CLSI PROCEDURE

Product Name: **Status HCG Strip (urine only)**	
Item Number: 35235	**Waived**

Institution:	
Prepared By:	Date:
Title:	

Accepted By:	Date:
Title:	

Accepted By:		Date:	

Discontinued By	Date:

CONTENTS

SECTION 1 - TEST NAME

Status HCG Strip urine only
One Step Pregnancy Test Strip

SECTION 2 - INTENDED USAGE

Status hCG Strip — One Step Pregnancy Test Strip is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

SECTION 3 - SUMMARY AND EXPLANATION OF TEST

The **Status hCG Strip — One Step Pregnancy Test Strip** is a rapid urine test for detecting hCG. The test is a solid phase, immunochromatographic assay in which a combination of monoclonal and polyclonal antibodies is used to selectively detect elevated levels of hCG in urine with a high degree of sensitivity. In the test procedure, urine is added to the tube with an aid of a transfer pipette and a **Status hCG Strip** is inserted into the test tube. If hCG is present in the specimen, it will react with the conjugated dye, which binds to the antibody on the membrane and generate a colored line. Presence of two colored lines indicates a positive result, while one line at Control position indicates a negative result.

SECTION 4 - PRINCIPLE OF TEST

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 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 menses and peaking in the range of 30,000-100,000 mIU/mL 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]

SECTION 5 - KIT CONTENTS AND STORAGE

The **Status hCG Strip** kit contains enough reagents to perform all the tests.

• **Status hCG Strip** with a polyclonal anti-hCG antibody coated membrane and a pad containing mouse monoclonal anti-hCG antibody–dye conjugate in a protein matrix containing 0.1% sodium azide.

Storage and Stability

The **Status hCG Strip — One Step Pregnancy Test Strip** should be stored at 2–30°C (35–86°F) in its sealed pouch.

SECTION 6 - MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable specimen dispensers
- Test tubes
- Test tube rack
- Urine collection cup
- Timer
- Latex Gloves

SECTION 7 - WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use beyond the expiration date which appears on the package.
- The **Status hCG Strip** should remain in the original sealed pouch until ready for use.

SECTION 8 - PATIENT PREPARATIONS AND SPECIMEN COLLECTION

Specimen Collection and Preparation

- Approximately 1 mL of urine is required for each test.
- For optimal detection of early pregnancy, a first-morning specimen is preferred since it generally contains the highest concentration of hCG. However, urine collected at any time in a day may be used.
- Collect the urine specimen in a clean glass, plastic, or wax coated container without preservatives.
- Urine containing excessive bacterial contamination should not be used since spurious results may occur with such specimens.

Specimen Storage

- If testing will not be performed immediately, the specimens should be refrigerated (2–8°C) or kept reasonably cool (below 25°C) for up to 24 hours.
- Specimens may be frozen (–20°C or below) for longer periods of storage. The frozen specimen must be completely thawed and thoroughly mixed prior to testing. Avoid repeated freezing and thawing.
- If specimens are to be shipped, add sodium azide to a concentration of 0.1% as a preservative and ship by the quickest means possible. Pack the samples in compliance with Federal regulations covering the transportation of etiologic agents.

SECTION 9 - QUALITY CONTROL AND ASSURANCE

Control standards are not provided with this kit; however, it is recommended that controls be tested as good testing practice. For information on how to obtain controls, contact LifeSign's Technical Services.
The control line in the Control area can be considered an internal procedural control. A distinct pinkish-purple line will always appear if the test has been performed correctly. If the control line does not appear, the test is invalid and a new test should be performed. If the problem persists, contact LifeSign for technical assistance. The internal procedural control may satisfy the requirements of testing a control on a daily basis. However, it is recommended to follow federal, state, and local guidelines.

SECTION 10 - TEST PROCEDURE

Procedural Notes

The instructions below must be followed in order to achieve optimal test reactivity with urine specimens. Follow the assay procedure and always perform the test under carefully standardized conditions.

- A test tube or any other sample container can be used for testing as long as the container will hold the required amount of urine sample and is free of contaminating substances.
- To avoid cross-contamination, use a new dropper or pipette tip and a test tube for each specimen.
- Use a test tube rack to hold the test tubes.
- Several tests may be run at one time.
- Keep the **Status hCG Strip** in the sealed pouch until the test is ready to be performed.
- Handle all specimens as if capable of transmitting disease.
- After testing, dispose of the test tubes, the **Status hCG Strip**, and the specimen dispenser following good laboratory practices. Consider each material that comes in contact with specimen to be potentially infectious.

The procedure consists of adding the specimen to the tube, inserting the test strip, and watching for the appearance of a colored line(s) on the membrane.

Test Protocol 1

1. For each test, set up one test tube in a test tube rack.
2. Dispense 1 mL of the urine into the test tube, label the tube and insert a new **Status hCG™ Strip**. Make sure the urine reaches the dotted area on the strip (Dipping Zone).
3. Read the result after 3 minutes, but within 5 minutes.

Test Protocol 2

1. Collect the urine in a urine cup.
2. Dip the **Status hCG™ Strip** in the urine up to the dotted area (Dipping Zone), and keep it there for at least 10 seconds. The strip can then be removed and placed on a flat surface, or left in the sample.
3. Read the result after 3 minutes, but within 5 minutes.

SECTION 11 - INTERPRETATION OF RESULTS

How to Read the Test

1. If there is one pinkish-purple line each in the Test line area and in the Control line area, the test result is **positive** (pregnancy hormone has been detected).
2. If there is no distinct pinkish-purple line in the Test line area other than the normal faint background color, and there is a pinkish-purple line in the Control line area, the test result is **negative**.

Positive

A specimen containing a detectable level of hCG will generate two pinkish-purple lines within 3 minutes. The time required to generate the line is dependent on the hCG concentration in the sample. Some positive results can be read as early as one minute. To be interpreted as positive, the pinkish-purple lines should be clearly distinguishable from the background color of the membrane.

Negative

In the absence of hCG, or in the case that the hCG concentration is below the detection limit of the test, there will be the Control line only with no apparent pinkish-purple line in the Test line area of the membrane.

Inconclusive or Invalid Results

A control line should always appear; the absence of a pinkish-purple control line indicates the test is invalid and should be repeated. If there is a suspected color band visible, but it is not distinct, the test is inconclusive. If there is a suspected procedural error made by the user, the result should be considered inconclusive.

SECTION 12 LIMITATIONS

• 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, testing of another specimen obtained at least 48 hours later is recommended.

• 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 intensity of the Test line.
• The physician should evaluate data obtained with 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 with low specific gravity may not contain representative levels of hCG. If such a sample is negative or weakly positive, a first morning specimen should be tested.

SECTION 13 EXPECTED RESULTS

Status hCG Strip — One Step Pregnancy Test Strip is capable of detecting hCG levels of 25 mIU/mL (WHO 4th International Standard). HCG levels in normal early pregnant women are varied. Average hCG levels are around 25 mIU/mL by the first day of the missed menstrual period.[13] The test is usually capable of confirming pregnancy by the first day of the missed menstrual period.

SECTION 14 PERFORMANCE CHARACTERISTICS

Clinical Evaluation
A total of 245 blind clinical samples from women were tested, and the results are shown in Table 1. These specimens were assayed with **Status hCG Strip — One Step Pregnancy Test Strip** and Tandem Icon II according to the package inserts. Thirty-five samples from menopausal women were included.
Table 1. Status hCG Strip — One Step Pregnancy Test Strip vs. Tandem Icon II

Test Result	Tandem Icon II	Status hCG Strip
Positive (+)	76	76
Negative (–)	134	134
Menopausal	Not Determined	35 (Negative)

The data demonstrate the excellent correlation between **Status hCG Strip — One Step Pregnancy Test Strip** and Tandem Icon II. The clinical accuracy and sensitivity of the two tests are found comparable.

SECTION 15 REFERENCES

1. Braunstein, G.D., Rasor, J., Adler, D., Danzer, H., and Wade, M.E. Serum Human Chorionic Gonadotropin Levels Throughout Normal Pregnancy. *Am. J. Obstet. Gynecol. 126*:678, 1976.
2. Krieg, A.F. Pregnancy Tests and Evaluation of Placental Function in: *Clinical Diagnosis and Management by Laboratory Methods,* 16th ed., Henry, J.B. (ed.) W.B. Saunders Co., Philadelphia, pp. 680, 1979.
3. Brody, S. and Carlstrom, G. Immunoassay of Human Chorionic Gonadotropin in Normal and Pathologic Pregnancy. *J. Clin. Endocrinol. Metab. 22*:564, 1962.
4. Hussa, R.O. Human Chorionic Gonadotropin, A Clinical Marker: Review of its Biosynthesis. *Ligand Review 3*:6, 1981.

5. Swaminathan, N. and Bahl, O.P. Dissociation and Recombination of the Subunits of Human Chorionic Gonadotropin. *Biochem. Biophys. Res. Commun. 40*:422, 1970.
6. Ross, G.T. Clinical Relevance of Research on the Structure of Human Chorionic Gonadotropin. *Am. J. Obstet. Gynecol. 129*:795, 1977.
7. Reuter, A.M., Gaspard, U.J., Deville, J-L., Vrindts-Gevaert, Y. and Franchimont, P. Serum Concentrations of Human Chorionic Gonadotrophin and its Alpha and Beta Subunits. 1. During Normal Singleton and Twin Pregnancies. *Clin. Endocrinol. 13*:305, 1980.
8. Morrow, C.P., Kletzky, O.A., Disaia, P.J., et al. Clinical and Laboratory Correlates of Molar Pregnancy and Trophoblastic Disease. *Am. J. Obstet Gynecol. 128*:424-430, 1977.
9. Dawood, M.Y., Saxena, B.B., Landesman, R. Human Chorionic Gonadotropin and its Subunits in Hydatidiform Mole and Choriocarcinoma. *Obstet. Gynecol. 50*: 172-181, 1977.
10. Braunstein, G.D., Vaitukaitis, J.L., Carbone, P.P., et al. Ectopic Production of Human Chorionic Gonadotropin by Neoplasms. *Ann. Inter. Med. 78*: 39-45, 1973.
11. Steier, J.A., Bergsjo, P., Myking, O.L. Human Chorionic Gonadotropin in Maternal Plasma After Induced Abortion, Spontaneous Abortion, and Removed Ectopic Pregnancy. *Obstet. Gynecol. 64*:391-394, 1984.
12. Thorneycroft, I.H. When You Suspect Ectopic Pregnancy. *Diagnosis* January: 67-82, 1976.
13. Cole, L.A., Seifer, D.B., Kardana, A., and Braunstein, G.D. Selecting human chorionic gonadotropin immunoassays: Consideration of cross reacting molecules in first-trimester pregnancy serum and urine. *Am. J. Obstet. Gynecol. 168*: 1580, 1993

SECTION 17 TECHNICAL ASSISTANCE

Technical assistance is available from the distributor, LifeSign, LLC, Skillman, New Jersey, between the hours of 8:30 a.m. and 4:45 p.m. E.S.T.
Phone: 1-800-526-2125
Fax: 1-732-246-0570
Email: info@lifesignmed.com

Helpful CLIA brochure links to explain Clinical Laboratory Improvement Amendments (CLIA) regulation requirements

Individualized Quality Control Plan- IQCP

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure11.pdf

Proficiency Testing

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf

Proficiency Testing Providers

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf

Personnel Competency Assessment

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

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Test Validation Form

Account Name: _____

Address: _____

_____

Telephone: _____

Test Name: _____ Lot # : _____

Start Date: _____

Supervisor Signature: _____

Sample Number	Expected Results	Test Result	Tester's Initials	Comments

Reviewed by: _____

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Corrective Action Form

Problem /Error	Corrective Action

Laboratory Technologist: _____ Date: _____

Laboratory Director: _____ Date: _____

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Certification of Training

This is to verify that personnel responsible for running _____ test at _____ have been thoroughly in-serviced on the test and the test procedure(s).

This has included:

Review of the package insert
Demonstration of the product assay
Successful performance of the test and interpretation of results

Names of the personnel who have been trained with the above test and are responsible for reporting patient results:

Print Name	Signature	Date

Signature(s) of those responsible for personnel and testing:

_____ _____
Signature Date

_____ _____
Signature Date

_____ _____
Signature Date

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Quality Control

Name of Facility _____

Use this cover sheet with each new shipment and/or with each new kit lot

Product _____ Lot# _____ Exp Date _____

Date Received _____ Rec'd By _____

	Date	Positive Control	Negative Control	Initials
Initial QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				

Reviewed by _____ Date _____

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Testing Personnel Competency Assessment

Test _____

Procedure	Satisfactory	Unsatisfactory	Not Applicable	Comments/Corrective Action(s)
Observation of Test performance				
Patient Sample Preparation				
Specimen Handling/Processing				
Testing				
Recording/Reporting Results				
Assessment of Test Performance Using Known Samples				
Review of Records				
Patient/Quality Control Log Sheet Records				
Proficiency Testing Records				
Assessment of Problem Solving Skills				

(Attach all supporting documents)

Evaluator: _____ Date: _____

Testing Personnel: _____ Date: _____