HealthPartners®

Subject	Attachments
Pregnancy Test Procedure - Serum	☐ Yes ☒ No
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Level of Complexity Non-waived	**Contact** Laboratory Technical Consultants
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APPROVAL(S) Laboratory Medical Director	

Pregnancy Test –Serum

I. PURPOSE/PRINCIPLE

Human Chorionic Gonadotropin (hCG) is a hormone secreted by the placenta during pregnancy. Conditions other than normal pregnancy that may be associated with detectable hCG include ectopic pregnancy, molar pregnancy, trophoblastic disease and non-trophoblastic neoplasms. In ectopic pregnancy, hCG concentrations may remain below 50 mIU/mL. HCG may remain detectable for a few days to several weeks after delivery or abortion.

The QuickVue One-Step hCG Combo test is a sensitive immunoassay for the qualitative detection of hCG in serum for the early detection of pregnancy. The QuickVue One-Step hCG Combo test uses a monoclonal antibody specific to the beta subunit of hCG in a single step technology to accurately detect hCG.

Serum is added to the Sample Well on the Test Cassette. If hCG is present in the specimen at a level of 25 mIU/mL or greater, a pink to red Test (T) line will appear along with a blue procedural Control (C) line in the Result Window. If hCG is present at very low levels, or not present in the specimen, only a blue procedural Control line will appear in the Result Window.

II. POLICY

Laboratory Staff will follow the approved techniques outlined in this procedure.

Specimen:

1. **Serum**: Serum specimens may be stored at room temperature for up to 8 hours or refrigerated for up to 72 hours prior to assay. Samples may be frozen once. If frozen, mix after thawing. Do not refreeze. Do not chemically modify this serum in any way.
2. HCG Quant If specimens should have the hCG performed ASAP. If positive, it should be sent for quantitative results to Central Lab in the next reroute.

Reagents/Materials:

1. Individually wrapped Test Cassettes
2. Disposable pipettes
3. Timer
4. External hCG controls

Storage Options:

1. Store kit at room temperature, out of direct sunlight. Do not freeze.
2. Expiration date is that which is printed on the outer box carton.
3. The Test Cassette must remain sealed in the pouch just prior to use.

Quality Control:

External QC should be performed EACH DAY of patient testing.
Document the positive and negative commercial controls on the pregnancy worksheet when they are run.
There are three levels of controls; Negative, 25 miU/ml and 250 miU/ml. Use the negative and low (25 miU/ml for external controls.

Negative External Control:
Process the negative commercial control as you would a patient sample.
Positive External Control:
Process the positive commercial control as you would a patient sample.

Internal
The QuickVue test contains built-in control features. Document this procedural internal quality control on the pregnancy worksheet for each sample that is run.

Negative Internal Control:
A clear background in the test result window is an internal background negative control. If the test has been performed correctly the background should be white to light pink within 3 to 5 minutes and not interfere with the reading of the test result.

Positive Internal Control:
The appearance of a blue procedural Control line is an internal positive control. This indicates that sufficient sample fluid was added for capillary flow to occur and the correct procedural technique was used. If this line does not develop, the test result is considered invalid.

If any of the controls do not perform as expected, do not use the test results. Refer to the Quality Control/Troubleshooting section of this procedure or contact a Technical Consultant or Technical Assistance at 1-800- 874-1517.

III. PROCEDURES

1. Remove the Test Cassette from the foil pouch just before use and place it on a clean, dry, level surface.
2. Draw serum into the disposable pipette and dispense **3 drops** to the round sample well on the test cassette. The test cassette should not be handled or moved until the test is complete and ready for reading.
3. Read result at 5 minutes for serum. ***Note:*** Some positive results may appear sooner.
   a. **Positive Result:** Any pink to red Test line (T) along with a blue Control line (C) is a positive result for the detection of hCG.
   b. **Negative Result:** A blue Control line (C) and no pink Test line (T) is a negative result.
   c. **Invalid Result:** The test result is invalid if a blue Control line (C) is not visible at 3 to 5 minutes. If this happens, retest using a new sample and a new Test Cassette or contact Quidel Technical Assistance Line at 1-800- 874-1517 or a Technical Consultant.
   d. **Inconclusive Result:** If you are unable to determine whether a result is positive or negative and the procedural controls are valid you can result the test as INCN (Inconclusive, Suggest Repeat information will be appended). See the Lab Computer Procedure for further instructions.
4. If a patient serum result is positive or inconclusive and a hCG, Quant If is ordered, send the sample to Central Lab for testing.

REPORTING RESULTS

Clinic Labs: see the Computer Entry section of this procedure

PROCEDURE NOTES

1. Since hCG levels at 25 mIU/mL have been observed as early as 7 to 10 days post conception, hCG MAY be detected before a missed menses.
2. There are occasional discrepancies between the qualitative and quantitative serum results; therefore, if the qualitative result does not agree with the patient's clinical picture, a quantitative hCG should be performed.
3. If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48-72 hours and tested.
4. While pregnancy is the most likely reason for the presence of hCG in serum and urine, elevated hCG concentrations unrelated to pregnancy have been reported in some patients. Conditions other than normal pregnancy may be associated with detectable hCG, including for example, ectopic pregnancy or molar pregnancy. Patients with trophoblastic and nontrophoblastic disease may have elevated hCG levels, therefore, the possibility of hCG secreting neoplasms should be eliminated prior to the diagnosis of pregnancy.
5. HCG may remain detectable for a few days to several weeks after delivery, abortion, natural termination or hCG injections.
6. Serum hCG is rapidly cleared into the urine and the concentration of hCG in serum is approximately equal to the concentration in urine.

TROUBLESHOOTING

1. Verify two levels of Internal Procedural Quality Control.
   - A blue line appearing in the control region (C) is considered an internal positive procedural control.
   - A clear background in the result area is considered an internal negative procedural control.
2. Check expiration date of kit and controls.
3. Repeat the controls.
   - There are 3 levels of controls available to you, a negative, a low positive (25mIU/mL) and a high positive (250 mIu/mL). When trying to determine an inconclusive patient result, compare the patient result intensity with the low positive control intensity.
4. If the controls are still not performing as expected, open and run a new set of controls.
5. If control results are still unacceptable, try a kit with a different lot number.
6. Notify a lab technical consultant. The manufacturer may also be called.

- Reminder: According to the Internal Quality Control Policy, if expected QC values are not attained, patient results will not be reported until troubleshooting is complete.

REFERENCES
QuickVue hCG Serum/Urine kit package insert.

AUTHOR/REVIEWER(S)
Denise Bergo, Gail Brors, Barb Johnson
Sherry Cooper
Anne Howard
Nancy Butala
JAGayken

IV. DEFINITIONS

V. COMPLIANCE
Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

VII. OTHER RESOURCES

VIII. ENDORSEMENT
Laboratory Administration

Computer Order and Result Entry

PREGNANCY TEST
Order Codes:
HCGSE (HCG, Serum)
HCGRF (HCG, Quant if)

RESULTING: HSCSG
WORKSHEET:
Function MEM Worksheet CP_ _ (Chem Preg)
RESPONSE:
NOTE: If results are invalid (control line not visible), re-test per procedure instructions.

SQ Order: **HCGSE**	(A battery which includes the HCGS test for the result and QA tests to document your kit quality tests.)	
Code	**Name**	**Response**
HSCON	HCG Serum Pos Con Bar	Y or N Y (= YES, the control bar is present) N (= NO, the control bar is NOT present)
HSBAC	HCGS Neg Clear Background	Y or N Y (= YES, the background is clear) N (= NO, the background is NOT clear)
HSKIT	HCGS Kit Lot Number	Enter the lot number (12345) from the kit box. If there is a letter in the kit lot number, put a **;** in front of the lot number (;A1234)
HCGS	HCG, Serum Qual	POS, NEG, INCN • If NEG, computer will append result with NPREG and RPREG. (Negative=<25 mIU/ml. If pregnancy is suspected, suggest repeat in 48-72 hours or confirm results with a quantititative hCG test). • If POS, computer will append result with PPREG (Positive=>25 mIU/ml). • If inconclusive, and controls are valid, result with INCN (Inconclusive). Computer will append results with RPREG (If pregnancy is suspected, suggest repeat in 48-72 hours or confirm results with a quantitative hCG test).

RESULTING: HSCRF
WORKSHEET:
Function MEM Worksheet CP_ _ (Chem Preg)
RESPONSE:
NOTE: If results are invalid (control line not visible), re-test per procedure instructions.

SQ Order: **HCGRF**	(A battery which includes the HCGIF test for the result and QA tests to document your kit quality tests.)	
Code	**Name**	**Response**
HSCON	HCG Serum Pos Con Bar	Y or N Y (= YES, the control bar is present) N (= NO, the control bar is NOT present)
HSBAC	HCGS Neg Clear Background	Y or N Y (= YES, the background is clear) N (= NO, the background is NOT clear)
HSKIT	HCGS Kit Lot Number	Enter the lot number (12345) from the kit box. If there is a letter in the kit lot number, put a **;** in front of the lot number (;A1234)
HCGIF	HCG, Serum Qual	POS, NEG, INCN • If NEG, computer will append result with NPREG and RPREG. (Negative=<25 mIU/ml. If pregnancy is suspected, suggest repeat in 48-72 hours or confirm results with a quantititative hCG test). • If POS, computer will append result with PPREG (Positive=>25 mIU/ml). • If inconclusive, and controls are valid, result with INCN (Inconclusive). Computer will append results with RPREG (If pregnancy is suspected, suggest repeat in 48-72 hours or confirm results with a quantitative hCG test).

NOTE: If results are invalid (control line not visible), re-test per procedure instructions.

AUTHOR/REVIEWER(S)
SMHoehn
LEJohnson
GEFelland
SMDent
AKHoward
ANicholas