

5. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.^{6,7} Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

The Alere™ hCG Dipstick (25 mIU/mL) test has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS
METHOD COMPARISON

A multi-center clinical evaluation was conducted comparing the results obtained using the Alere™ hCG Dipstick (25 mIU/mL) test to another commercially available urine membrane hCG test. The study included 150 urine specimens: both assays identified 72 negative and 78 positive results.

| | | Reference hCG Method | |
|------------------|----------|----------------------|----------|
| | | Positive | Negative |
| Alere™ Method | Positive | 78 | 0 |
| | Negative | 0 | 72 |

ANALYTICAL SENSITIVITY AND SPECIFICITY

The Alere™ hCG Dipstick (25 mIU/mL) test detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to hCG negative and positive specimens.

All substances listed in mg/dL unless otherwise noted.

| | | | |
|------------------------|-------|---------------------|-------|
| Acetaminophen | 20 | Acetone | 1,000 |
| Acetylsalicylic Acid | 20 | Acetoacetic Acid | 2,000 |
| Ampicillin | 20 | Ascorbic Acid | 20 |
| Atropine | 20 | Albumin | 2,000 |
| β-Hydroxybutyrate salt | 2,000 | Benzoylcegonine | 10 |
| Bilirubin | 20 | Brompheniramine | 20 |
| Caffeine | 20 | Cannabinol | 10 |
| Clomiphene | 100 | Cocaine | 10 |
| Codeine | 10 | Cholesterol | 500 |
| Creatine | 20 | Dextromethorphan | 20 |
| DMSO | 5% | EDTA | 80 |
| Ephedrine | 20 | Ethanol | 1% |
| Estriol | 2 | Estrone 3-Sulfate | 10 |
| Gentisic Acid | 20 | Glucose | 2,000 |
| Hemoglobin | 1,000 | Heroin | 1 |
| Ibuprofen | 20 | Methadone | 10 |
| Methamphetamine | 10 | Methanol | 10% |
| Morphine | 0.6 | Oxalic Acid | 40 |
| Phenothiazine | 20 | Phenylpropanolamine | 20 |
| Pregnanediol | 2 | Salicylic Acid | 20 |
| Tetracycline | 20 | Triglycerides | 1,200 |
| Theophylline | 20 | Urea | 2,000 |
| Uric Acid | 20 | | |

None of the substances at the concentration tested interfered in the assay.

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hCG Dipstick (25 mIU/mL)

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine.
For professional *in vitro* diagnostic use only. Rx Only.
CLIA Complexity: Waived

INTENDED USE

The Alere™ hCG Dipstick (25 mIU/mL) test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in urine as early as 7 to 10 days after conception.^{1,2,3,4} hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,^{2,3,4} 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 the early detection of pregnancy.

The Alere™ hCG Dipstick (25 mIU/mL) test is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the Alere™ hCG Dipstick (25 mIU/mL) test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The Alere™ hCG Dipstick (25 mIU/mL) test 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 immersing the test strip in a urine specimen and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens 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 suggests 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.

REAGENTS

The test dipstick contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test dipstick should remain in the closed canister until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test dipstick should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the closed canister at 2°-30°C. The test dipstick is stable through the expiration date printed on the canister label. The test dipstick must remain in the closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date. Note: once the canister has been opened, the remaining test dipsticks are stable for 12 months.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

SPECIMEN STORAGE

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

MATERIALS PROVIDED

- 50 Test dipsticks
- 1 Directional insert

MATERIALS REQUIRED BUT NOT PROVIDED

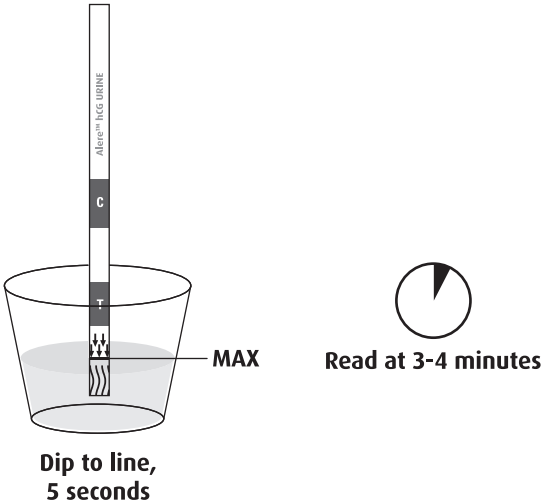
- Specimen collection container
- Timer

DIRECTIONS FOR USE

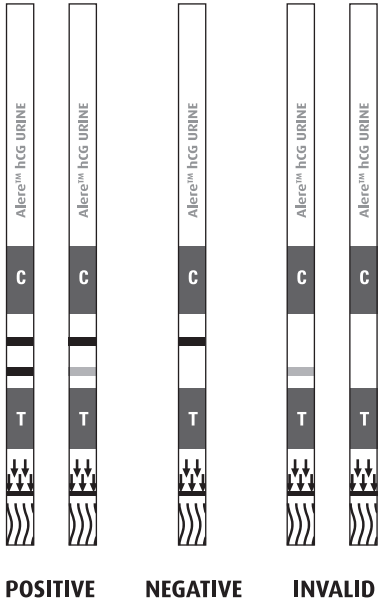
(Please refer to the illustration)

Allow the test dipstick, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test dipstick from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of test dipsticks. Record the initial opening date on the canister. Once opened, the remaining test dipsticks are stable for 12 months.
2. With arrows pointing toward the urine specimen, immerse the test dipstick vertically in the urine specimen for at least 5 seconds. Do not pass the maximum line (MAX) on the test dipstick when immersing the dipstick. See the illustration.
3. Place the test dipstick on a non-absorbent, flat surface, start the timer and wait for the red line(s) to appear. **Read the result at 3-4 minutes. Do not interpret results after the appropriate read time.** It is important that the background is clear before the result is read.



INTERPRETATION OF RESULT



POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

Note: A sample hCG concentration below the cut-off level of this test might result in a weak line appearing in the test region (T) after an extended period of time. A line in the test region (T) seen after the read time could be indicative of a low hCG level in the sample. If such results are seen, it is recommended that the test be repeated with a new sample in 48-72 hours or that an alternate confirmation method is used.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. 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 dipstick. If the problem persists, discontinue using the test kit immediately and contact Alere Technical Support at (866) 216-0094.

***Note:** 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.

QUALITY CONTROL

Internal procedural 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 test result.

It is recommended that a positive hCG control (containing ≥ 25 mIU/mL hCG in urine) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance with each new lot, each new shipment, monthly as a check on storage, each new untrained operator and as otherwise required by your lab internal quality system procedures.

LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,⁵ a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.