

K970467

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EXCEL

Attachment #9

SUMMARY OF SAFETY AND EFFECTIVENESS
EZ Sure™ OneStep Ovulation Predictor Home Test Kit

1. *EZ Sure™ OneStep Ovulation Predictor Home Test Kit* is Excel Scientific, Inc.'s name for OTC use of solid phase immunoassay in vitro diagnostic test kit for the qualitative determination of Luteinizing Hormone (LH) in urine. *EZ Sure™ OneStep Ovulation Predictor Home Test Kit* is based on comparative data with *Conceive® OneStep Ovulation Predictor test*, a semi-quantitative test for the determination of LH currently being marketed by Quidel Corporation.

The *EZ Sure™ OneStep Ovulation Predictor Home Test Kit* is a sandwich solid phase dye-conjugate non-enzyme immunoassay. As the specimen is added to the reaction device, the gold-sol-antibody conjugate binds to the LH in the specimen forming an antibody-antigen complex. This complex binds to the anti-LH antibody in the positive reaction zone and produces a rose pink color band when LH concentration is present in the specimen. In the absence of LH, there is no rose-pink line in the positive reaction zone. The reaction continues to flow through the absorbent device, pass the positive reaction zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly. This working principle can also be applied for the *Conceive® OneStep Ovulation Prediction Test*.

2. The performance of *EZ Sure™ OneStep Ovulation Predictor Home Test Kit* is summarized as follows:
- It is capable to discern an LH concentration between ≥ 30 mIU/mL and < 30 mIU/mL in the urine. When the LH concentration in the urine is ≥ 30 mIU/mL, it is indicative that LH surge is in progress.
 - It is not interfered by the presence of homologous hormones (such as 1,000 mIU/mL hFSH or 1,000 μ IU/mL TSH), common drugs (such as acetaminophen, acetylsalicylic acid, ascorbic acid, atropine, caffeine or gentisic acid, each at 20 mg/dL), or other substances (such as 2 g/dL glucose, 1 mg/dL hemoglobin, 20 mg/dL ampicillin, or 20 mg/dL tetracycline) in the specimen.
 - Using this test kit, consumers (103 female volunteers) were able to obtain results that were equivalent to those obtained by trained laboratory technicians who employed another commercially available one-step ovulation prediction test (*Conceive®* by Quidel) and a quantitative microtiter EIA LH assay (Medix) on the same patient urine specimens.
 - No detectable intra- and inter-assay variation between replicates of the same reagent lots and between different reagent lots using spiked urine pool or patient specimens with known LH concentrations have been substantiated.
 - An eighteen-month shelf-life has been substantiated by the real-time and accelerated stability testing of the sample reagent.
3. The exact differences between the *EZ Sure™ OneStep Ovulation Predictor Home Test Kit* and *Conceive® OneStep Ovulation Prediction Test* are as follows:

	Conceive® OneStep Ovulation Prediction Test	EZ Sure™ OneStep Ovulation Predictor Home Test
SPECIMEN VOLUME	3 drops	4 drops
REAGENT	No Liquid Reagent	No Liquid Reagent
INCUBATION	3 Minutes	5 Minutes
STEPS	1 Step	1 Step
SURGE CUTOFF	≥ 30 mIU/mL	≥ 30 mIU/mL

4. For any questions pertaining to this 510(K) application, please contact :

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