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Attachment #5

Summary of Safety and Effectiveness

EZ Sure™ (Excel) Urine Midstream Early Pregnancy Home Test is Excel Scientific, Inc.'s name for OTC use of solid phase migratory chromatography immunoassay in vitro diagnostic test kit for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine. EZ Sure™ (Excel) Urine Midstream Early Pregnancy Home Test is based on comparative data with Syntron Quikpac II pregnancy test (BeSure Home Test), an assay also for human Chorionic Gonadotropin currently being marketed.

The Principle of EZ Sure™ (Excel) Urine Midstream Early Pregnancy Home Test is as follows:

1. The EZ Sure™ (Excel) Urine Midstream Pregnancy Home Test also is a sandwich solid phase dye-conjugated non-enzyme immunoassay. The stream of urine goes directly into the absorbent windows of the reaction device. The labeled antibody dye-conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produce a rose-pink color band when hCG concentration is equal to or greater than 25 mIU/mL. In the absence of hCG, there is no line formation in the positive reaction zone. The reaction mixture continues to flow through the device and migrates to the control reaction zone by producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.
2. The Quikpac II (or BeSure Home Test) also is a solid phase sandwich dye-conjugate non-enzyme immunoassay. As the specimen is added to the reaction device, the labeled antibody dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a rose-pink color band when hCG concentration is equal to or greater than 25 mIU/mL in the specimen. In the absence of hCG, there is no line formation in the positive reaction zone. The reaction mixture continues to flow through the device and migrates into the control reaction zone by producing a rose-pink color band control, demonstrating that the reagents and device are functioning correctly.
3. The exact differences between the EZ Sure™ (Excel) Urine Midstream Early Pregnancy Home Test protocol and the Syntron's Quikpac II pregnancy test (BeSure Home Test) protocol are as follows :

	Quikpac II pregnancy test (BeSure Home Test)	EZ Sure™ (Excel) Urine Midstream Early Pregnancy Home Test
Specimen Volume	8 drops	Urine stream
Incubation	5 minutes	5 minutes
Reagent	No	No
Step	one step	one step
Cutoff	25 mIU/mL	25 mIU/mL
Urine Cup	Yes	No

4. The EZ Sure™ (Excel) Urine Midstream Early Pregnancy Home Tests has been found to be greater than 99% in agreement with another test (the Syntron Quikpac II test) that is currently available commercially. Comments from consumers also support that the test is simple to perform and the results are fast.
5. For questions concerning the safety and effectiveness of the EZ Sure™ Urine Midstream Early Pregnancy Home Test, please contact:

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