Wake Forest Baptist Medical Center	hCG Rapid Test, qualitative serum by SP Brand Combo Rapid Test CCL-006	Dept: 324318	Critical Care Labs
		Effective Date:	Oct 2007
		Revised Date:	Feb 2019
		Contact:	Ann Shoffner
Name & Title: Gregory Pomper, MD CLIA Laboratory Director		Date:	2/25/19
Signature: GPom			

1) **General Procedure Statement:** SP Brand Rapid Test hCG Cassette is a rapid chromatographic immunoassay for the qualitative determination of human chorionic gonadotropin (hCG). The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding serum 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.

   a. **Purpose:** To provide instruction and guidelines to lab staff for performing rapid hCG testing.

   b. **Responsible Department/Party/Parties:**
      i. Procedure owner: Ann Shoffner
      ii. Procedure: Critical Care Lab (CCL) Staff
      iii. Supervision: Ann Shoffner
      iv. Implementation: Ann Shoffner and Critical Care Lab (CCL) Staff

2) **PPE Requirements:** Lab Coat. Gloves.

3) **Procedure:**

   A. **Sample Requirements:** Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear, non-hemolyzed specimens when possible. Serum can be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

   B. **Supplies and Equipment Needed:**
   Timer, Serum hCG Quality Controls, hCG Combo SP Brand Rapid Test (p/n B1077-23)
   Each test kit package contains one disposable specimen dropper. Store cassette devices in the sealed pouch at room temperature 18-30°C until ready to use. Do not freeze. Product is stable through package expiration date. Do not use beyond package expiration date. Do not reuse cassettes. Do not use cassette if package is torn, ripped or if the cassette itself is damaged.

   C. **Quality Control:** This test uses an IQCP
   Internal QC:
   1. An internal procedural control is included in each test cassette that indicates sufficient specimen volume and correct procedural technique.
   2. A colored line appearing in the control region is considered an internal positive procedural control indicating that sufficient sample fluid was added for capillary flow to occur and correct procedural techniques were followed.

Internal QC continued...

3. A clear background in the result window is considered an internal negative procedure control. If the test is performed correctly and proper flow has occurred, the background will clear, giving a distinct result.
4. Test cassettes that fail the internal positive or negative control should be discarded. Repeat testing using a new cassette.
5. Document all internal cassette QC results on the current *CCL-F005 SPREG Patient Testing Result Log*. The current log that is in use can be found in the clipboard on the counter. Additional forms are located in the *Current Year's Maintenance, QC and Patient Logs* notebook. Acceptable QC is noted by placing a check mark in the QC box associated with the appropriate test for that patient.

Liquid Serum hCG Quality Control: External serum liquid positive and negative controls should be run with every new lot, new shipment, monthly and if performance of the test kit is in doubt. Refer to the pkg insert for manufacturer's guidelines for frequency of performing external QC.
Stanbio hCG Tri-Level Serum Control, levels Neg, Low Pos and High Pos. OR Lab will use the Neg and Low Pos (25 mIU/mL) QC levels. Store unopened at 2-30°C through package expiration date. Once opened, controls are stable for 90 days when stored at 2-30 °C and tightly capped after each use. Unopened QC material is table through package expiration date.

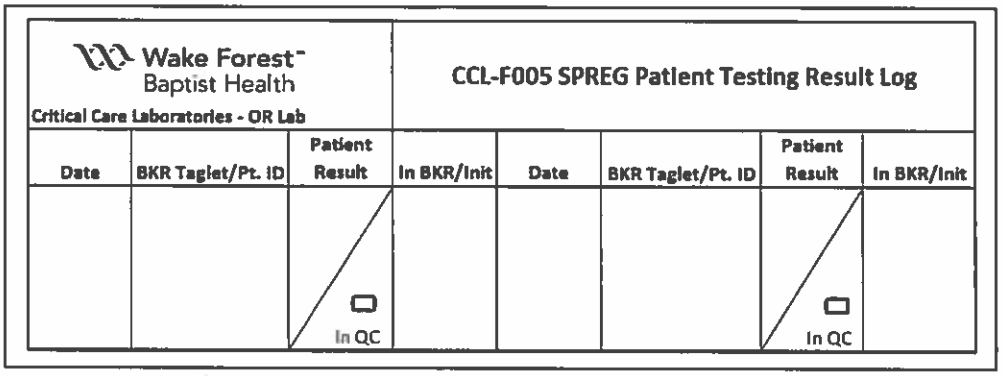
1. Verify QC expiration date is in range prior to use.
2. hCG controls should be brought to room temperature 20-30°C prior to testing.
3. Gently mix the controls prior to use.
4. Add 5 drops of either the Positive or Negative Control to the sample well of the test device.
5. Set a timer for 4 minutes. A positive result may be seen within 40 seconds. A negative result requires a reaction time of 4 minutes.
6. Document all QC results on *CCL-F018 Serum PREGS Liquid QC Log* found in the Current Year's *Maintenance, QC and Patient Logs* notebook.

Wake Forest Baptist Health Critical Care Laboratories - OR Lab						CCL-F018 **Serum PREG Liquid QC Log 2017**				
Liquid QC	**Results**	**QC Lot #**	**Exp.Date**			**Liquid QC**	**Results**	**QC Lot #**	**Exp.Date**	
C-SPGN						C-SPGN				
C-SPGL				**Init**		C-SPGL				**Init**
Date QC ran						Date QC ran				
Kit Lot #		Exp. Date				Kit Lot #		Exp. Date		

7. Order and Result QC in Beaker. For assistance, refer to *Ordering and Resulting QC* in the *Beaker Training Guide.*
8. Kits that fail QC should not be used for patient testing. Repeat testing on new cassettes from the same kit first. If testing fails, repeat testing on cassettes from a different box, preferably a different shipment. Test kits with persistent QC failures should be removed from use and reported to the lab manager. If the QC failure is unable to be resolved, forward all patient testing to the Core Lab.

D. Ordering Patient Testing in the LIS:

Order patient testing in Beaker. For assistance, refer to the *Beaker Training Guide*. Obtain the sample's taglet and place it on the *CCL-F005 SPREG Patient Testing Result Log.*



Wake Forest Baptist Health
Critical Care Laboratories - OR Lab

CCL-F005 SPREG Patient Testing Result Log

Date	BKR Taglet/Pt. ID	Patient Result	In BKR/Init	Date	BKR Taglet/Pt. ID	Patient Result	In BKR/Init
		In QC				In QC	

E. Testing Procedure:

1. Verify test cassette is within the manufacturer's expiration date. Patient samples should be brought to room temperature (20-30°C) before testing. Do not open the test cartridge pouch until ready to perform the test. Remove the cassette from its protective pouch.
2. Draw sample into the pipette. Dispense 3 full drops into the sample well. For each sample or control, use a separate pipette and device.
3. Set a timer for 5 minutes.
4. Wait for the pink-colored lines to appear. Depending on the concentration of hCG, positive results may be observed as soon as 40 seconds. However, to confirm negative results, the complete reaction time of 5 minutes is required. Do not interpret results after the maximum stated time for serum samples.
5. Serum samples are retained in the refrigerator for 48 hours before being discarded.

F. Interpretation of Results:

POSITIVE: Two distinct pink-colored lines will appear, one in the control region and another pink colored line in the test region. The color intensity on the test line may vary depending on the concentration of the hCG present. However, neither the quantitative value not the rate of increase in hCG can be determined by a qualitative test.

NEGATIVE: Only one pink-colored line appears in the control region. No distinct pink line appears in the test region.

INVALID: Absence of a pink colored line in the control region is an indication of insufficient specimen, procedural error or that test reagent deterioration might have occurred. Repeat test with a new device and read for presence of a colored control line. If problems persist, report your findings to the lab manager. Do NOT report results, refer sample to the Main Lab for testing.

G. Result Reporting:

1. Manually document patient test results on the current *CCL-F005 SPREG Patient Testing Result Log.* The current log that is in use can be found in the clipboard on the counter. Additional forms are located in the *Current Year's Maintenance, QC and Patient Logs* notebook.
2. Report results Beaker. Note that the Kit lot number and expiration dates are entered along with each patient's results. For assistance, refer to *Manually Entering Results* in the *Beaker Training Guide.*

H. Limitations of the Procedure:

1. False negative results may occur when the levels of hCG are below the sensitivity of the test. When pregnancy is still suspected, quantitative testing should be considered or a first morning serum specimen should be collected 48 hours later and tested.
3. Weakly positive samples should be confirmed by quantitative testing or a first morning serum specimen should be collected 48 hours later and tested.
4. This test reliably detects intact hCG up to 500,000mIU/mL. It does not reliably detect hCG degradation products including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.
5. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer and lun cancer cause elevated levels of hCG. Therefore, the presence of hCG in serum should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.

I. Normal Values:

Negative results are expected in healthy non-pregnant women and healthy men.

J. Sensitivity:

The hCG Combo Rapid Test has a sensitivity of 10mIU/mL in serum and is capable of detecting pregnancy as early as 1 day after the first missed menses. The test has been standardized to the W.H.O. Fourth International Standard (75/589).

4) Attachments: none

5) Related Forms:

CCL-F018 Serum PREGS Liquid QC Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenanc and QC Forms\CCL-F018 Serum PREG Liquid QC log.xlsx)

CCL-F005 SPREG Patient Testing Result Log. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\RESULT LOGS\CCL-F005 SPREG Patient Testing result log.xlsx)

6) Review/Revision/Implementation:

- Review Cycle: All procedures must be reviewed at least every 2 years.
- Office of Record: Department of Pathology, Critical Care Laboratory

7) Previous Revision Date(s): 2/13, 5/15, 11/15, 12/16

8) Revised/Reviewed Dates and Signatures:

Reviewed/Revision Date:_____ Signature:_____

Reviewed/Revision Date:_____ Signature:_____

Reviewed/Revision Date:_____ Signature:_____