TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	2/28/2014
Department:	Core	**Due Date:**	3/31/2014
		Implementation:	**4/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Qualitative hCG by Cen-Med Elite Plus
GEC.U07 / SGAH.U09 / WAH.U10 v2

Description of change(s):

Section	Reason
8	Revise timing for reading results
10.1	Replace 'red line' with 'colored line'
13,14	Updated to match package insert revision of 7/13/12.

Read section 8 carefully. Note that:

- **Timing to read urine and serum specimens is DIFFERENT**
- **Negative results must be read at after a longer time period.**
- **Both specimen types must be read before a certain number of minutes**

This revised SOP will be implemented on April 1, 2014

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 2)

Technical SOP

Title	**Qualitative hCG by Cen-Med Elite Plus**		
Prepared by	Robert SanLuis	Date:	8/22/2011
Owner	Robert SanLuis	Date:	10/18/2012

Laboratory Approval	**Local Effective Date:**	
Print Name	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
HCG, Qual (Urine)	Chromatographic immunoassay	UHCG
HCG, Qual (Serum)		HCG

Synonyms/Abbreviations
Urine Pregnancy Test Qualitative Serum Pregnancy Test, HCG

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2. ANALYTICAL PRINCIPLE

The hCG One Step Pregnancy Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Specimens with detectable levels of hCG 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 indicates 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.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Urine: A first morning-voided specimen is preferred since it generally contains the highest concentration of hCG; however, specimens collected any time of day are acceptable. Serum: Blood should be collected aseptically. Separate the serum from the blood as soon as possible to avoid hemolysis.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Urine from a first morning void/ Serum Urine from any time of day	
Collection Container	Urine collection container/SST or plain red top tube	
Volume - Optimum **- Minimum**	10 mL urine / 8.0 mL blood 0.5 mL urine or blood	
Transport Container and Temperature	Urine transport container, or Blood collection tube at room temperature	
Stability & Storage Requirements	Room Temperature:	(15-30°C) Urine 8 hours Serum 24 hours
	Refrigerated:	(2-8°C) Urine 48 hours Serum 48 hours

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Criteria	
	Frozen: Urine not established Serum 1 year
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Urine specimens with visible precipitates should be centrifuged, filtered or allowed to settle prior to testing.
Other Considerations	If serum sample is frozen, mix after thawing and bring to room temperature prior to testing. Do not re-freeze. Do not chemically modify the serum in any way.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Elite Plus hCG kit	CenMed Enterprises, Inc. Cat. No. 4230025

4.2 Reagent Preparation and Storage

NOTE: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.

Assay Kit	
Reagent	Test devices
Supply	Disposable pipettes
Container	Sealed pouch
Storage	Store as packaged in the sealed pouches at 2-30°C DO NOT FREEZE
Stability	Stable until the expiration date printed on the sealed pouch. Test device must remain in sealed pouch until use.
Preparation	Allow the test device to equilibrate to room temperature (15-30°C) prior to testing.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Serum Controls	Supplier and Catalog Number
Liquichek™ Immunoassay Plus Control Level 3 (Positive)	Bio-Rad Laboratories Cat. No. 363
Male serum (Negative)	Patient sample

Urine Controls	Supplier and Catalog Number
Liquichek™ Urine Chemistry Control Level 2 (Positive)	Bio-Rad Laboratories Cat. No. 397
Liquichek™ Urine Chemistry Control Level 1 (Negative)	Bio-Rad Laboratories Cat. No. 398

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	Liquichek™ Immunoassay Plus Control, Level 3
Preparation	• Refer to the control insert sheet for preparation, storage, and handling instructions. • Before sampling, allow the control to reach room temperature (18-25°C) and swirl gently to mix. Do not use a warming device. Do not use a mechanical mixing device. • Promptly replace the stopper and return to 2-8°C storage after each use. • If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.
Storage/Stability	• Unopened controls are stable until the expiration date when stored at -20 to -70°C. • **Thawed and Unopened**: When the control material is thawed and stored unopened at 2-8°C, stable for 30 days. Record date of thaw on the vial. • **Thawed and Opened**: Once the control material is thawed and opened, it will be stable for 14 days when stored tightly capped at 2-8°C. Date vial when thawed and opened on vial. Record new expiration date on vial.

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	• Discard the vial if there is evidence of microbial contamination or excessive turbidity. • Do not refreeze control. • Do not use after the expiration date.

Control	**Male serum**
Preparation	None required
Storage/Stability	2-8°C for 7 days

Control	**Liquichek™ Urine Chemistry Control Levels 1 and 2**
Preparation	• Before sampling, allow the control to reach room temperature (18-25°C) and swirl gently to ensure homogeneity.
Storage/Stability	• This product will be stable until the expiration date when stored unopened at 2-8°C. • Once the control is opened, all analytes will be stable for 30 days when stored tightly capped at 2-8°C. • This product is shipped under refrigerated conditions. • Do not use this product past the expiration date. • If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial. • This product is not intended for use as a standard.

6.3 Frequency

Internal procedural controls are included in each test device.

The external negative and positive control must be performed once per week for both urine and serum.

6.4 Tolerance Limits

Controls must be read in a well-lit area.

Internal Controls are included in the test.

- A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
- A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the result.

External Controls

The negative control must read negative and the positive control must read positive.

If any control fails to produce the expected result, the test is invalid. The test should be repeated using another Test Device. Do not report patient results until acceptable QC results are obtained.
If repeat testing does not produce acceptable QC, then notify supervisor immediately.

6.5 Review Patient Data

Review patient results for unusual patterns, trends, or distributions in patient results, such as an unusually high percentage of abnormal results

6.6 Documentation

- Record all quality control results on the manual HCG log sheets.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number or new shipment of the same lot of reagent must be tested with external control materials. Performance of the new lot must be equivalent to the previous lot.
- Training must be successfully completed and documented prior to performing this test.
- The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

Timer

7.3 Supplies

N/A

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

Step	Action
1	Allow the test device, controls and/or specimens to equilibrate to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

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2	Place the device on a clean and level surface.
3	Label each test device with a patient identifier.
4	Draw the sample up the pipette and dispense 2 – 3 drops into sample well. Avoid adding drops that contain air since air bubbles in the well may cause uneven flow or prevent the flow of the sample onto the test strip.
5	Using a new dropper for each control or specimen, repeat steps 3-4 for each control and specimen.
6	**Urine Specimen**: The results should be read at 3 – 5 minutes. However, positive result may be read and reported as early as 1 minute, but negative result must be reported at 3 minutes only. **DO NOT** interpret the result after 5 minutes past the addition of sample.
7	**Serum Specimen**: The results should be read at 5 – 8 minutes. However, positive results may be read and reported as early as 3 minutes, but negative result must be reported at 5 minutes only. **DO NOT** interpret the result after 8 minutes past the addition of sample.

9. CALCULATIONS

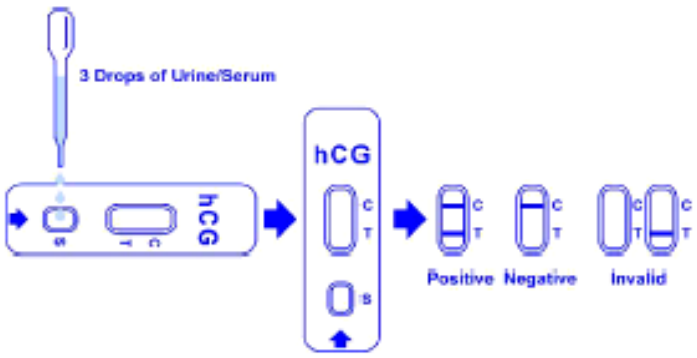
None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The shade of pink on the (T) test band region will vary depending on the concentration of hCG present. However, neither the quantitative value nor the rate of increase in hCG can be determined by a qualitative test.

Positive	Two colored lines should be observed in the viewing window. The line in the test region (T) is the hCG probe line, and the line in the control region (C) is the control line.
Negative	Only one colored line appears in the control region (C). The absence of a line in the test region (T) indicates a negative result.
Invalid	No line appears in the control region (C). Under no circumstances should any results be identified until the control line (C) forms in the viewing area.



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10.2 Rounding
N/A

10.3 Units of Measure
N/A

10.4 Clinically Reportable Range (CRR)
N/A

10.5 Repeat Criteria and Resulting

IF the result is …	THEN…
Negative	Report as NEG in the LIS
Positive	Report as POS in the LIS
Invalid	Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device.

Report Comments

HCG	None
UHCG	Low levels of HCG occurring in pregnancy/implantation may not be detected in dilute urine samples. Serum is recommended for evaluation of early pregnancy/ectopic pregnancy.

11. EXPECTED VALUES

11.1 Reference Ranges
Negative

11.2 Critical Values
None established

11.3 Priority 3 Limit(s)
None established

12. CLINICAL SIGNIFICANCE

In normal pregnancy, hCG can be detected in both urine 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 urine soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for early detection of pregnancy.

13. PROCEDURE NOTES

- **FDA Status:** Approved/cleared for serum, Exempt for urine
- **Validated Test Modifications:** None

- The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.
- If a patient suspected to be pregnant receives a negative test result or if a faint line appears in the test region, the test should be repeated with a sample obtained 48 hours later, or perform a quantitative assay.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

Lab spiked hCG urine and serum controls were used to evaluate the precision performance of Elite Plus hCG Pregnancy Serum/Urine Cassette and Dipstick Tests. Three lots of devices were evaluated at three Point-of-Care sites.

14.3 Interfering Substances

The performance of Cen-Med Elite Plus TM hCG Serum/Urine Pregnancy test at negative and cutoff points are not affected when the pH range of urine specimens is at 3.0 to 8.5 and the specific gravity range of urine specimens is at 1.000 to 1.030.

A number of conditions other than pregnancy including trophoblastic disease and certain non-trophoblastic neoplasm cause elevated levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.

Immunologically interfering substances such as those used in antibody therapy treatments may invalidate the test results.

14.4 Clinical Sensitivity/Specificity/Predictive Values

- The Cen-Med Elite Plus hCG One Step Urine/Serum Pregnancy Tests detects serum or urinary hCG at a concentration of 25 mIU/mL or greater.
- Cross-reactivity (Specificity) evaluated at negative (0 mIU/mL) and positive (25 mIU/mL) hCG specimens showed no cross-reaction.
- If a urine specimen is too dilute (low specific gravity) it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained from the patient 48 – 72 hours later and tested.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm.

Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Material Safety Data Sheets (MSDS)
4. Current package insert, CenMed Elite Plus™ hCG One Step
5. HCG Quality Control Log (AG.F42)

17. REFERENCES

1. CenMed Elite Plus™ hCG One Step package insert, Cen-Med Enterprises, NJ, Current version.
2. Package Insert, Bio-Rad Liquichek™ Immunoassay Plus Control Levels 1, 2 and 3, Current version.
3. Package Insert, Bio-Rad Liquichek™ Urine Chemistry Control Levels 1 and 2, Current version.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP U012.002		
000	10/18/12		Update owner	L Barrett	R SanLuis
000	10/18/12	3.2	Revise refrigerated urine stability	C Reidenauer	R SanLuis
001	2/6/14	8	Revise timing for reading results	A Chini	R SanLuis
001	2/6/14	10.1	Replace ‘red line’ with ‘colored line’	A Chini	R SanLuis
001	2/6/14	13,14	Updated to match package insert revision of 7/13/12.	A Chini	R SanLuis
001	2/6/14	16	Move form from section 9	L Barrett	R SanLuis
001	2/6/14	Footer	Version # leading zero’s dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis

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19. ADDENDA

None