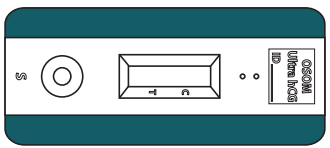
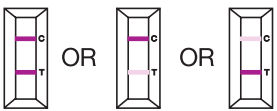
osom® Ultra hCG Combo Test



STEP 1
For each test, open one OSOM hCG Serum/ Urine pouch, and label the OSOM device with the patient ID.

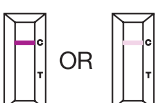
STEP 2
Holding the dropper in a vertical position, add 3 drops of sample into the Sample Well (S)

STEP 3
Read the results at 3–5 minutes.
Do not interpret the results after 5 minutes.



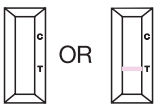
(examples of positive results)

Positive
Two pinkish-purple lines, one each at the Test Position (T) and at the Control Position (C). Each of the following indicates a positive test result.



(examples of negative results)

Negative
Only one pinkish-purple line, at the Control Position (C).



(examples of invalid results)

Invalid
A distinctive colored line at the Control Position (C) should always appear. The test is invalid if no Control line forms.

SEKISUI DIAGNOSTICS

Rev. P-51560, 04/15

OSOM®

Ultra hCG Combo Test

CLIA Complexity: Waived for Urine
Non-Waived for Serum

THIS TEST IS FOR PROFESSIONAL USE IN PHYSICIANS' OFFICES AND CLINICAL LABORATORIES.

INTENDED USE

OSOM Ultra hCG Combo Test is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early confirmation of pregnancy.

SUMMARY AND PRINCIPLE

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the placental trophoblastic cells shortly after the fertilized ovum is implanted in the uterine wall.[1-4] The primary function of hCG is to maintain the corpus luteum during early pregnancy. The appearance of hCG in both the urine and serum soon after conception and its rapid rise in concentration make it an excellent marker for confirmation of pregnancy. The hormone may become detectable in both urine and serum as early as 7 to 10 days after conception.[1-4] The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 30,000–100,000 mIU range by 10 to 12 weeks into pregnancy. The hormone is comprised of two non-covalently bound dissimilar subunits containing approximately 30% carbohydrate by weight.[5] The alpha subunit is structurally similar to other human pituitary glycoprotein hormones, whereas the beta (ß) subunit confers unique biological and immunological specificity to the molecule.[6,7]
The OSOM Ultra hCG Combo Test is a rapid serum or urine test for detecting hCG. The test is a solid-phase, two-site immunometric assay in which a combination of monoclonal and polyclonal antibodies is used to selectively detect elevated levels of hCG in serum or urine with a high degree of sensitivity. In the test procedure, sample is added to the sample well with the aid of a transfer pipette and sample is allowed to soak in. If hCG is present in the specimen, it will react with the conjugate dye, which binds to the antibody on the membrane to generate a colored line. Presence of two colored lines, one in the Test position (T) and the other in the Control position (C), indicates a positive result, while the absence of the line in the Test position indicates a negative result.

REAGENTS AND MATERIALS PROVIDED

OSOM Ultra hCG Combo Test kit contains enough reagents and materials to perform all the tests.

- 25 OSOM Ultra hCG devices (Test device containing the polyclonal anti-hCG coated membrane and a pad with the mouse monoclonal IgG (anti-hCG)-dye conjugate in a protein matrix containing 0.1%sodium azide)
- Disposable dropper
- Package insert

NOTE: Two extra devices have been included in the kit for external QC testing.

MATERIALS MAYBE REQUIRED BUT NOT PROVIDED

- Timer
- Specimen cup
- Latex gloves
- Positive and Negative Controls (Sekisui Diagnostics recommends the OSOM hCG Urine Control (Catalog number 134) and the OSOM hCG Serum Control (Catalog Number 138)).

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use beyond the expiration date.
- The OSOM Ultra hCG Combo Test device should remain in its sealed pouch until ready for use.
- Use appropriate precautions for the collection, handling, and storage of specimens. All human blood products should be treated as potentially infectious and handled with good laboratory practices.

STORAGE AND STABILITY

OSOM Ultra hCG Combo Test kit should be stored at 2–30°C (36–86°F) in the sealed pouch.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

- For optimal early detection of pregnancy, a first morning urine specimen is preferred since it generally contains the highest concentration of hCG. However, randomly collected urine specimens may be used.
- Collect the urine specimen in a clean glass or plastic cup.
- Urine containing excessive bacterial contamination should not be used since spurious results may occur with such specimens.

Serum Assay

- Remove the serum from the clot as soon as possible to avoid hemolysis. When possible, clear, non-hemolyzed specimens should be used. Specimens containing particulate matter may give

inconsistent test results. Such specimens should be clarified by centrifugation prior to assaying.
- If refrigerated, bring specimens to room temperature (18–30°C) prior to testing.
- Frozen specimens must be completely thawed, thoroughly mixed, and brought to room temperature prior to testing by allowing the specimens to stand at room temperature for at least 30 minutes.

SPECIMEN STORAGE
- If testing will not be performed immediately, the specimens should be refrigerated (2–8°C) for up to 48 hours. Bring specimens to room temperature prior to testing.
- For prolonged storage, specimens may be frozen and stored below –20°C. Frozen specimens must be completely thawed, thoroughly mixed, and brought to room temperature prior to testing by allowing the specimens to stand at room temperature for at least 30 minutes. Avoid repeated freezing and thawing.
- If specimens are to be shipped, they should be packed in compliance with Federal regulations covering the transportation of etiologic agents. For urine samples, add sodium azide to a concentration of 0.1% as a preservative and ship by the quickest means possible.

PROCEDURES

PROCEDURAL SUMMARY

The procedure consists of adding the specimen to the sample well in the device and watching for the appearance of colored lines on the membrane.

PROCEDURAL NOTES

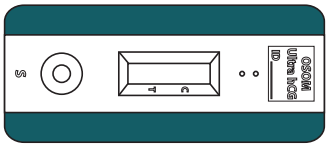
The instructions below must be followed to achieve optimal test reactivity with serum or urine specimens.
- Allow specimens and the OSOM Ultra hCG Combo Test device to stand at room temperature for at least 30 minutes prior to testing.
- Label the OSOM device with the patient name or control number.
- Allow the dropper to fill with sample. Holding the dropper in a vertical position, add 3 drops of sample into the Sample Well (S).
- Handle all specimens as if capable of transmitting disease.
- After testing, dispose of the OSOM device and the dropper following good laboratory practices. Consider each material that comes in contact with specimen to be potentially infectious.

TEST PROCEDURE

STEP 1
For each test, open one OSOM Ultra hCG Combo Serum/Urine pouch, and label the OSOM device with the patient ID.

STEP 2
Holding the dropper in a vertical position, add 3 drops of the sample into the Sample well (S).

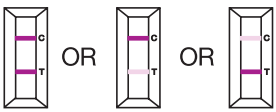
STEP 3
Read the results at 3–5 minutes.
Do not interpret the results after 5 minutes.



INTERPRETATION OF RESULTS

Positive

Two pinkish-purple lines, one each at the Test Position (T) and at the Control Position (C). Each of the following indicates a positive test result.

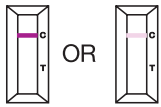


(examples of positive results)

NOTE: A specimen containing a detectable level of hCG will generate a pinkish-purple line at the Test Position (T) within 3–5 minutes. The time required to generate the line is dependent on the hCG concentration in the sample. Some positive results can be read in as early as one minute. To be interpreted as positive,the pinkish-purple line in the Test Position (T) should be clearly distinguishable from the background color of the membrane. In strong positive tests, the color intensity of the line at the Control Position (C) may be much lighter than that of the line at the Test Position (T).

a. Two strong pinkish-purple lines, one each at the Test (T) and Control (C) Positions
b. One strong pinkish-purple line at the Test Position (T) and one light pinkish-purple line at the Control Position (C).
c. One light pinkish-purple line at the Test Position (T) and one pinkish-purple colored line at the Control Position (C).

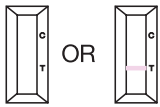
Negative
Only one pinkish-purple line, at the Control Position (C).



(examples of negative results)

NOTE: In the absence of hCG, or in the case that the hCG concentration is below the detection limit of the test, there will be no apparent line at the Test position. The control line at the Control Position should be clearly readable.

Invalid
A distinctive colored line at the Control Position (C) should always appear. The test is invalid if no Control line forms.



(examples of invalid results)

NOTE: If there is no distinct pinkish-purple line visible at the Control Position, the test is inconclusive. If there is a suspected procedural error made by the user, the result should be considered inconclusive. It is recommended that in this case the test be repeated or a fresh specimen be obtained and tested. A Control line should always appear. The absence of a pinkish-purple line at the Control Position means the test is invalid and should be repeated with a new test device.

LIMITATIONS

- As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse IgG antibodies (HAMA) in the sample. Similarly, specimens from patients who have been routinely exposed to animals or to animal serum products may contain heterophile antibodies which may cause erroneous results.
- Elevated hCG levels have been reported in patients with both gestational and nongestational trophoblastic diseases.[8, 9, 10] The hCG of trophoblastic neoplasms is similar to that found in pregnancy, so these conditions, including choriocarcinoma and hydatidiform mole, should be ruled out before pregnancy is diagnosed.
- An extremely low concentration of hCG during the early stage of pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
- The hCG level may remain detectable for several weeks after normal delivery, delivery by cesarean section, spontaneous abortion, or therapeutic abortion.[11]
- The hCG level in the case of spontaneous abortion may be very low and eventually decrease. The test is highly sensitive, and specimens which test positive during the initial days after conception may later be negative due to natural termination of the pregnancy. Natural termination occurs in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall.[12] Subsequent testing of a new urine or serum sample after an additional 48 hours is recommended in order to confirm that the hCG level is rising as indicated in a normal pregnancy.
- The concentration of hCG may be very low in the case of ectopic pregnancy.[13] A suspected ectopic pregnancy may be further evaluated using a quantitative hCG assay.
- Very high levels of hCG may exist in certain pregnancies and pathological conditions (e.g., choriocarcinoma and hydatidiform mole). This may weaken the signal line.
- The physician should evaluate data obtained from this kit in light of other clinical information.
- Samples which contain excessive bacterial contamination or have been subjected to repeated freezing and thawing should not be used because such specimens can give spurious results.
- Urine samples collected after consumption of a large amount of fluids may contain a lower hCG concentration. If such a sample is negative, a first morning specimen should be obtained and retested.
- In rare occasions, persistent low levels of hCG present in men and in nonpregnant women (concentrations 3 to 100 mIU/mL) may result in positive results.[14,15]

USER QUALITY CONTROL

INTERNAL CONTROL: Each OSOM Ultra hCG Combo Test device has a built-in control. The Control line is an internal positive procedural control. A distinct reddish-purple Control line should appear at C position indicating an adequate sample volume is used, the sample and reagent are wicking on the membrane, and the test reagents at the Control line and the conjugate-color indicator are reactive. In addition, the clearing background in the Result window is considered as an additional procedural control by providing a distinct readable result. This may be considered an internal negative procedural control. If background color appears in the Result window which interferes with your ability to read the test result and obscure the formation of the control band, your result may be invalid. If the problem persists, contact Sekisui Diagnostics Technical Service at 800-332-1042 (US Customers only)

EXTERNAL CONTROL: External controls may also be used to assure that he reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be

tested before using a new lot, untrained operator or a new shipment of kit as good laboratory testing practice and that users follow federal, state, and local guidelines for quality control requirements. For information on how to obtain controls, contact Sekisui Diagnostics Technical Service: Tel 800-332-1042 (U.S. Customers only).

EXPECTED VALUES

OSOM Ultra hCG Combo Test is capable of detecting hCG levels of 25 mIU/mL (WHO 3rd International Standard). HCG levels in normal early pregnant women vary and hCG levels often exceed 100 mIU/mL by the first day of the missed menstrual period.[1] The test is usually capable of detecting hCG by the first day of the missed menstrual period.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation-Urine Assay

A total of 247 blind clinical urine samples were studied. These specimens were assayed with OSOM Ultra hCG Combo Test and Tandem® Icon™ II according to the package inserts (Table 1). Thirty-six (36*) samples are from menopausal women

TABLE 1 (URINE ASSAY)

OSOM Ultra hCG Combo Test vs. Tandem®Icon™ II with Urine Specimens

TEST RESULT (# OF SAMPLES)

	Tandem®Icon™ II	OSOM Ultra hCG Combo
Positive	78	78
Negative	133	133
Menopausal	Not Determined	36 (Negative)

The data demonstrate the excellent correlation between OSOM Ultra hCG Combo Test and Tandem® Icon™ II. The clinical accuracy and sensitivity of the two tests are found comparable.

Overall Accuracy: 100%
Relative Sensitivity: 100%
Relative Specificity: 100%

Clinical Evaluation—Serum Assay

A total of 425 blind clinical serum samples were studied. These specimens were assayed with OSOM Ultra hCG Combo Test and Tandem® Icon™ II according to the package inserts. The results demonstrate 100% relative sensitivity, 99% relative specificity and 99.5% overall accuracy (Table 2).

TABLE 2 (SERUM ASSAY)

OSOM Ultra hCG Combo Test vs. Tandem®Icon™ II with Serum Specimens.

TEST RESULT (# OF SAMPLES)

		Tandem®Icon™ II	
		+	-
OSOM Ultra hCG Combo (Serum/Urine)	Positive	215	2
	Negative	0	208
	Total	215	210

Overall Accuracy: 99.5%
Relative Sensitivity: 100%
Relative Specificity: 99%

PHYSICIANS' OFFICE LABORATORY EVALUATION (Proficiency Study)

Reproducibility of OSOM Ultra hCG Combo test results was evaluated at three physicians' office laboratories using a total of 120 blind control samples. The control panels were prepared in serum or urine. Each panel consisted of 5 negative (–), 5 low positive (25 mIU/mL hCG), 5 moderate positive (200 mIU/ mL hCG), and 5 high positive (500mIU/mL hCG) samples. The results obtained at each site agreed 100% with expected results and with predicate tests compared in parallel.

Sensitivity- Urine Assay

Standard controls (calibrated to the WHO 3rd International Standard) ranging from 5 mIU/mL to 40 mIU/mL in urine were tested in 20 replicates. The results confirmed sensitivity of 25 mIU/mL.

Sensitivity- Serum Assay
Standard controls (calibrated to the WHO 3rd International Standard) ranging from 5 mIU/mL to 40 mIU/mL in serum tests were tested in 20 replicates. The results confirmed sensitivity of 25 mIU/mL.

Specificity
Thirty-six (36) urine specimens collected from menopausal women were studied. Specimens from menopausal women are known to interfere frequently with pregnancy tests due to cross-reactivity with other gonadotropin hormones. These specimens were assayed with OSOM Ultra hCG Combo Test. All 36 specimens were found negative. The assay is free from interference with other commonly known homologous hormones when tested at the levels specified below (Table 3).

TABLE 3

Homologous Hormones:	Urine	Serum
hFSH	1000 mIU/mL	1000 mIU/mL
hLH	500 mIU/mL	500 mIU/mL
hTSH	1000 µIU/mL	1000 µIU/mL)

POTENTIALLY INTERFERING SUBSTANCES
Potentially interfering substances were prepared at the following concentrations in both urine and serum which contain either 0 or 25 mIU/mL hCG. These samples were tested with the OSOM Ultra hCG Combo. No interference was found (Table 4).

TABLE 4

Substance Added:	Concentration Added in Urine	in Serum
Drugs		
Acetaminophen	20 mg/dL	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	20 mg/dL
Ampicillin	20 mg/dL	20 mg/dL
Ascorbic Acid	20 mg/dL	20 mg/dL
Atropine 20	20 mg/dL	20 mg/dL
Caffeine 20	20 mg/dL	20 mg/dL
Gentisic Acid	20 mg/dL	20 mg/dL
Phenothiazine	20 mg/dL	20 mg/dL
Phenylpropanolamine	20 mg/dL	20 mg/dL
Salicylic Acid	20 mg/dL	20 mg/dL
Tetracycline	20 mg/dL	20 mg/dL
Urinary Analytes		
Bilirubin	2 mg/dL	30 mg/dL
Glucose	2000 mg/dL	2000 mg/dL
Hemoglobin	25 mg/dL	250 mg/dL
Ketones	100 mg/dL	-
Protein	2000 mg/dL	14000 mg/dL
Triglycerides	-	2000 mg/dL
Homologous Hormones		
hFSH	1000 mIU/mL	1000 mIU/mL
hLH	500 mIU/mL	1000 mIU/mL
hTSH	1000 µIU/mL	1000 µIU/mL

REFERENCES

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ASSISTANCE

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

REORDER

Item No. 1004 (25 Test Kit)

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SEKISUI DIAGNOSTICS

Lexington, MA 02421
Tel: 800-332-1042
www.sekisuidiagnostics.com

SYMBOLS KEY

	Instructions For Use (Read)
REF	Item Number
	Store At
	Expiration Date
CONT	Contents
DEV	Test Device
IFU	Instructions For Use
PIP	Transfer Pipette
	Do Not Reuse
IVD	For I*n Vitro* Diagnostic Use
LOT	Lot Number
	Manufacturer
MF	Manufactured For