SAMPLE PROCEDURE

This “Sample Procedure” is not intended as a substitute for your facility’s Procedure Manual or reagent labeling, but rather as a model for your use in customizing for your laboratory’s needs.

Space has been provided within the document to allow you to update this template with information specific to your facility. It is suggested that a current version of the manufacturer’s directional insert be maintained as a supplement.

PROCEDURE

Title: Sekisui Diagnostics OSOM® Card Pregnancy Test

Procedure #:

Institution: _____

Prepared by: _____ Date:_____

Title: _____

Accepted by: _____ Date adopted: _____

Title: _____

Reviewed by:_____ Date:_____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Discontinued by:_____ Date:_____

I. TEST NAME

OSOM® Card Pregnancy Test

II. INTENDED USE

The OSOM® Card Pregnancy Test is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early determination of pregnancy. This test is for professional use in physicians' offices and clinical laboratories.

III. SUMMARY AND EXPLANATION OF TEST

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta. After fertilization, the concentration of hCG rapidly rises in both the urine and serum of pregnant women. The detection of hCG in these fluids is an excellent marker for confirming pregnancy. The OSOM® Card Pregnancy Test is a rapid test which can detect the presence of hCG in urine. The test utilizes monoclonal and polyclonal antibodies to hCG.

IV. PRINCIPLES OF TEST

OSOM® Card Pregnancy Test is a solid phase, sandwich-format immunochromatographic assay for the qualitative detection of hCG. Urine is added to the sample well of the Test Device using the pipette provided. The sample migrates through reaction pads where hCG, if present in the sample, binds to a monoclonal anti-hCG dye conjugate. The sample then migrates across a membrane towards the results window, where the labeled hCG complex is captured at a test line region containing immobilized rabbit anti-hCG. Excess conjugate will flow past the test line region and be captured at a control line region containing an immobilized antibody directed against the anti-hCG dye conjugate (with or without hCG complexed to it).

The appearance of 2 black bands in the results window – one at "T: Test" and the other at "C: Control" – indicates the presence of hCG in the sample. If a detectable level of hCG is not present, only the control band will appear in the result window.

V. KIT CONTENTS AND STORAGE

Contents:

- OSOM Card Pregnancy Test Devices individually pouched, each containing a disposable pipette
- Directional Insert

Store OSOM® Card Pregnancy Test at room temperature, 15° to 30°C (59° to 86°F), out of direct sunlight. Test Devices are stable until the expiration date printed on the kit or foil pouch. **DO NOT FREEZE.**

If the control band does not appear when running the test, the Test Cassette or kit may have been stored or handled improperly or the foil pouch may not have been intact.

At this facility, kits are stored: _____.

VI. MATERIALS REQUIRED BUT NOT PROVIDED

Clock or timer
Sample collection cups or tubes
Positive and Negative Controls. Sekisui Diagnostics recommends the OSOM® hCG Urine Control (Catalog number 134).

VII. PRECAUTIONS

- For *in vitro* diagnostic use. Federal law restricts this device to sale by or on the order of a physician.
- Do not use beyond the expiration date printed on the kit or foil pouch.
- The lot numbers may be different on the foil pouch and the kit.
- Use appropriate precautions for the collection, handling, and storage of specimens.
- Dispose of all used Test Devices pipettes and specimens in suitable biohazardous waste containers.
- Test Devices are stable in the unopened foil pouches until the expiration date. Do not remove the Test Device from the pouch until needed.

If specimen has been stored refrigerated, allow it to warm to room temperature before use. Several tests can be run at the same time. Use a new pipette with each test to avoid contamination errors.

VIII. SPECIMEN COLLECTION & PREPARATION

This facility's procedure for patient preparation is: _____.

This facility's procedure for sample labeling is: _____.

Specimen Collection and Handling:

No filtration or centrifugation of urine specimens is required for testing with the OSOM® Card Pregnancy Test.

Urine specimens may be collected in any clean, dry, plastic or glass container. For early determination of pregnancy, the first morning specimen of urine is recommended since it usually contains the highest concentration of hCG. Urine specimens may be stored at room temperature (15° to 30°C) for up to 8 hours, or refrigerated at 2° to 8°C for up to 72 hours.

This facility's procedure for transporting specimens is: _____.
_____.

This facility's procedure for rejected specimens is: _____.
_____.

IX. QUALITY CONTROL & ASSURANCE

Internal Quality Control
Several controls are incorporated into each OSOM® Card Pregnancy Test for routine quality checks.

The same labeled conjugate antibody results in the appearance of both the test and the control bands. The appearance of the control band in the results window is an internal positive procedural control which validates the following:

Test System: The appearance of the control band assures that the detection component of both the test line and control line is intact, that adequate volume was added and that adequate capillary migration of the sample has occurred. It also verifies proper assembly of the Test Device.

Operator: The appearance of the control band indicates that an adequate volume of fluid was added to the sample well for capillary migration to occur. If the control band does not appear at the read time, the test is invalid.

The clearing of the background in the results area may be documented as a negative procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light gray and not interfere with the reading of the test. The test is invalid if the background fails to clear and obscures the formation of a distinct control band.

If the Control band fails to appear with a repeat assay, do not report patient results. Contact Sekisui Diagnostics Technical Service.

External Quality Control
Sekisui Diagnostics recommends that external hCG controls are run with each new lot, and with each new untrained operator. The OSOM® hCG Urine Control (Catalog Number 134) is designed for this purpose. Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements.

QC Testing Frequency and Documentation

For this facility, external QC is run: _____.
_____.

Results of External QC and action(s) taken when control results are unacceptable are documented: _____.
_____.

X. TEST PROCEDURE

Patient specimens and control material must be brought to room temperature (15°-30°C; 59°-86°F) prior to testing.

- Remove the Test Device and pipette from the pouch. Place the Device on a flat surface.
- Squeeze the bulb of the pipette and insert the barrel into the patient sample. Release the bulb and draw up enough sample to **fill the barrel to the line indicated on the pipette. Do not overfill.**
- Expel the entire contents of the barrel (135 µL) into the sample well of the Test Device. No drop counting required.
- Discard the pipette in a suitable biohazardous waste container.
- Read the results at 3 minutes.
- **Results are invalid after the stated read time. The use of a timer is recommended.**

For this facility, used devices and pipettes are disposed: _____.
_____.

XI. INTERPRETATION OF RESULTS

Positive
Two separate black or gray bands – one at “T: Test” and the other at “C: Control” are visible in the results window, indicating that the specimen contains detectable levels of hCG. While the intensity of the test band may vary with different specimens, the appearance of 2 distinct bands should be interpreted as a positive result.

Negative
If no band appears at “T” and a black or gray band is visible at the “C: Control” position the test can be considered negative, indicating that a detectable level of hCG is not present.

Invalid
If no band appears at the “C: Control” or incomplete or beaded bands appear at either the “T: Test” or “C: Control” the test is invalid. The test should be repeated using another OSOM® Card Pregnancy Test Device.

Note: The test is valid if the control line appears by the stated read time, regardless of whether the sample has migrated all the way to the end of the sample window.

In the event this test becomes inoperable, this facility's course of action for patient samples is: _____.

XII. RESULT REPORTING

This facility's procedure for patient result reporting is: _____.
_____.
_____.
_____.

XIII. LIMITATIONS

- This assay is capable of detecting only whole molecule (intact) hCG, which is the predominant form of hCG in early pregnancy. It cannot detect the presence of hCG fragments or free subunits.
- In later term pregnancies (generally beyond the first trimester), occasional urine samples can contain very high levels of hCG fragments. Therefore the OSOM Card Pregnancy Test is most effective when used for the detection of pregnancy in its earlier stages.
- For diagnostic purposes, hCG test results should always be used in conjunction with other methods and in the context of the patient's clinical information (e.g., medical history, symptoms, results of other tests, clinical impression, etc.). Ectopic pregnancy cannot be distinguished from normal pregnancy by hCG measurements alone[2,3]
- If the hCG level is inconsistent with, or unsupported by, clinical evidence, results should also be confirmed by an alternative hCG method. **Test results should be confirmed using a quantitative hCG assay prior to the performance of any critical medical procedure.**
- Interfering substances may falsely depress or falsely elevate results. These interfering substances may cause false results over the entire range of the assay, not just at low levels, and may indicate the presence of hCG when there is none. As with any immunochemical reaction, unknown interferences from medications or endogenous substances may affect results.
- Infrequently, hCG levels may appear consistently elevated and could be due to, but not limited to, the presence of the following[4-7]
    - trophoblastic or nontrophoblastic neoplasms: abnormal physiological states that may falsely elevate hCG levels. [8, 9] This test should not be used in the diagnosis of these conditions.
    - hCG like substances
- Because of the high degree of sensitivity of the assay, specimens tested as positive during the initial days after conception may later be negative due to natural termination of the pregnancy. Overall, natural termination occurs in 22% of clinically unrecognized pregnancies and 31% of other pregnancies.[10] In the presence of weakly positive results, it is good laboratory practice to sample and test again after 48 hours.
- If the test band appears very faint, it is recommended that a new sample be collected 48 hours later and tested using another OSOM® Card Pregnancy Test Device.

- Dilute urine specimens may not have representative levels of hCG.
- Detection of very low levels of hCG does not rule out pregnancy[4] as low levels of hCG can occur in apparently healthy, nonpregnant subjects.[11,12] Additionally, post-menopausal specimens may elicit weak positive results due to low hCG levels unrelated to pregnancy. In a normal pregnancy, hCG values double approximately every 48 hours.[13] Patients with very low levels of hCG should be sampled and tested again after 48 hours, or tested with an alternative method.
- Some antipsychotic agents/drugs are known to cause false positive results in pregnancy test.[14]

XIV. EXPECTED RESULTS

hCG is not normally detected in the urine specimens of healthy men and non-pregnant women. In normal pregnancy, 20 mIU/mL hCG is reported to be present in urine 2 to 3 days before the first missed menstrual period[15'16]. The levels of hCG continue to increase up to 200,000 mIU/mL at the end of the first trimester.

XV. CROSS REACTIVITY

The addition of luteinizing hormone (300 mIU/mL of LH), follicle stimulating hormone (1000 mIU/mL of FSH), or thyroid stimulating hormone (1000 µIU/mL of TSH) to negative urine serum specimens gives negative results in the OSOM® Card Pregnancy Test.

The following substances were added to urine specimens containing 0 or 20 mIU/mL hCG. The substances at the concentrations listed below were not found to affect the performance of the test.

Interferring Substance	Concentration
Acetaminophen	20 mg/dL
Acetoacetic acid	2000 mg/dL
Acetyl salicylic acid	20 mg/dL
Amitriptyline	100 mg/dL
Amphetamines	10 ug/mL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Benzoylecogonine	10 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Chlorpromazine	5 mg/dL
Codeine	10 mg/dL
Desipramine	20 mg/dL
Diazepam	2 mg/dL
Ephedrine	20 mg/dL
Estradiol	25 ng/mL
Estriol	1 mg/dL
Ethanol	200 mg/dL

Gentisic acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	250 mg/dL
Human albumin	2000 mg/dL
Ibuprofen	40 mg/dL
Imipramine	100 mg/dL

Interferring Substance	**Concentration**
Lithium	3.5 mg/dL
Methadone	10 mg/dL
Mezoridazine	1 mg/dL
Morphine	6 ug/mL
Nortriptyline	100 mg/dL
Phenobarbital	15 mg/dL
Phenylpropanolamine	20 mg/dL
b-Hydroxybutyrate	2000 mg/dL
Pregnanediol	1500 µg/dL
Progesterone	40 ng/mL
Proteins	2000 mg/dL
Salicylic acid	20 mg/dL
Tetracycline	20 mg/dL
Thioridazine	2 mg/dL

XVI. PERFORMANCE CHARACTERSITICS & POL STUDIES

Refer to Directional Insert –OSOM® Card Pregnancy Test

XVII. REFERENCES

Refer to Directional Insert –OSOM® Card Pregnancy Test

XVIII. ASSISTANCE

For technical assistance, call Sekisui Diagnostics Technical Service at 800-332-1042.