Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	1/2/2013
Department:	Core	**Due Date:**	1/31/2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Qualitative hCG by CenMed Elite Plus GEC.U07, SGAH.U09, WAH.U10 v001

Description of change(s):

Section	Reason
3.2	Revise refrigerated urine stability

Note:
The SOP for the **backup** qual hCG test (Qualitative hCG by OSOM hCG Combo Test v002) is also being revised because the vendor name has changed from Genzyme to Sekisui Diagnostics. A copy of the SOP is NOT included with this update because no technical or test performance changes were made.

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

Technical SOP **Approved draft for training (v001)**

Title	**Qualitative hCG by CenMed 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.		

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

Form revised 7/01/01

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

Criteria		
Stability & Storage Requirements	Room Temperature:	(15-30°C) Urine 8 hours Serum 24 hours
	Refrigerated:	(2-8°C) Urine 48 hours Serum 48 hours
	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. Catalog # 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, Catalog # 360 Tri-Level or # 363
Male serum (Negative)	Patient sample

Urine Controls	Supplier and Catalog Number
Liquichek™ Urine Chemistry Control Level 2 (Positive)	Bio-Rad Laboratories Cat # 87328
Liquichek™ Urine Chemistry Control Level 1 (Negative)	Bio-Rad Laboratories Cat # 87334

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. • 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.

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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 Technologist 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.
2	Remove the test device from the sealed pouch and place on a clean level surface.
3	Label each test device with a patient identifier.
4	Hold the pipette vertically and transfer 3 full drops of control or specimen to the specimen well (S) of the test device. Avoid trapping air bubbles in the specimen well (S).
5	Using a new dropper for each control or specimen, repeat steps 3-4 for each control and specimen.
6	Set the timer for **3 minutes for urine** **5 minutes for serum**
7	Wait for the red line(s) to appear. In a well-lit area, read the result at **3 minutes for urine; 5 minutes for serum.** It is important that the background is clear before the result is read. **Note**: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, **DO NOT** interpret the result after the appropriate read time.

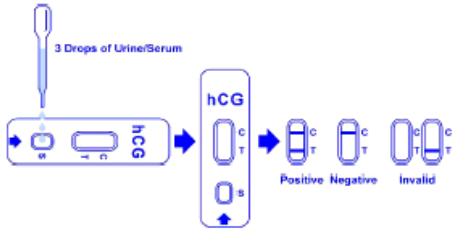
9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Positive	2 distinct red lines should appear. One line should be in the Control region (C) and another line should be in the test region (T)
Negative	One red line should appear in the Control region (C). No apparent red or pink line appears in the test region (T)
Invalid	Control line fails to appear. 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.



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	Repeat the test using 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 test device should remain in the sealed pouch until use.
- 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.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

- As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. 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.

- The addition of 300 mIU/mL LH, 1000 mIU/mL FSH and 1000 μIU/mL TSH to negative and positive specimens showed no cross-reactivity.

14.4 Clinical Sensitivity/Specificity/Predictive Values

- The Elite Plus hCG One Step pregnancy test device qualitatively detects the presence of hCG at the sensitivity of 25 mIU/mL. This assay is standardized to the W.H.O. 3rd I.S.
- Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning specimen should be collected 48 hours later and tested.
- False negative results may occur when the levels of hCG are below the sensitivity level of the test (25 mIU/mL). When pregnancy is still suspected, a first morning specimen should be collected 48 hours later and tested.
- Very low levels of hCG (<50 mIU/mL) are present in serum and urine shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning specimen collected 48 hours later.
- 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. Quantitative assay used to detect hCG my detect hCG degradations products and therefore may disagree with the results of this rapid test.
- A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer and lung cancer cause elevated levels of hCG. Therefore, the presence of hCG should not be used to diagnose pregnancy unless these conditions have been ruled out.
- This test provides a presumptive diagnosis of pregnancy. A confirmed pregnancy diagnosis should only be made by a 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

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

19. ADDENDA

HCG Quality Control Log (see Attachment tab of Infocard)