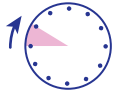


Note:
False results may occur
if urine level goes above
Sample Line

Positives can be
read as soon as the
control line appears



5 min.

KEY TO COMPONENT LABELING



Use by YYYY-MM



Batch code



Catalog number



Contents sufficient for <n> tests



In vitro diagnostic medical device



Temperature limitation



Manufacturer/Manufactured by



Consult instructions for use



Authorized representative
in the European Community



Caution, consult
accompanying documents.

osom[®]

hCG-Urine Test

CLIA Complexity: Waived

FOR LABORATORY AND PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

For the qualitative determination of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

SUMMARY AND EXPLANATION OF TEST

The hormone hCG is produced by the placenta⁽¹⁾. Urine hCG provides an early indication of pregnancy. However, because detectable hCG may be associated with conditions other than pregnancy^(1,2) such conditions should be ruled out when diagnosing pregnancy.

PRINCIPLES OF TEST

The OSOM[®] hCG-Urine Test uses color immunochromatographic dipstick technology with mouse monoclonal and rabbit polyclonal antibodies coated on the nitrocellulose membrane. The Test Stick is dipped into the urine sample and the sample migrates along the membrane. If hCG is present in the sample, it will form a complex with the anti-hCG antibody conjugated color particles. The complex will then be bound by the anti-hCG capture antibody and a visible blue Test Line along with a red Control Line will appear to indicate a positive result.

KIT CONTENTS AND STORAGE

Each kit contains 50 (No. 101) Test Sticks in a container and one directional insert. The Test Sticks must be stored tightly capped at 15°–30°C (59°–86°F). Do not use Test Sticks after expiration date.

MATERIALS REQUIRED BUT NOT PROVIDED

Urine containers and a timer or watch.

PRECAUTIONS

Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens⁽³⁾.

QUALITY CONTROL

If external quality control testing is desired, Control Set Catalog No. 134 may be purchased separately from Sekisui Diagnostics. Some commercial controls may contain interfering additives, therefore the use of these controls is not recommended. Test the control in the same manner as a patient sample. The red Control Line is an internal positive procedural control; if the test has been performed correctly (e.g. the proper volume of sample was absorbed into the Test Stick) and the Test Stick is working properly (i.e. the antibodies and conjugate are active), this indicator will appear. A clear background is an internal negative procedural control; if the test has been performed correctly and the Test Stick is working properly, the background will clear to give a discernible result. Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot and with each new untrained operator.

EXPECTED VALUES

Normally, hCG is not detected in urine of healthy men and healthy non-pregnant women. In normal pregnancy, hCG levels in urine can reach 25 mIU/mL as early as 7 to 10 days post conception, and continue rising to reach a maximum concentration in excess of 200,000 mIU/mL at the end of the first trimester⁽²⁾.

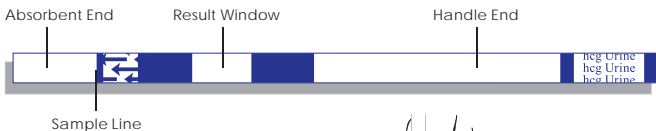
LIMITATIONS

- 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 hCG Urine 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^(4,5).
- 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:⁽⁶⁻⁹⁾
 - Trophoblastic or nontrophoblastic neoplasms: abnormal physiological states that may falsely elevate hCG levels^(10,11). 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⁽¹²⁾. 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[®]hCG Urine Test Stick.
- Dilute urine specimens may not have representative levels of hCG.
- Detection of very low levels of hCG does not rule out pregnancy⁽⁶⁾, as low levels of hCG can occur in apparently healthy, nonpregnant subjects^(13,14). 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⁽¹⁵⁾. Patients with very low levels of hCG should be sampled and tested again after 48 hours, or tested with an alternative method.

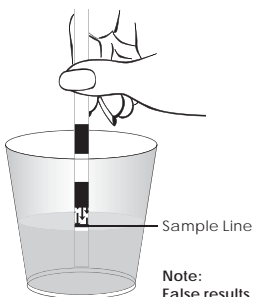
TEST PROCEDURE

Urine collected anytime may be used. Urine specimens may be refrigerated (2°–8°C; 36°–46°F) and tested within 48 hours. Urine specimens and control material must be at room temperature (15°–30°C; 59°–86°F) prior to testing.



- Remove Test Stick(s) from the container; **re-cap container immediately.**

- Dip the Absorbent End of the Test Stick into the sample **up to the Sample Line for at least 3 seconds.**



- Remove the Test Stick from the sample. Place it on a clean, flat, dry disposable surface such as a paper towel.

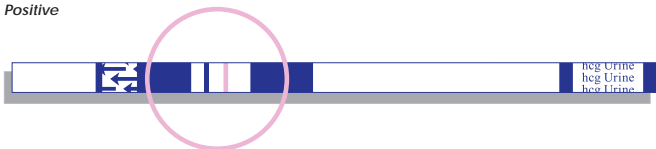
Note:
False results may occur if urine level goes above Sample Line.

- Read results. Positive results can be read as soon as the red Control Line appears. Confirm negatives at 5 minutes. Results read after 5 minutes are invalid.



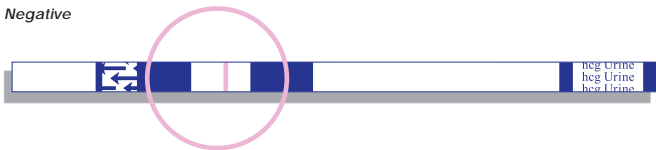
INTERPRETATION OF TEST RESULTS

Positive



A blue Test Line and a red Control Line is a positive result and the sample contains hCG. Note that the blue line can be any shade of blue, and can be lighter or darker than the line in the picture.

Negative



A red Control Line but no blue Test Line is a negative result and the sample contains no detectable hCG.

Invalid

If after 5 minutes, no red Control Line appears, or background color makes reading the red Control Line impossible, the result is invalid and the test should be repeated with a new Test Stick.

PERFORMANCE CHARACTERISTICS

Sensitivity

Urine specimens containing as low as 25 mIU/mL hCG (calibrated against WHO 3rd IS 75/537) will yield positive results when tested with the OSOM hCG-Urine Test.

Interference Testing

The following substances were tested individually in hCG-free urine and urine containing 25 mIU/mL hCG. None of the substances, at the levels tested, affected expected results:

hLH (500 mIU/mL), hFSH (1,000 mIU/mL), hTSH (1,000 μ IU/mL), Estriol (2 mg/dL), Pregnenediol (2 mg/dL), Acetaminophen (20 mg/dL), Acetoacetic Acid (1,000 mg/dL), Acetone (1,000 mg/dL), Acetylsalicylic Acid (20 mg/dL), Albumin (2,000 mg/dL), Ampicillin (20 mg/dL), Ascorbic Acid (20 mg/dL), Atropine (20 mg/dL), Bilirubin (2 mg/dL), Caffeine (20 mg/dL), Gentisic Acid (20 mg/dL), Glucose (2,000 mg/dL), Hemoglobin (1,000 mg/dL), Hydroxybutyric Acid (100 mg/dL), Phenothiazine (20 mg/dL), Phenylpropranolamine (20 mg/dL), Salicylic Acid (20 mg/dL), Tetracycline (20 mg/dL).

Accuracy

A total of 40 urine specimens were evaluated in a clinical study in which test results of the OSOM hCG-Urine Test were compared to results obtained with a commercially available visual test for hCG.

		Comparative Test	
		+	-
OSOM hCG-Urine Test	+	14	0
	-	0	26

The OSOM hCG-Urine Test, when compared to a commercially available visual test for hCG, results in a sensitivity of 100% and specificity of 100%.

An evaluation of the OSOM hCG-Urine Test was conducted at three physician's offices. Each site tested the randomly coded panel consisting of negative, low positive and moderate positive samples for three days. The results obtained had 100% agreement with the expected results.

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ASSISTANCE

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

RE-ORDER

No.101 (50 Tests)

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