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MiniStick Pregnancy Test for Consumer Use

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510(k) Summary of Product Safety and Effectiveness

The trade name of this device is **MiniStick** Pregnancy Test. It is a qualitative visual test system for the detection of human Chorionic Gonadotropin (HCG) in urine as an indicator of pregnancy and would be classified as a Human Chorionic Gonadotropin Test System.

Vanguard Biomedical Corporation considers the **MiniStick** to be substantially equivalent to other comparable FDA-approved products in intended use, test procedure, and test principles.

INTRODUCTION

Human Chorionic Gonadotropin (HCG) is a glycoprotein hormone produced by the placenta and found in the urine of pregnant women (1). This hormone increases rapidly during pregnancy and normally reaches levels in excess of 100,000 mIU/ml during the first trimester (2).

The molecular structure of HCG is similar to other glycoprotein hormones normally found in the urine, i.e., Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), and Thyroid Stimulating Hormone (TSH). However, HCG can be differentiated from the others by using a monoclonal antibody against a specific site on the HCG molecule. **MiniStick** Pregnancy Test is a qualitative immunoassay which uses a specific monoclonal antibody for HCG detection. This test is virtually 100% accurate in laboratory testing and is greater than 99% accurate in clinical trials.

REFERENCES

- (1) Braunstein, G.D., Rasor, J., Adler, D., Danzer, H., and Wade, M.E., *Am. J. Obstet. Gynecol.*, 126:678 (1976).
- (2) Lenton, E.A., Neal, L.M., and Sulaiman, R., *Fertility and Sterility*, 37:773 (1982).

PRINCIPLES OF THE TEST SYSTEM

The **MiniStick** Pregnancy Test is an immunodiagnostic system that detects the presence of HCG in the urine sample through the formation of a complex which is held together by the HCG molecule.

The patient's urine sample enters a paper reservoir which is in contact with a pad containing a dried conjugate of colloid gold-monoclonal antibody (reddish in color). The urine sample will then reconstitute the dried conjugate. If HCG is present in the sample, it will react with the monoclonal antibody to form a complex of colloid gold-monoclonal antibody-HCG. This complex migrates up a membrane strip chromatographically and through a band of immobilized goat anti-HCG. Because the antibody of this immobilized goat anti-HCG is able to bind the HCG molecule of the migrating complex, a visible reddish band is formed along the exact location of the immobilized goat anti-HCG antibody. If there is no HCG present in the sample, the colloid gold-monoclonal antibody conjugate will pass through the immobilized goat anti-HCG band and no colored line will form —a negative test result.

Further up the membrane, past the anti-HCG test region, is a control region consisting of a band of immobilized goat anti-mouse IgG. This band of antibody will bind only conjugate and form a colored line, regardless of whether HCG is present in the urine or not. Appearance of the control line assures reagent integrity as well as correct testing procedure.

SUBSTANTIAL EQUIVALENCE

Vanguard Biomedical Corporation considers the **MiniStick** Pregnancy Test to be substantially equivalent to other comparable FDA-approved products in intended use, test principles, and test procedures.

INTENDED USE

The **MiniStick** Pregnancy Test is a monoclonal antibody-based immunoassay intended for the visual qualitative detection of human Chorionic Gonadotropin (HCG) in urine as an early indicator of pregnancy. Its intended use is identical to that of several professional products currently available for use in clinical laboratories or physicians' offices.

These include: ANSWER 1-Step Pregnancy Test	Carter Products Division Carter-Wallace, Inc. New York, NY 10105
1 Step ADVANCE Pregnancy Test	Advanced Care Products Ortho Pharmaceutical Corp. Raritan, NJ 08869
Conceive Pregnancy Test	Quidel Corp. 10165 McKellar Court San Diego, CA 92121

For the reasons presented below, and by the data presented in the Clinical Performance Section, Vanguard Biomedical Corporation believes that the **MiniStick** Pregnancy Test is substantially equivalent to commercially available products for the visual qualitative detection of HCG in urine specimens.

SYSTEMS COMPARISON

The **MiniStick** Pregnancy Test is similar in immunological principles and procedures to ANSWER 1-Step Pregnancy Test from Carter-Wallace, Inc. A comparison of the two systems is described below.

- 1 Both tests are visual qualitative immunoassays for the detection of HCG in urine as an indicator of pregnancy.
- 2 Both tests are "sandwich" type immunoassays in which HCG is captured between an antibody attached to a solid phase and a colloid gold-monoclonal antibody conjugate in the liquid phase.
- 3 Both tests use polyclonal antibodies on the solid phase .
- 4 Both tests use color deposition on the solid phase through chromatographic migration of the colloid gold-monoclonal antibody conjugate, as an indicator of a positive result, i.e., the presence of HCG in the sample.
- 5 Both tests use monoclonal anti-HCG Beta subunit antibodies to assure specificity for HCG.
- 6 Both tests have a control band by which the user can be assured that the assay was performed correctly and the reagents were working properly. This band shows color each time the test is run regardless of the sample being positive or negative for HCG. Should color fail to appear at the control band, the user is alerted to potential problems invalidating the test results.
- 7 Both tests collect sample by holding the sample collection region in the urine stream for direct application.

CLINICAL PERFORMANCE

A total of 206 clinical urine specimens (55 positive and 151 negative) were assayed with the **MiniStick** Pregnancy Test and with the *HOMECLINIC* One-Step Pregnancy Test [510 (k) Number K914253] following package directions. The **MiniStick** Pregnancy Test is chemically and structurally identical to the *HOMECLINIC* One-Step Pregnancy Test; however, the former has sample applied directly to a collection region by holding the tip of the Test Unit in the urine stream, whereas the latter requires a urine sample to be collected first, then a few drops of that sample are applied to a sample well in the test unit. Assay results were equivalent in all specimens tested, resulting in a 100% correlation in test results between the **MiniStick** Pregnancy Test and the *HOMECLINIC* One-Step Pregnancy Test.

The results of the Clinical Evaluation showed substantial equivalence in accuracy of clinical performance for the **MiniStick** Pregnancy Test and the *HOMECLINIC* One-Step Pregnancy Test, as determined by laboratory testing by Vanguard personnel.

All the women participating in the study had a favorable response to performing the test by holding the device in their urine stream to obtain a sample.