April 2018

PRODUCT INFORMATION NOTICE

Dear Valued Customer,

McKesson is the distributor of one or more of the following privately labeled rapid human chorionic gonadotropin (hCG) tests used for early detection of pregnancy. This letter is intended to affirm the intended use and limitations as stated in the existing labeling for the rapid hCG tests distributed by McKesson. These are the applicable products.

Product Part No.	**Description**
5000	CONSULT™ diagnostics hCG Dipstick
5001	CONSULT™ diagnostics hCG Cassette
5002	CONSULT™ diagnostics hCG Combo Cassette

Please distribute the following product information to the end-users of your privately labeled rapid hCG tests:

INTENDED USE

The hCG test is a rapid chromatographic immunoassay for the qualitative detection of hCG in serum (serum/urine hCG tests only) or urine to aid in the early detection of pregnancy.

PRECAUTIONS

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

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[1], a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. 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.[2,3] Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
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.

IMPORTANT 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.

If you have any questions, please contact Technical Services at 1-866-216-0094.

REFERENCES

1. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", *Obstet. Gynecol.* 1984; 64(3): 391-394
2. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", *Obstet. Gynecol.* 1977; 50(2): 172-181
3. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", *Ann. Intern Med.* 1973; 78(1): 39-45