TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	3/19/2018
Department:	Core Lab	**Due Date:**	4/9/2018
		Implementation:	**4/4/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Qualitative hCG by CenMed Elite Plus SGAH.U09 v3

This has been converted to a system SOP

Description of change(s):

SOP: Most changes are format updates

Section	Reason
Header	Add other sites
4,6	Remove individual section labeling instructions and add general one
6.1	Corrected catalog numbers
10.5	Move patient review from section 6
11.3	Moved report comment from 10.6
15	Update to new standard wording

This revised SOP will be implemented on April 4, 2018

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

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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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

Department
Core Lab

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**: Normal blood collection procedure.
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 / 1.0 mL serum 0.5 mL urine or serum
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

Criteria		
	Refrigerated:	(2-8°C) Urine 48 hours Serum 48 hours
	Frozen:	Urine not established Serum 1 year
Timing Considerations	Separate serum from lood as soon as possible to avoid hemolysis.	
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.	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

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.

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

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. 398
Liquichek™ Urine Chemistry Control Level 1 (Negative)	Bio-Rad Laboratories Cat. No. 397

6.2 Control Preparation and Storage

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	• **Frozen:** Stable until expiration date stored at -20 to -70°C. • **Thawed and Unopened**: Stable for 30 days stored at 2-8°C. Record date of thaw on vial.

	• **Thawed and Opened**: 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	• **Unopened**: Stable until expiration date at 2-8°C. • **Opened**: Stable for 30 days when stored tightly capped at 2-8°C. • 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.

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 and Criteria for Acceptable QC

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 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.

6.6 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.

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.

Step	Action
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.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

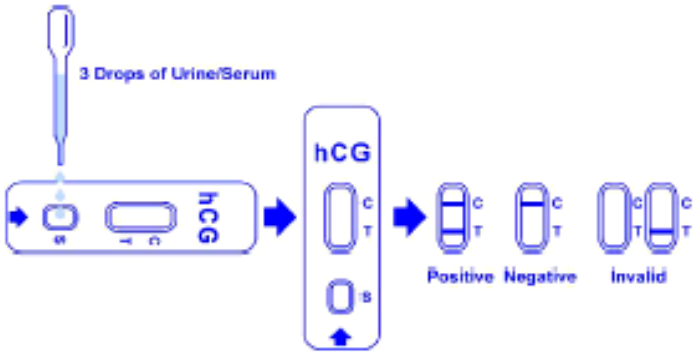
None

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.



10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Review Patient Data

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

10.6 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.

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

11.3 Standard Required Messages

Each result for a urine sample will have the following comment automatically added to the report by the LIS:

> 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.

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

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
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
2	3/9/18	4,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
2	3/9/18	6.1	Corrected catalog numbers	L Barrett	R SanLuis
2	3/9/18	10.5	Review data moved from section 6	L Barrett	R SanLuis
2	3/9/18	11.3	Moved report comment from 10.6	L Barrett	R SanLuis
2	3/9/18	15	Update to new standard wording	L Barrett	R SanLuis

19. ADDENDA

None