sent out for a confirmation normally, document "Would refer" or "Test Not Performed".

The Laboratory is required to be tested by an 'independent lab" three times a year for proficiency testing.

Analysis of material

This test consists of laboratory evaluation of five unknown samples for each type of test performed by the lab that is CLIA "covered".

Receipt of survey materials

Upon receipt of survey samples, document date on report form. Examine package for content and breakage. Read and follow instructions.

- Review and Reporting

A passing grade for this test is 100%. The results of the test are recorded on the lab patient log and accurately on the data survey form. The lab director will review the results documented on the patient log

for that day prior to signing the original data survey form which is then submitted to American Association of Bioanalysts. It is the responsibility of the lab director to ensure:

1. Test results are transferred with the appropriate numeric code to the data survey form.
2. Test results are entered in the appropriate space provided for the analyte tested on the data survey form.

All PT survey documents will be maintained 2 years from the date the PT survey was conducted and reviewed. Copies of the completed form will be kept on file in the filing cabinet in the doctor's office in the personnel file of the employee who performs the test and the file labeled "Proficiency Tests." Each time a proficiency test is performed, the test kit is retained in the lab refrigerator until test scores have been received. Test scores will be reviewed and signed by the lab director and copies placed in the "Proficiency Test" file and the employee's file. It is the responsibility of the Administrator to ensure the results are signed by the Lab Director. It is also the responsibility of the Administrator to maintain a yearly calendar of proficiency testing dates in the lab and ensure proficiency tests are completed and submitted in a timely manner by the lab personnel assigned to the lab when the tests are received.

- Corrective Action of a PT Failure

In the event a score of less than 100% is received, the Lab Director and Administrator will be immediately notified. The following action will be taken to investigate the source of error and resolution.

1) Clerical Error

The lab log for the day the test was run will be reviewed for any discrepancy

2) Procedural

Check QC records for any bias, check reagents logs for their open stability, and maintenance records for any problems during PT testing performance.

3) PT material and specimen handling

Check date to make sure the samples were analyzed within the indicated timeframe. Were the PT samples stored correctly and instructions followed? The test will be run again by the personnel who performed the original test. The results for both days will be compared by the Lab Director.

In the event any portion of the test originally submitted by the lab personnel is found to be in error, remedial training as deemed appropriate by the Lab Director will documented.

G. Quality Assurance

To provide a quality plan to maintaining and achieving quality results for our patients and physicians in the treatment of our patients. This is achieved by good laboratory practices, maintaining regulatory standards of testing. Continual assessment will be done to ensure effectiveness of the Quality Assurance Plan.

Assessment Monitors:

1) Quality Control

Performance of valid required QC documentation.

2) Proficiency Test

Enrollment in an acceptable PT program for PT required test.

3) Documented logs

Maintenance, temperature and reagent log inventory.

4) Internal Audit Procedure

An internal audit of patient records will occur to ensure the effectiveness of the entire laboratory program. The focus of this QA is to ensure all test results are accurately documented. An audit of Rh results are consistent with clinical history, with Rh results on the lab log, confirmation Rh negative patients were given Rh immune globulin and all analytic systems are documented. All lab test results will be periodically checked for accuracy of documentation.

Audits will be done periodically at minimal twice a year the Laboratory Director will review and sign the completed Quality Assurance Audit of Rh Factor testing. Audits will consist of at least 20 patient chart reviews. A copy of the completed Rh test audit will be kept on file in the doctor's office.

Staff Responsibility

It is the responsibility of the Administrator to ensure all record keeping; including evaluations, testing and documentation are occurring in a timely fashion. All above materials should be current and available in the filing cabinet in the doctor's office at all times. It is also the responsibility of the Administrator to secure the Lab Director's signature on any amendment or revisions to the procedure manual prior to the implementation of any changes. Any staff member may be asked to assist in keeping these records current and ensuring they are in the filing cabinet in the physicians' office.

H. Laboratory Testing: use standard precautions PPE wear gloves when testing and perform all checks for appropriate tests.

Micro-Hematocrit

PRINCPLE: Whole blood is centrifuged for maximum red blood cell packing. The space occupied by the blood cells is measured and expressed as a percentage of the whole blood volume.

SPECIMEN NEEDED:

- Capillary blood (fingertip)

MATERIAL AND EQUIPMETN NEEDED:

- Two heparinized capillary tubes (black).
- Sealing clay for capillary tubes.
- Micro-hematocrit centrifuge (10,000-12,000 rpm.)
- One sterile lancet.
- One alcohol prep (70%).
- One dry gauze pad (2x2).

TEST PROCEDURDES:

Patient testing

Have patient seated in chair with armrest. Tell the patient this will be a finger stick.

- Assemble materials (lancet, alcohol pre and gauze pad.)
- Holding the patient's hand downward, grasp the middle or ring finger firmly.
- Open alcohol prep and have dry gauze ready. Clean the site with the prep pad. Use the lancet to make a deep stick quickly on the side of the finger or across the fingertip pattern. Use dry gauze to wipe away the first drop of blood. The blood will flow freely. If blood does not flow freely, gently massage the finger. If this doesn't produce a free flowing supply of blood, then make another puncture.
- Collect the blood specimen by placing the end of the capillary tube against the blood drops. Allow the tube to fill without any air bubbles. Seal the ends of the tubes with sealing clay. Mix by tilting left and right and by rolling capillary tubes between hands. Place the tube in the hematocrit machine and follow the instructions for operating the HemataSTAT II (see examples 18 & 19). Read the results when the machine has stopped, record on log (see example #16) and green sheet (see example #13).
- Clean the patient's finger with gauze pad and have patient apply pressure to the finger with her thumb until bleeding has stopped.

NORMAL VALUES:

- Adult males: 40-54%
- Adult females: 38-47% if a patient indicates she has been hospitalized within the past two weeks for dehydration or if her Hct. is 50% or higher she should be taken to the Recovery room at which time the nurse will start an IV.

CONDITIONS THAT CAUSE THE HEMATOCRIT TO VARY FROM NORMAL.

High Hematocrits:

- Polyeythemia
- Dehydration

Low Hematocrits

- Anemia
- Leukemia
- Hydremia

SOURCES OF ERROR:

- Improper sealing of capillary tube.

- Improper centrifugation leads to varied results.
- Misreading the red cell level by including the buffy coat.

Hematocrit Reference Control (HemaChek)

1) Ensure bottle cap is tightly closed.

2) Vigorously tap the bottle against the palm of your free hand. As soon as the plastic mixing bead can be heard, continue to tap bottle for one minute.

3) After mixing for one minute, check through the bottom of bottle for clumping if any seen repeat above steps.

4) Use this mixing technique each time before filling capillary tubes. Follow procedure above to test.

5) After each use, clean the threads of the vial and cap with an absorbent material.

6) Always replace the cap after use.

Rh Testing

Principle:

The D determinant is one of over 50 antigens in the Rhesus system. Approximately 85% and 92% of whites and blacks, respectively, have inherited the D gene. When agglutination of red cells at the immediate spins or incubated phases of testing with Anti-D indicates the presence of the D antigen, they are Rh+. No agglutination at this phase signifies either the absence of D, or that the cells possess a weakened form of the D antigen. Negative reaction obtained at the antiglobulin phase of testing will confirm the absence of D. At the beginning of each day Rh testing is performed controls must be run and documented.

Procedure for Running Quality Controls Tube Test:

Supplies needed:

Disposable test tubes, 10x 75 or 12 x 75

Serological Centrifuge

Rh Blood Grouping Reagents (Anti-D)

NaCL (0.85%) with expiration date clearly documented on bottle in use

Screening Cells I, II, and III

Timer (for weak D)

37 C incubator (for weak D)

Anti-IgG AHG (for weak D)

Coomb's control cells (IgG-coated Red Blood Cells for weak D)

- Label tubes as 1, 2, and 3 and Rh.

- Place two drops of Anti-D in each test tube labeled 1-3.
- Place one drop of NaCl in each test tube labeled 1-3.
- Place one drop of screening cell 1 in test tube one.
- Place one drop of screening cell 2 in test tube two.
- Place one drop of screening cell 3 in test tube three.
- In the tube that is labeled Rh, place two drops of Gamma Control Rh, one drop of NaCL.
- Mix the contents of the tubes thoroughly and centrifuge the tube for 15 seconds.
- Remove the test tubes from the centrifuge and gently agitate the tube to dislodge the cell button, observing for agglutination.
- Read, grade and record FOR POSITIVE agglutination results on designated forms in the QC book. For negative results perform weak D test.

Weak D Test

1) Add 1 drop of Ant-D to negative result of screening cell tube prepared above tube test.
2) Mix the contents of tube thoroughly. Incubate tube at 36-38 C for 15 minutes.
3) Wash at least 3 times with isotonic saline. Decant tube completely after each wash.
4) Add 2 drops of anti-human globulin and mix content thoroughly.
5) Centrifuge the tube. Gently resuspend the red cell button and read macroscopically for agglutination. Record result.
6) Use IgG coated red blood cells to confirm the validity of a negative antiglobulin test.

CAUTION:

All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived form human blood will not transmit infectious agents.

LIMITATION:

- Reagent Antisera and Rd Blood Cells may suffer a loss of specificity or potency or both as result of deterioration during shipping or storage or as a result of contamination during preparation of microorganisms. For these reasons, individual laboratories must confirm that each reagent, on each day of use is suitably reactive when used according to manufacturer's direction.

Patient testing:

SPECIMEN Requirement:

- The patient's red blood cells (finger stick method).

REAGENTS, MATERIALS AND EQUIPMENT NEEDED:

- Rh Blood Grouping Reagents (Anti-D)
- Serological centrifuge (3,400 rpm)
- Applicator sticks
- NaCL (0.85%)
- Marking pensTimer (for weak D)
- 37 C incubator (for weak D)
- Anti-IgG AHG (for weak D)
- Coomb's control cells (IgG-coated Red Blood Cells for weak D)

RH (D) TYPING (TUBE TEST TECHNIQUE):

- Place test tube in the test tube rack for each patients
- Add one drop of NaCl and two drop of Anti-D to each tube
- Prick patient's finger and using applicator, stick swipe one small drop of patient's blood on to applicator stick and place in to test tube (this will make a 2-5% suspension).
- Mix the contents of the tube thoroughly and centrifuge the tube for 15 seconds.
- Remove test tube from centrifuge and gently agitate the tube to suspend the cell button. Examine for agglutination.

INTERPRETATION:

- Positive Test: Agglutination of red blood cells in vitro.
- Negative Test: No agglutination of red blood cells in vitro.

Check all suspicious and negative test results for weak D using steps above for controls substituting the negative screening cell tube with the negative patient specimen tube. Record results on the green sheet and lab log. If negative, record the result in red on the green sheet and lab log. The chart should be stamped Rh- in red on the front of the chart, on the green sheet, and pink sheet (see example #12, 13, and 14). The patient should also be given the Rh- information sheet. (See example #18).

CAUSES OF FALSELY POSTIVE OR FALSELY NEGATIVE TEST RESULTS

- Bacterial or chemical contamination of test materials.
- Improper centrifugation of test tubes.
- Improper storage of materials or omission of test reagents.

Note: Finger stick method (see procedure for hematocrit).

Control Acceptability Criteria For Rh Typing

- Reagent red blood cells from Gamma Biological will be tested every day of patient testing. The testing protocol will follow the guidelines set up by Gamma Biological. See "Directions for Use Reagent Red Blood Cells- Gamma Trio".
- Results will be documented in writing where designated on the laboratory log.
- If the control tests are at variance with the known samples (Gamma Biological reagent Red Blood Cells), then new reagents will be utilized and retested with reagent red blood screening cells.
- Those results will also be documented in writing where designated on the laboratory log.
- If the control test is still at variance patients will be referred for testing elsewhere within 72 hours or all patients will be given a shot of Rh antibody.
- In the event of 2 false tests results the Medical Director and Administrator will be notified.
- A deviation report will be filed with the Medical Director and Administrator.
- Appropriate action to correct the deviation will include procuring new reagent red blood cells and new antigen and anti D serum.
- When (and only when) accurate testing occurs using positive and negative reagent blood cells, Rh testing and laboratory will recommence.
- The accurate tests must be documented in the laboratory log. A copy must be submitted to the Medial Director and the Administrator.
- Assay sheets included in screening cells will be attached to the patient log on the initial date the screening cells are used. This will remain on file with lab records a minimum of five years.

Lab Procedure for Abortion Patients

It is important to remember the lab work on abortion patients is the first step in the 'actual' abortion. Patients may appear nervous or tentative and the lab technician should take this into account. A professional, yet friendly, attitude will help the patient relax and the lab technician and patient will benefit. If the patient appears unduly agitated, emotional or proceeds to ask numerous questions that should already have been addressed, the lab technician should refer her back to counseling. This will enable the counselor to address the problem without tying up the lab technician. The patient can either have a seat back in the waiting room or in an empty counseling office if she is visibly upset.

The charts for patients ready for lab work will be located in the chart slot on the lab wall marked "In". When calling a patient to the lab, she is called by her first name and the first letter of her last name. Once in the lab, however, verify she is the right person by asking her name and date of birth.

The lab technician should confirm a positive pregnancy test was obtained at Hope Medical Group. Ensure results are recorded on the green operative notes and lab log.

The patient's blood pressure and pulse is taken and recorded on the green operative notes and lab log. Using the finger stick method two tests are run and recorded on the green operative notes and lab log. The two tests performed are: hematocrit and Rh factor.

The technician should always ask the patient about drug allergies and record her responses. Use the red allergy stamp to note allergies on front of the chart, on the green operative notes, and pink nurse's notes. Also ask if the patient is currently taking any medications. Any medications should be noted on the green operative notes, the pink nurse's notes and on the front of the chart. If this has not already been done by the staff counselor, it should be done by the lab technician. Of particular importance is determining if the patient is on Methadone. Patients on Methadone should never be given Butorphanol or Nubain. All second trimester patients and some first trimester patients are given Butorphanol or Nubain by the nurse. It is imperative the chart is properly documented to avoid any adverse event.

1. Surgical Abortion Patients:

When the lab technician is not pressed for time, and does not have several patients awaiting lab work, he/she should take the patient back to relaxation herself. If he/she is pressed for time, he/she should place the chart in the "out box" on the lab wall by the doorway. The person in charge of patient flow will then ensure the patient is taken to relaxation. The patient is then instructed to undress from the waist down (leaving her socks on). To do this she will step behind the curtain in relaxation or she can use any available restroom. There are patient bags for her belongings and sheets to wrap around the waist. She should be told to keep her bladder as empty as possible and to have a seat in relaxation.

2. Non-surgical Abortion patients:

These charts are designated by a blue dot in the lower right corner of the chart. Non-surgical abortion patients should be moved in front of all patients except second trimester patients when the chart is received in the lab.

J. Lab procedure for Pregnancy Testing

1. Protocol for Pregnancy Testing on Abortion Patients

Any patient entering the facility for pregnancy termination at Hope Medical Group will be tested for pregnancy by a sensitive urine pregnancy test. Pregnancy tests are CLIA waived (One Step Cassette Style hCG), however good lab practice necessitates internal and external controls be used to ensure test results are accurate. The internal control should be documented for each test run. External controls will be documented each time a new box is opened minimally every 30 days and every shipment of new lots.

UPT Procedure

Intended Purpose

One Step Cassette Style hCG Urine Pregnancy test is a test kit for the determination of hCG (Human Chorionic Gonadotropin) in urine specimens. This test is used for in vitro diagnostic use to obtain a visual, qualitative result for the early detection of pregnancy.

1. Verify that External Quality Control (2 levels) has been performed and is documented on Log.
2. Verify the specimen was collected in a dry and clean container with proper Patient Identifiers on the container.

NOTE: Pregnancy Tests should be maintained in an area where patient confidentiality can be protected.

3. Open the sealed pouch and label the test device.
4. Use the pipette provided, dispense 3 drops of urine into sample well of the device.
5. Sample should flow across the Test (T) region and Control (C) region on the device.
6. Wait for red bands to appear. Positive results may be observed as soon as 60 seconds. **To confirm a negative result, allow a reaction time of 3 minutes.**

Results are invalid after 10 minutes.

***If no band appears at the "C" Control Region the test is invalid. DO NOT** report patient test result. Repeat test with a new Test Device!

7. Record patient result on the Urine Pregnancy Test (UPT) Log.
   - Negative: one color band appears in the control region and no band in the test region.
   - Positive: distinct bands appear on the control and test regions.
   - Invalid: No visible band at all or no color band appears on the control (C) region after 3 minutes. Repeat with a new test device. If the problem persists, discontinue test kit immediately and contact Administration or local distributor.
8. Record results of IC (Internal Control) with a check mark √ meaning passed if
   - Acceptable Internal Control visual of color **band in "C" region is Present** for each testing device
9. If IC (Internal Control) failed mark with and F, and repeat test with another test device.
10. Complete information on UPT Log, Sign and date.

Urine Controls
Follow same steps as above using urine controls for specimen tested.

Storage and Stability
The test kit can be stored at temperatures between 2 and 30C in the sealed pouch to date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. Do not freeze.

Specimen
The first morning urine specimen is preferred since it usually contains the highest concentration of hCG: however, urine specimens collected at any time of the day may be used. Urine specimens may be stored at 2-8 C for up to 48 hours prior to testing.

Limitations

- Very Dilute urine specimens, as indicated by a low specific gravity may not contain representative levels of hCG. False negative results may occur when the levels of hCG are below the sensitivity level of the test. If pregnancy is still suspected, a first morning urine specimens should be collected 48 hours later and tested.
- Very low levels of hCG are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
- A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including breast cancer, and lung cancer, cause elevated levels of hCG.

Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.

- Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, APL) can give a false positive.
- The test provides a presumptive diagnose for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Precautions
For in vitro diagnostic use only.
Do not use test kit beyond expiry date.
The test device should not be reused.

Urine Pregnancy Logs are maintained for 2 years inspection purposes.

2. Protocol for Serum Pregnancy Testing

a. Quantitative hCG

The most common serum pregnancy test performed at Hope Medical Group is quantitative hCG. If no gestational sac is detected during gross exam immediately post-op, the physician will order a serum Quantitative hCG. For all blood draw orders, the collection tubes expiration date will be vision-ally rechecked before using to draw a patient's blood. The patient should then have the blood draw repeated within 72 hours. We will perform the second blood draw here in the clinic or the patient can have the draw done in her home town if there is a Lab Corp available. If the results from the second blood draw are at least 50% less than the first draw, then no further follow up is needed. If there is not at least a 50% decrease, we will need to continue to follow up with the patient. A supervisor will contact the patient and schedule them to come in for follow up.

All post-operative draws performed at Hope Medical Group will be done at no additional cost to the patients.

b. Serum Qualitative hCG

The Qualitative hCG is a simple yes or no blood pregnancy test, which is referred to another lab. It is generally only used when a women feels she is pregnant but has a negative urine pregnancy test. This test is never ordered post-operatively but still requires a physician's orders. The procedure for the draw is the same as the quantitative hCG except the test requested on the requisition form is specified as qualitative hCG.

In the event staff is unavailable to perform the blood draw, the patient can go directly to any of the Lab Corp locations. In this case she should be provided with the physician's order to take with her or it can be faxed to them prior to her arrival.

The laboratory at Hope Medical Group for Women will be managed and operated in accordance with the guidelines as prescribed in this manual. All laboratory personnel will be trained and evaluated as described. No personnel shall deviate from the guidelines in any manner without approval from the Laboratory Director.

Dale V. Bauman, M.D. 8/24/17

Dale V. Bauman, M.D. Date

Lab Refrigerator Temperature / Maintenance Log

Month/Year_____

1. Check refrigerator temperatures record on *TD and **Min/Max on the last day of ***NTD and sign. Any other day write closed.
2. If out of normal range, adjust temperature and recheck within 4 hours. Record rechecked temperature.
3. If out of range after second check , take action:
   A. Notify Office Manager
   B. Notify administrator for instruction of controls storage
   C. Refrigerator taken out of service
4. Clean inside of refrigerator weekly with hospital approved disinfectant.

Date	*TD Temp 2-8°C	***NTD ***Mim/Max Temp 2- 8°C	Within Normal Range Y/N	Temp @ Recheck	Circle Action Taken	Signature of Person Checking Temperature	Refrigerator Cleaned by: Signature
1					A B C		
2					A B C		
3					A B C		
4					A B C		
5					A B C		
6					A B C		
7					A B C		
8					A B C		
9					A B C		
10					A B C		
11					A B C		
12					A B C		
13					A B C		
14					A B C		
15					A B C		
16					A B C		
17					A B C		
18					A B C		
19					A B C		
20					A B C		
21					A B C		
22					A B C		
23					A B C		
24					A B C		
25					A B C		
26					A B C		
27					A B C		
28					A B C		
29					A B C		
30					A B C		
31					A B C		

*TD Testing Day **Minimal / Maximum ***NDT NonTesting Day

Hope Medical Group for Women
210 Kings Highway, Shreveport, LA 71104

Lab Room Temperature / Maintenance Log

Month/Year_____

1. Check Room temperatures record on *TD and **Min/Max on the last day of ***NTD and sign. Any other day write closed.
2. If out of normal range, adjust temperature and recheck within 4 hours. Record rechecked temperature.
3. If out of range after second check , take action:
    a. Notify Office Manager
    b. Notify administrator for instruction of controls storage
    c. Maintenance Service Call
4. Clean countertops with hospital approved disinfectant and flush sink with water 1 minute after testing on *TD.

Date	*TD Temp 15-30°C	***NTD ***Min/Max Temp 15-30°C	Within Normal Range Y/N	Temp @ Recheck	Circle Action Taken	Signature of Person Checking Temperature	Cleaned by: Signature
1					A B C		
2					A B C		
3					A B C		
4					A B C		
5					A B C		
6					A B C		
7					A B C		
8					A B C		
9					A B C		
10					A B C		
11					A B C		
12					A B C		
13					A B C		
14					A B C		
15					A B C		
16					A B C		
17					A B C		
18					A B C		
19					A B C		
20					A B C		
21					A B C		
22					A B C		
23					A B C		
24					A B C		
25					A B C		
26					A B C		
27					A B C		
28					A B C		
29					A B C		
30					A B C		
31					A B C		

*TD Testing Day **Minimal / Maximum ***NDT NonTesting Day

LAB PATIENT LOG

LAB TECHNICIAN: _____ **DATE:** _____

LAB DIRECTOR: DALE V. BAUMAN, M.D.

Rh control Lot # _____ **Expiration:** _____ **Positive results:** _____ **Negative results:** _____

	PT #	NAME	BP	Pulse	HCT	Rh	if RH neg Du checked Y / N	P.T./sono
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
24								

GAMMA LOG

DATE: _____

TECH: _____

	ANTI D	RH CONTROL	CELL 1	CELL 2	CELL 3
LOT #					
EXPIRATION DATE					
Performance/ Appearance					
Du Testing					
Satisfactory/ Unsatisfactory					

Comments:

_____

_____

HOPE MEDICAL GROUP FOR WOMEN

LAB DEVIATION REPORT FORM

PROBLEM:

STEPS TAKEN TO SOLVE PROBLEM:

CORRECTIVE ACTION TO AVOID THIS PROBLEM IN THE FUTURE:

ADDITIONAL COMMENTS:

Prepared by: _____ Date:

Reviewed by: _____ Date:

Lab Director: _____ Date:

PREGNANCY TEST RESULTS

IMMUNO hCG Detector: Kit lot # _____
Exp. Date: _____
Controls: Lot # _____ Exp: _____ Result: _____
Lot # _____ Exp: _____ Result: _____
Technician: _____

	Name	*IC √	Result	Type AB,W or V-up	Time	Tech	Date
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

*IC Internal Control
√ means presence of color band in "C" region on test device
If no band... Invalid (retest with another device)

Hope Medical Group for Women
210 Kings Highway, shreveport, LA 71104

Lab forms: September 2017

2017 Proficiency Testing Tracking Form

D (Rho) Typing

1st Quarter	Exp. Ship Date: 02/21/17	Received Date:	Mailed:	Results Received:	Name:
2nd Quarter	Exp. Ship Date: 05/16/17	Received Date:	Mailed:	Results Received:	Name:
3rd Quarter	Exp. Ship Date: 10/17/17	Received Date:	Mailed:	Results Received:	Name: