PATIENT RADIATION PROTECTION & SAFETY (INCLUDING PREGNANCY)

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I. POLICY

The objective of performing medical imaging in a pregnant patient is to minimize patient and embryo/fetal radiation exposure to the greatest extent possible while still obtaining a diagnostic test.

II. PROCEDURE

A. General Patient Radiation Protection and Safety Guidelines

1. All YNHH patients (adult and pediatric) will be provided with gonadal shielding and other appropriate lead shielding whenever applicable; Attachment I.12 A - Patient Shielding Guidelines in CT.

2. Optimal study acquisition parameters will be used, taking into consideration achieving the highest image quality at the lowest possible radiation dose.

3. Attachment I.12C-Table of Estimated Fetal Radiation Exposure for various radiology exams will be consulted as a reference on potential fetal doses.


1. All Female inpatients, outpatients and ED patients who have started their menses or are between the ages of **10 and 55** undergoing a non-emergent radiology exam listed in Appendix A (which may impart > 50 mGy to the embryo/fetus, involves intravenous contrast for MRI or involves radiopharmaceuticals) must have pregnancy testing. A urine hCG will be performed in radiology. If urine can not be produced, a serum pregnancy test can be obtained. Pregnancy testing can be waived if:

   a. The patient is 18 years or older, has capacity to provide informed consent, and does not want to have a pregnancy test done. A waiver may be signed in this setting. Yale New Haven Hospital Waiver for Pregnancy Testing (F6460). *Pediatric patients ages 10-17 (or their parent/guardian) cannot waive testing.

   b. The patient has a clearly documented hysterectomy or bilateral ovarian removal or meets medical definition of post-menopausal (no menses for over one year and NOT taking any type of hormone contraception). All other female patients will follow standard protocol including those with IUD, Essure device or tubal ligation as they are not 100% effective.
c. A negative serum pregnancy test within 72 hours or urine test within 24 hours of the procedure is available for ED or outpatients. In-patients do not need repeat testing if a negative serum or urine pregnancy test is available from the current admission.

d. A test for an inpatient or ED patient is deemed medically emergent by the referring clinician where the benefit of rapid imaging outweighs any loss of time for pregnancy testing and potential risk of fetal exposure to radiation, MRI contrast agent, or radiopharmaceutical. This can also be discussed with the consulting radiologist.

For ED and in-patients, a urine or serum pregnancy test should be performed on the inpatient or ED unit prior to the radiology test (however urine pregnancy testing in the radiology department may be permitted if necessary). For outpatients, a point of care urine test will be performed while in the radiology department, prior to the radiology test.

Either the referring physician or radiologist will place an order for the pregnancy test. Dept of Lab Medicine Attachment I.12D. Procedure for Point of Care Urine hCG Pregnancy Testing. https://ynhh.ellucid.com/documents/view/200

e. In the case of positive test findings, please call Labor & Birth for guidance and assistance with informing the patient and their referring physician of the test results. This service is available 24/7, and for all imaging sites.  
(a) The York Street campus – via Labor & Birth at 688-2309
(b) The Saint Raphael campus – 789-3461

2. Female outpatients between the ages of 10 and 55 undergoing radiology exams not listed in Appendix A will be discretely asked if they are or might be pregnant. If yes, appropriate steps will be taken as outlined in section III.A of this policy and related attachments.

Appendix A.- Tests that require pregnancy testing (or exemption listed above)
- CT involving the abdomen and/or pelvis including CT lumbar spine
- Any exam involving intravenous MRI contrast
- Fluoroscopic exams which include the pelvis e.g.: VCUG, hysterosalpinogram, barium enema, small bowel series, lumbar puncture, Interventional Radiology procedures
- Invasive/surgical or other radiology procedures with anesthesia/conscious sedation; excludes IV insertion for routine IV contrast exams
- All Nuclear Medicine and PET exams, except brain death scans which is optional. Note: all Nuclear Medicine therapy procedures require a Beta hCG within 48hours. Patients may not sign a waiver. If a total hysterectomy, documented post menopausal, or bilateral ovarian removal is clearly documented, the patient will be exempt from requiring a pregnancy test.
- All diagnostic Nuclear Medicine “non-therapy” Iodine 131 procedures require a urine
pregnancy test within 48 hours, unless a total hysterectomy or bilateral ovarian removal is clearly documented.

III. PREGNANCY STATUS AND ACTION

A. If a patient is determined to be pregnant, the procedure below is to be followed:

1. For those exams listed in Appendix A, the exam should not be performed except in life threatening emergencies. If a life threatening emergency is presented and the patient is determined to be pregnant, please follow these steps:
   a. The technologist will inform the radiologist that the patient is pregnant.
   b. The radiologist will contact the referring physician to ascertain the emergent status of the exam and consult in the decision to proceed, limit or cancel the exam. The YNHH Radiation Safety Officer or radiology physicist is available for consult or to calculate fetal dose for any exams requested, especially CT and Nuclear Medicine exams.
   c. If a decision is made to proceed with the exam emergently as ordered or as modified by the radiologist, the radiologist will discuss with the patient the risk vs. benefit associated with the exam based on pregnancy status, if possible.
   d. When possible, both the patient and radiologist will sign standard Consent for Operation or Special Procedure.
   e. The technologist is responsible for documenting the pregnancy status, and the authorizing MD or radiologist in the RIS Study Notes. The technologist will also scan the signed YNHH consent form into the chart.
   f. The radiologist dictating the exam will include the pregnancy status and the decision to proceed with the exam in the report for documentation in the patient’s medical record.

2. For exams involving ionizing radiation listed in Appendix B, the technologist will inform the radiologist that the patient is pregnant. The following steps are to be followed:
   a. The radiologist will make a decision to proceed, limit or cancel the exam. Written informed consent is not necessary given insignificant fetal exposure for these exams, however a radiologist will be available to discuss the exam if needed.
   b. The technologist will document the patient’s pregnancy status and the radiologist’s instructions in the RIS study notes.
   c. The radiologist dictating the exam will include the pregnancy status and the decision to proceed with the exam in the body of the report for documentation in the patient’s medical record.
   d. For exams involving ionizing radiation not listed in Appendix A or B, the exam is performed in a normal manner using patient protective shielding of the abdominal area, if applicable. The technologist will document the patient’s pregnancy status in the RIS Study Notes.
Appendix B

- X-rays of any region of the abdomen or pelvis, including L-S spine
- Hip x-rays
- CT of the chest in the second and third trimester

B. If an outpatient is unsure if they are pregnant, they can have a point of care urine pregnancy test performed or reschedule the exam.
   1. In the case of positive test findings, please call Labor & Birth for guidance and assistance with informing the patient and their referring physician of the test results. This service is available 24/7, and for all imaging sites. Ask for the on-call attending covering the General Obstetrics Service
      (a) The York Street campus – via Labor & Birth at 688-2309
      (b) The Saint Raphael campus – via Labor & Birth at 789-3461

C. If it is discovered that a patient is pregnant after the exam is performed:
   1. The YNHH Radiation Safety Officer or radiology physicist should be contacted for calculating fetal dose.
   2. A patient incident report must be completed in RL Solutions Event Reporter.
   3. The radiologist will be notified and an addendum will be added to the exam report to document discussions with the referring physician and/or patient, and fetal dose, if indicated.

IV. DOCUMENTATION

A. Technologist: The technologist is responsible for documentation in the Radiology Information System Study Notes.

B. Radiologist: The radiologist is responsible for documentation in the body of the exam report.
To alleviate patient/family anxiety the CT Technologist will shield the pediatric patient while performing CT Scans unless the area being imaged is in question.

The adult patients will not be routinely provided with shielding. In case of special instructions or per patient request, a lead apron may be used if it does not interfere with the imaged area. In all situations, the shield has to be carefully placed so that it will not interfere with the imaged area.
Estimated Fetal Exposure for Various Diagnostic Imaging Methods

<table>
<thead>
<tr>
<th>Examination type</th>
<th>Estimated fetal dose per examination (mGy)</th>
<th>Number of examinations required for a cumulative 50 mGy dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plain films</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skull</td>
<td>0.04</td>
<td>1,580</td>
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<tr>
<td>Dose</td>
<td>0.001</td>
<td>50,000</td>
</tr>
<tr>
<td>Cervical spine</td>
<td>0.02</td>
<td>2,500</td>
</tr>
<tr>
<td>Upper or lower extremity</td>
<td>0.41</td>
<td>4,000</td>
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<tr>
<td>Chest (two views)</td>
<td>0.0007</td>
<td>71,420</td>
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<tr>
<td>Mammogram</td>
<td>0.20</td>
<td>250</td>
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<tr>
<td>Abdominal (multiple views)</td>
<td>2.45</td>
<td>20</td>
</tr>
<tr>
<td>Thoracic spine</td>
<td>0.09</td>
<td>655</td>
</tr>
<tr>
<td>Lumbar spine</td>
<td>3.60</td>
<td>10</td>
</tr>
<tr>
<td>Intravenous pyelogram</td>
<td>13.38</td>
<td>2</td>
</tr>
<tr>
<td>Pelvis</td>
<td>0.40</td>
<td>128</td>
</tr>
<tr>
<td>Hip (single view)</td>
<td>2.13</td>
<td>23</td>
</tr>
<tr>
<td>CT scans (slice thickness: 10 mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head (10 slices)</td>
<td>&lt; 0.50</td>
<td>&gt; 100</td>
</tr>
<tr>
<td>Chest (10 slices)</td>
<td>1.00</td>
<td>20</td>
</tr>
<tr>
<td>Abdomen (10 slices)</td>
<td>3.60</td>
<td>1</td>
</tr>
<tr>
<td>Lumbar spine (5 slices)</td>
<td>36.00</td>
<td>1</td>
</tr>
<tr>
<td>Pelvis (1 slice with scout film)</td>
<td>2.50</td>
<td>20</td>
</tr>
<tr>
<td>Fluoroscopic studies</td>
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<td></td>
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<tr>
<td>Upper GI series</td>
<td>0.06</td>
<td>89</td>
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<tr>
<td>Barium enema</td>
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<td>320</td>
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<tr>
<td>Barium enema</td>
<td>39.36</td>
<td>1</td>
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<tr>
<td>Nuclear medicine studies</td>
<td></td>
<td></td>
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<tr>
<td>Most studies using technetium (&lt;Tc)</td>
<td>&lt; 0.50</td>
<td>&gt; 10</td>
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<tr>
<td>Hepatobiliary technetium HIDA scan</td>
<td>1.50</td>
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<tr>
<td>Venography/embolization scan (total)</td>
<td>2.12</td>
<td>23</td>
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<tr>
<td>+ Perfusion position: technetium</td>
<td>1.76</td>
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<tr>
<td>+ Perfusion position: xenon (&lt;Xe)</td>
<td>0.40</td>
<td>136</td>
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<td>Environmental sources (for comparison)</td>
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</tr>
<tr>
<td>Environmental background radiation</td>
<td>1.00</td>
<td>N/A</td>
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</table>

(cumulative dose over nine months)

Effects of Ionizing Radiation on Conceptus

<table>
<thead>
<tr>
<th>PHASE</th>
<th>WEEKS TO CONCEPTION</th>
<th>RADIATION EXPOSURE Levels</th>
<th>POSSIBLE CONCEPTUS HEALTH EFFECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Implantation</td>
<td>0 to 2 weeks</td>
<td>Less than 50 mGy (&lt;5)</td>
<td>End-to-end implantation failure; end-to-end death by 4 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Greater than 50 mGy (&gt;5)</td>
<td>Fetal loss, stillbirth, preterm birth</td>
</tr>
<tr>
<td>Oogenesis</td>
<td>2 to 7/8 weeks</td>
<td>Less than 50 mGy (&lt;5)</td>
<td>Neurological defects, microencephaly, microphthalmia, congenital anomalies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Greater than 50 mGy (&gt;5)</td>
<td>Fetal loss, stillbirth, preterm birth</td>
</tr>
<tr>
<td>Fertilization</td>
<td>9 weeks to 12 weeks</td>
<td>Less than 50 mGy (&lt;5)</td>
<td>No significant effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Greater than 50 mGy (&gt;5)</td>
<td>Moderate growth retardation, IQ reduction, malformations</td>
</tr>
<tr>
<td>Early Fetal Development</td>
<td>14 weeks to 23 weeks</td>
<td>Less than 50 mGy (&lt;5)</td>
<td>No significant effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Greater than 50 mGy (&gt;5)</td>
<td>Moderate growth retardation, IQ reduction, malformations</td>
</tr>
<tr>
<td>Late Fetal Development</td>
<td>24 weeks to delivery</td>
<td>Less than 50 mGy (&lt;5)</td>
<td>No significant effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Greater than 50 mGy (&gt;5)</td>
<td>Moderate growth retardation, IQ reduction, malformations</td>
</tr>
</tbody>
</table>

References

PROCEDURE

1. REMOVE TEST CASSETTE FROM POUCH.
   Place on a clean, dry, level surface.

2. DISPENSE THREE DROPS OF SPECIMEN INTO SAMPLE WELL.
   The specimen should be at room temperature.

3. READ RESULTS AFTER THREE MINUTES

RESULTS REPORTING

1. POSITIVE RESULT INDICATED BY PINK-PURPLE LINE NEXT TO “T”, ALONG WITH BLUE LINE NEXT TO “C” IN RESULTS WINDOW.

2. NEGATIVE RESULT INDICATED BY BLUE LINE NEXT TO “C” AND NO LINE NEXT TO “T” IN RESULTS WINDOW.

3. IF NO BLUE LINE APPEARS NEXT TO “C”, THE TEST IS INVALID AND MUST BE REPEATED.

4. RECORD AND INITIAL RESULT IN PATIENT RECORD: URINE HCG(+) OR URINE HCG(-)

DO NOT USE KIT BEYOND EXPIRATION DATE ON OUTSIDE OF KIT CARTON.

Note: If any problems occur consult the full procedure or consult the unit Point-of-Care Testing coordinator at 688-5212.
PURPOSE / INTENDED USE
The hCG Cassette Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is used in women of child-bearing potential for many different purposes, especially to evaluate symptoms such as missed menstrual period, malaise, or nausea, and to establish the safety of taking certain medications or receiving treatments that would be contraindicated by pregnancy.

APPLICABILITY
This policy applies to Yale New Haven Hospital and each of the affiliated entities including but not limited to Temple Medical Center, Shoreline Medical Center, North Haven Medical Center, School-based Health clinics, and Radiology locations.

PRINCIPLE/CLINICAL SIGNIFICANCE
Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception. HCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy. The hCG Cassette Rapid Test qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of antibodies including mouse monoclonal anti hCG antibodies and goat polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG Cassette Rapid Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH, and hTSH at high physiological levels.

The assay is conducted by adding a urine specimen to the specimen well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

SPECIMEN COLLECTION
The urine must be collected in a clean, dry plastic container and labeled with the patient name and MRN or date of birth. A first morning urine is preferred since it generally contains the
highest concentration of hCG; however, urine collected at any time of day may be used. Urine specimens exhibiting visible precipitates should not be used and it is recommended that a blood sample be collected instead and sent to the laboratory for testing. Urine specimens may be stored at 2°-8°C (36°-46°F) for up to 48 hours prior to testing.

PRECAUTIONS
1. For professional in vitro diagnostic use only. Do not use kit beyond manufacturer’s expiration date.
2. The test cassette should remain in the sealed pouch until use.
3. All specimens should be considered potentially hazardous and handled and discarded using Universal Precautions.

REAGENTS/MATERIALS
A. Cardinal hCG Cassette Rapid Test kit (Cat. B1077-22)

Each kit contains:
- Thirty (30) individually packaged test cassettes each containing one disposable specimen dropper
- One directional insert.

Storage and stability
Store as packaged in the sealed pouch at room temperature, 2-30°C (36-86° degrees F). The test cassette is stable through the expiration date printed on the sealed pouch. Do not freeze. Do not use beyond the expiration date.

B. Quality Control Reagent
1. Level 1 and Level 2 Quantimetrix “Dropper Plus” Urine Dipstick Control, #1440-04 – Lawson order # 148910.

Storage and Stability
1. The Urine Dipstick Control should be stored at 2-8 C before initial use. DO NOT FREEZE. When stored at 2-8 C the controls are stable until the expiration date stated on the label.
2. Once opened:
   - If stored at 2-8°C, bottles are stable to the manufacturer’s printed expiration date.
   - If stored at room temperature, discard bottles 30 days after opening.

QUALITY CONTROL:
A. Internal Quality Controls:
The hCG Cassette Rapid Test contains built-in control features used during each test performed.
1. The development of the red procedural control line above the letter C on the test cassette is a positive procedural control. The appearance of the control line indicates the test cassette is working properly. The control line must appear for the test to be valid.
2. The absence of the control line may indicate deterioration of reagents or
insufficient specimen volume. The absence of the control line means the test is invalid.

3. A clear background is a negative procedural control. If background color appears in the result window which interferes with your ability to read the test or there are stray lines which to not appear next to the C and T areas, the results are invalid. If this occurs contact the hospital Point-of-Care Testing Coordinator and a blood hCG should be ordered.

**Note:** If either of the internal controls do not perform as expected the test results must be considered invalid. The test should be repeated using a new test cassette and making sure that sufficient sample was added to the sample well. If test still does not perform properly or if analytical performance is questioned for any reason, contact the Point-of-Care Testing Coordinator.

**B. External Quality Control**
External quality control will be accomplished by the use of the Level 1 and Level 2 Quantimetrix “Dropper Plus” Urine Dipstick Control.
1. Frequency - Both external controls must be run when a new box is opened and weekly thereafter. Control results are documented on a QC log
2. Procedure for external urine hCG quality control
   a. Check the handwritten expiration date on the control bottle. Do not use an expired bottle. Remove the controls from the refrigerator and allow to come to room temperature (about 15-20 minutes).
   b. If stored at room temperature, confirm that the one-month, expiration date has not been exceeded.
   c. Don Gloves
   d. Remove the cap and invert bottle.
   e. Dispense 3 drops of the Level 1 control into the sample well of a reaction cassette
   f. Dispense 3 drops of the Level 2 control into the sample well of a second reaction cassette.
   g. The quality control results should be read in three minutes.

**Expected Results**
Control Control Line Test Line
Level 1 Present Absent
Level 2 Present Present

If any of the results do not agree with the expected results do not perform patient testing. Repeat the quality control test using a new test cassette and making sure that sufficient control was added to the sample well. If test still does not perform properly contact the Point of Care Coordinator.

**PATIENT PROCEDURE:**
1. Label the freshly collected patient urine with 2 patient identifiers.
2. Remove test cassette from pouch and place on a clean flat surface.
3. Don gloves and use universal precaution procedures.
4. Hold the dropper in a vertical position and dispense 3 full drops of the urine into the round specimen (S) well using transfer pipette supplied. Avoid trapping air bubbles in the specimen well.

**Note:** Do not use more than 3 drops of urine. The test cassette should not be moved until test is complete and ready for reading.
5. **WAIT** and read results at 3-4 minutes (background must be clear). Some positive results may be seen sooner.

**INTERPRETATION OF RESULTS:**

**Negative Results:**
The test is negative if one red line appears only in the C (control) area.

**Positive Results:**
The test is positive if one red line appears in the T (test) area and one red line appears in the C (control) area. Any red line in the T (test) area is considered a positive result. Colored lines may be lighter or darker than each other.

**Invalid Results:**
The test is invalid if no red line appears in the C (control) area even if a red line appears in the T (test) area and should be repeated using another device. If result is still invalid, a venous hCG should be sent to the Laboratory for testing. **DO NOT** report patient results on an invalid urine test.

**Expected Values:**
Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present. The amount will vary with gestational age and between patients. The hCG Cassette Rapid Test can detect hCG levels as low as 25 mIU/mL and is capable of detecting pregnancy as early as 1 day after the first missed menses with concentrations doubling every 32 to 48 hours. For some patients, an hCG level of 25 mIU/mL can be detected as early as two to three days before expected menses. By the first day of missed menses, hCG concentrations often exceed 100 mIU/mL.

**NOTE:** A specimen with a low level of hCG may show color development over time. If a negative result is obtained but pregnancy is suspected, a serum hCG should be ordered from the Main Laboratory or another specimen should be tested after 48-72 hours.

**REFERENCE RANGE/CRITICAL VALUE:**
Reference range: Negative
Critical Value: There is no critical value for this qualitative test.

**LIMITATIONS OF THE PROCEDURE:**
A) False negative results may occur on very dilute urine specimens or when the levels of hCG are below the sensitivity of the test. When pregnancy is still suspected, a venous blood sample should be collected and sent to the Lab for a quantitative hCG test.

B) Elevated levels of hCG may be found in trophoblastic disease, and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.

C) Ectopic pregnancies may produce very low levels of hCG. If this condition is suspected, further testing using a quantitative test is desirable.

D) Approximately one third of all conceptions end in natural termination. This may produce positive results when testing early in the pregnancy followed by negative results after the natural termination. Low positive results may be confirmed by re-testing with a first morning specimen collected 48 hours later.

E) This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. If a result is negative but pregnancy is still suspected, send blood to lab for confirmation by quantitative hCG. Quantitative assays used to detect hCG may detect degradation products and therefore may disagree with the results of this rapid test.

F) This test provides a presumptive diagnosis for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a diagnosis.

G) A positive result may be obtained for a few days to several weeks after delivery, abortion or hCG injection. This may occur with a negative result for serum hCG if the serum assay is specific for intact hCG.

**DOCUMENTATION:**
Point of Care (POC) personnel document patient result in the POC Urine Pregnancy area of the Electronic Medical Record which is opened by a task. Documentation must include the lot number and expiration date of the testing cassette and the indication that the internal quality control line was present when the test was interpreted.

**REFERENCES:**
I understand that pregnancy testing is offered to all female patients 18 through 55 years of age. I have been informed of the role of pregnancy testing in planning my treatment or procedure. I understand that the treatment/procedure may put a possible pregnancy at risk for harm. Identifying an unrecognized pregnancy will allow me and/or my physicians to make an informed decision before having a treatment/procedure that could be harmful to me and/or my fetus.

Understanding this, I decline to have a pregnancy test performed:

__________________________
Patient Signature

Date: _____________________
Time: _____________________

Printed Name

Entiendo que las pruebas de embarazo se les ofrecen a todas las pacientes mujeres entre los 18 a 55 años de edad. Se me ha informado del rol que tiene la prueba de embarazo en la planificación de mi tratamiento o procedimiento. Entiendo que el tratamiento/procedimiento puede poner un posible embarazo en riesgo de daño. Identificar un embarazo no conocido me permitirá a mí y/o a mis médicos tomar una decisión informada antes de tener un tratamiento/procedimiento que podría hacerme daño a mí y/o a mi feto.

Hablando comprendido esto, renuncio que se me realice una prueba de embarazo:

__________________________
Firma del paciente

Fecha: _____________________
Hora: _____________________

Nombre en letra de imprenta
This form is available in multiple languages. Please use an interpreter and the appropriate consent form for patients who do not speak English.

SECTION A

1. After discussing other options, including no treatment, with the responsible practitioner or his/her delegated representative, I give (insert name of person performing procedure) permission to perform the following operation, procedure(s) or treatment (list name or description of operation(s), procedure(s) and/or treatment(s) - indicate applicable level, site, or site):

2. I give permission to my responsible practitioner to do whatever may be necessary if there is a complication or unforeseen condition during my procedure.

3. My responsible practitioner has explained to me in a way that I understand: (a) the nature and purpose of the procedure(s); (b) the potential benefits and risks and possible side effects of the procedure(s) both during it and during recuperation, including bleeding, infection, accidental injury of other body parts, failure to permanently improve my condition or death, as well as the potential risks and benefits of the medications that may be administered to me as part of the procedure; and (c) the alternative(s) to the procedure(s) and their potential risks and benefits, including the option of not having the procedure. I understand that other complications may occur, including but not limited to:

☐ (Contents of discussion including risks, benefits and alternatives are documented in an office or hospital chart note)

4. I understand the purpose and potential benefits of the procedure in relation to my goals. My responsible practitioner has explained to me what results to expect, and the chances of achieving them. I understand that no promises or guarantees have been made or can be made about the results of the procedure(s).

5. I agree to have anesthesia as necessary to perform the procedure(s). I understand that if an anesthesiologist is to be involved he/she will speak to me about the risks of anesthesia in more detail and I may be asked to sign a separate anesthesia or sedation consent form.

6. I understand that my responsible practitioner may deem it necessary for me to have a blood transfusion during or after the procedure(s). I understand what a blood transfusion is, the procedures used, the benefits of receiving a transfusion and the risks involved. The benefits include better oxygen delivery to all parts of my body (for red blood cells) and treating or decreasing the risks of bleeding (for platelets and plasma products). The risks include: fever, chills, and allergic reactions which are generally mild and transient; on rare occasions major transfusion reactions occur such as rapid breakdown of blood cells and acute lung or kidney injury; and rarely bacterial, viral or other infections such as hepatitis B, hepatitis C, human immunodeficiency virus (HIV) and other pathogens. I understand these risks exist, although screening and testing of blood donors and their blood is performed to minimize these risks. My questions regarding alternatives have been addressed by the responsible practitioner in relation to my specific circumstances.

____ I agree to receive transfusions of blood or blood products if medically necessary. OR ____ I refuse to receive any transfusions of blood or blood products and understand that I may suffer severe injury or death as a result of my refusal.  

(Patient INITIAL one or the other)

7. I give permission to the hospital and/or its departments to examine and keep tissue, blood, body parts, or fluids removed from my body during the procedure(s) to aid in diagnosis and treatment, after which they may be used for scientific research or teaching by appropriate persons. If these things are used for science or teaching, my identity will not be disclosed. I will no longer own or have any rights to these things regardless of how they may be used.

8. If the procedure listed above involves the implantation/transplantation of tissue from a human or animal source, my responsible practitioner has described to me the risks and benefits of, and alternatives to, receiving this product.

1 In cases of refusal of blood by a parent or guardian of a minor in a situation in which transfusion may be anticipated, contact Legal and Risk Services immediately, as in most cases court intervention will be sought.
YALE NEW HAVEN HEALTH
CONSENT FOR OPERATION OR SPECIAL PROCEDURE

9. I understand that some of the system hospitals are teaching hospitals. Doctors or other health practitioners who are members of the care team and are in training may help my practitioner with the procedure. I understand that these trainees are supervised by qualified staff and the responsible practitioner will be present at all important times during the procedure. I also understand that associate(s), surgical assistants and/or other non-physicians or trainees may assist my responsible practitioner or perform parts of the procedure under the responsible practitioner’s supervision, as permitted by law and hospital policy. This includes compliance with the overlapping surgery policy which ensures that the attending surgeon will be present for the critical and key portions of my case and that an alternate attending physician will be designated should the need arise. If others who are not hospital staff will be present in the operating room, the responsible practitioner has spoken with me about this. I understand that a representative of an equipment vendor or a visitor may be present in the procedure area and that if that occurs, any visitor or vendor will comply with any applicable policy regarding observers in the Operating Room or other procedural area.

10. I give permission to the hospital and the above-named practitioner to photograph and/or visually record or display the procedure(s) for medical, scientific, or educational purposes. I understand that I will not be identified to those not involved in my care unless a separate consent is signed.

11. In the event a healthcare worker is exposed to my blood or body fluids in connection with my procedure, or during my hospital stay, I agree to the collection and testing of my blood for HIV.

12. I have read this form or had it read to me. I have had an opportunity to ask questions and to consider my decisions. All of my questions have been answered to my satisfaction.

Signature of Person Obtaining Consent Form

Printed Name
Date / Time

Signature of Patient

Printed Name
Date / Time

Signature of Authorized Representative
(person consenting for patient)

Printed Name
Date / Time

Relationship to Patient

☐ patient too severely ill ☐ patient unconscious ☐ patient lacks capacity ☐ patient is a minor

Name/code of the interpreter:

Interpreter info. recorded elsewhere in office or hospital chart

SECTION B – TELEPHONE CONSENT:

I have discussed in a witnessed telephone conversation all of the issues set forth in the CONSENT FOR OPERATION OR SPECIAL PROCEDURE with the patient’s authorized representative. This included a discussion of the risks, their likelihood, and alternative treatment options as set forth in Section A, above.

Consent was obtained by telephone on: / / AM/PM

Name of person who gave consent:

Date / Time

Relationship to Patient:

Signature of Person Obtaining Consent

Printed Name
Date / Time

Signature of Witness

Printed Name
Date / Time

Name/code of the interpreter:

Interpreter info. recorded elsewhere in office or hospital chart

SECTION C – EMERGENCY PROCEDURE:

The patient is in need of a procedure to save the patient’s life, limb or organ and is unable to consent for himself/herself and family is currently unavailable despite reasonable efforts.

Signature of Responsible Practitioner

Printed Name
Date / Time

SECTION D – MANDATORY SIGNATURE OF RESPONSIBLE PRACTITIONER:

Signature of Responsible Practitioner

Printed Name
Date / Time