

K96 0174

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8. 510(k) Summary of Information Respecting Safety and Effectiveness

A. Legally Marketed Device

Biotech Atlantic claims substantial equivalence to the UniStep™ HCG Pregnancy Test Device (K941090) currently in commercial distribution (outside the U.S.) by Biotech Atlantic, Inc.

B. Device Description

The UniMark™ Midstream Pregnancy Test Stick is a home use, rapid, visual, one step screening test for pregnancy.

Human chorionic gonadotropin (hCG) is a glycoprotein hormone synthesized by the placenta and released in blood and urine soon after the implantation of a fertilized ovum in the chorionic tissue. The rapidly rising levels of hCG provide a stimulus to the corpus luteum (luteotrophic effect). Instead of involution in a non-pregnant menstrual cycle, the corpus luteum continues to grow and secretes increasing quantities of hormone progesterone which is needed to maintain pregnancy. Thus, hCG is the principal signal and specific marker of the pregnancy.

A number of variations were used for the next 30 years. They have been rapidly superseded in the 1960s because of their cost and inconvenience since immunoassays were introduced. Like other members of glycoprotein hormones, such as Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH), hCG is composed of two subunits: an alpha-subunit, which is virtually identical in all four; and a beta-subunit, which is characteristic of the individual hormone, therefore determines the specificity of the action. Use of monoclonal antibodies to the beta-subunit of hCG is an important development which provides the feasibility to manufacture new generations of immunoassays with consistent specificity and high sensitivity to detect hCG. Pregnancy test now reaches a level which is generally considered unlikely to be surpassed either by better test or alternative technology.

UniMark™ is a colored solid-phase immunoassay for qualitative detection of elevated levels of hCG in urine for the early pregnancy diagnosis. It is based on a two-site sandwich immunometric assay which utilizes a unique combination of monoclonal and polyclonal antibodies to selectively identify hCG with a high degree of sensitivity. UniMark™ contains a strip with a sample pad and a membrane area. The former contains mouse anti-hCG monoclonal antibody conjugated with colloid gold. The latter is coated with goat anti-mouse IgG at the control zone and goat anti-hCG antibody at the test zone. During the test, the urine is sucked up through sample pad by capillary action, and hCG in the urine sample binds to the gold conjugate, moving chromatographically toward the membrane. The immobilized goat anti-hCG antibody at the test zone catches the resulting complexes, forming an antibody-hCG-gold conjugate complex. The appearance of a purple band in the test window resulted from the complex shows a

positive result, which indicates presence of hCG and suggests a pregnancy. Absence of this band, on the other hand, displays a negative result, i.e. no detectable hCG in the urine sample. The appearing of a purple band in the control window demonstrates proper performance and validity of the reactive reagent.

C. Intended Use

The UniMark™ Midstream Pregnancy Test Stick is intended for the qualitative measurement of human chorionic gonadotropin (hCG) in urine as a home use screening test for pregnancy.

D. Comparison with the Predicate Device

A summary comparison of the features of the UniMark™ and UniStep™ pregnancy tests is provided in Table 1 below.

Table 1.
Feature Comparison of the UniMark™ and UniStep™ Pregnancy Tests

	UniMark™	UniStep™
Intended Use	Qualitative measurement of hCG Home use	Qualitative measurement of hCG Professional use
Reagents/Materials	Goat anti-hCG Mouse anti-hCG Monoclonal conjugate Plastic device with splash guard and absorbent tip	Goat anti-hCG Mouse anti-hCG Monoclonal conjugate Plastic device
Assay Method	Colored solid-phase immunoassay Midstream	Colored solid-phase immunoassay Drop application
Specimen	Urine	Urine
Time of Collection	Any time of day	First a.m. preferred
Storage	2° to 30° C	2° to 30° C
Reaction Time	5 minutes	5 minutes
Positive Result	Purple band in Test Window	Purple band in Test Window
Standardization	WHO 3rd IS 75/537	WHO 3rd IS 75/537
Sensitivity	25mIU/ml or greater	25mIU/ml or greater
Accuracy	> 99%	> 99%
Specificity	No interferences	No interferences

E. Performance Data

Non-Clinical Tests

Sensitivity

UniMark™ Lot	HCG Concentration (mIU/ml), WHO 3rd IS 75/537)				
	0	20	25	50	100
1	-(100%)	-(95%) ---+ (5%)	+(100%)	++(100%)	+++ (100%)
2	-(100%)	-(95%) ---+ (5%)	+(100%)	++(100%)	+++ (100%)
3	-(100%)	-(95%) ---+ (5%)	+(100%)	++(100%)	+++ (100%)

Specificity

hLH Study

UniMark™ Lot	hLH (mIU/ml)			hLH + hCG (MIU/ml)			
	0	10	100	200	10+25	100+25	200+25
1	—	—	—	—	+	+	+
2	—	—	—	—	+	+	+
3	—	—	—	—	+	+	+

hFSH Study

UniMark™ Lot	hFSH (mIU/ml)		hFSH + hCG (mIU/ml)
	0	1000	1000 + 25
1	—	—	+
2	—	—	+
3	—	—	+

hTSH Study

UniMark™ Lot	hTSH (uIU/ml)		hTSH + hCG (uIU+ mIU/ml)
	0	1000	
	—	—	+
1	—	—	+
2	—	—	+
3	—	—	+

Clinical Tests

The UniMark™ was evaluated in a consumer study of 146 home users selected on a random basis as they presented themselves at a women's center in southern New Jersey. The home users represented a diversity of age, background and education.

The study was explained to the home users by either the center's nurse or lab assistant. If the home user agreed to participate, written and verbal instructions on how to perform the test were provided. In addition to performing the midstream test procedure, the home users were asked to collect a sample of the same urine specimen. At the conclusion of the test, each home user was asked to complete a questionnaire to obtain feedback on the test. The user test results were observed and verified by the lab assistant (to verify correct interpretation of positive or negative).

There was 100% correlation between the UniMark™ home user and CIDA professional test results, as shown in Table 2 below.

Table 2.
CIDA

	Positive	Negative
UniMark™	119	27
	0	0

146 ✓