

Summary of Safety and Effectiveness

EZ Sure™ Urine DipStick Pregnancy Home Test

EZ Sure™ Urine DipStick 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™ Urine DipStick Pregnancy Home Test* is based on comparative data with Syntron Quikpac EIA, an assay for human Chorionic Gonadotropin currently being marketed.

The Principle of *EZ Sure™ Urine DipStick Pregnancy Home Test* is as follows:

- Both the *EZ Sure™ Urine DipStick Pregnancy Home Test* and the QuikStrip (or E.Z. Strip) Pregnancy Home test are a sandwich solid phase dye-conjugated non-enzyme immunoassay. When the *EZ Sure™ Urine DipStick Pregnancy Home Test* is placed in a urine test cup containing the urine specimen, the urine will migrate by capillary action. The gold sol-antibody conjugate in the gold sol pad of the *EZ Sure™ Urine DipStick Pregnancy Home Test* binds to the hCG molecules in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody immobilized in the positive reaction zone in the white membrane area and produces a rose-pink color band when the hCG concentration is at or greater than 25 mIU/mL. In the absence of detectable levels of hCG, there is no rose-pink band in the positive reaction zone. The reaction mixture continues to flow through the absorbent device, pass the positive reaction zone, producing a rose-pink color band in the control zone of the white membrane area, demonstrating that the reagents and the device are functioning correctly.
- The Differences Between the *EZ Sure™ Urine DipStick Pregnancy Home Test* and the Syntron's QuikStrip (or E.Z. Strip) Pregnancy Home test are as follows :

| | QuikStrip (or E.Z. Strip) Pregnancy Home test | <i>EZ Sure™ Urine DipStick Pregnancy Home Test</i> |
|-----------------|-----------------------------------------------|----------------------------------------------------|
| Specimen Volume | 6 drops | 6 drops of urine |
| Incubation | 5 minutes | 5 minutes |
| Reagent | No | No |
| Step | one step | one step |
| Cutoff | 25 mIU/mL | 25 mIU/mL |
| Urine Cup | Yes | Yes |

- The Differences Between the *EZ Sure™ Urine DipStick Pregnancy Home Test* and the Syntron Quikpac EIA Pregnancy Test are as follows :

| | Syntron Quikpac EIA Pregnancy Test | <i>EZ Sure™ Urine DipStick Pregnancy Home Test</i> |
|-----------------|------------------------------------------------------|----------------------------------------------------|
| Specimen Volume | 3 drops of urine | 6 drops of urine |
| Incubation | 3 minutes with antibody and 3 minutes with substrate | 5 minutes |
| Reagent | 2 bottles | No |
| Step | 3 steps | one step |
| Cutoff | 25 mIU/mL | 25 mIU/mL |

EXCEL

"Commitment to Excellence"

3. For questions concerning the safety and effectiveness of the *EZ[®]Sure™ Urine DipStick Pregnancy Home Test*, please contact:

Min-Lee Cheng, Ph.D.
23071 E. La Palma Avenue
Yorba Linda, CA 92887
Tel: (714) 692-7151