



"Commitment to Excellence"

K962580

AUG 29 1996

Summary of Safety and Effectiveness

EZ Sure OneStep Pregnancy Test

EZ Sure OneStep Pregnancy 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 OneStep Pregnancy Test* is based on comparative data with BeSure OneStep immunoassay, an assay for human Chorionic Gonadotropin currently being marketed.

The Principle of *EZ Sure OneStep Pregnancy Test* is as follows:

- Both the *EZ Sure OneStep Pregnancy Test* and the BeSure OneStep Pregnancy Test are a sandwich solid phase dye-conjugated non-enzyme immunoassay. When the specimen is added to the reaction device, the gold-sol-antibody conjugate 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 viewing window and produces a purple-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 purple-pink band in the positive reaction zone. The reaction mixture continues to flow through the absorbent device, pass the positive reaction zone, producing a purple-pink color band in the control zone, demonstrating that the reagents and the device are functioning correctly.

The Differences Between the *EZ Sure OneStep Pregnancy Test* and the BeSure OneStep Pregnancy Test are as follows :

	BeSure OneStep Pregnancy Test	<i>EZ Sure OneStep Early Pregnancy Test</i>
Specimen Volume	6 drops	4 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

- For questions concerning the safety and effectiveness of the *EZ Sure OneStep Pregnancy Test*, please contact:

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Additional Data**Performance Characteristics****Accuracy :**

A study was performed using a total 180 positive and negative urine specimens. These specimens were assayed with *EZ[®]Sure OneStep Early Pregnancy Test* and Syntron's BeSure test according to the packaging insert.

		<i>EZ[®]Sure OneStep Early Pregnancy Test</i>	
		(Positive)	(Negative)
Syntron's BeSure	(Positive)	90	0
OneStep hCG Test	(Negative)	0	70

The above data do not include two specimens which were weakly reactive with both BeSure OneStep hCG and *EZ[®]Sure OneStep Early Pregnancy Tests*. The reactions of these specimens were considered to be inclusive. The accuracy study was also performed by determining the qualitative recovery of known amounts of hCG added to the urine pool.

Concentration of hCG in the Urine Pool (mIU/mL)	Expected	Observed
0	negative	one band (negative)
20	negative	one band (negative)
25	positive	two bands (positive)
100	positive	two bands (positive)
450,000	positive	two bands (positive)

The *EZ[®]Sure OneStep Early Pregnancy Test* can detect hCG in urine sample at concentration of 25 mIU/mL or greater. This sensitivity has been determined against the World Health Organization Third International Standard. In some cases, samples containing less than 25 mIU/mL of hCG can also test as positive.

Specificity :**Menopausal Urines :**

A study was conducted using urine specimens from 20 postmenopausal women. These specimens were chosen because urine from postmenopausal women frequently interfere with pregnancy tests due to cross reactivity with other gonadotropin hormones. All twenty urine specimens were negative when tested with the *EZ[®]Sure OneStep Early Pregnancy Test*.

Potentially interfering substances were added to urine samples which had hCG levels of 0 and 25 mIU/mL. In each case, no interference was observed when these spiked urine samples were tested with the *EZ[®]Sure OneStep Early Pregnancy Test*.

Substance	Concentration in Urine
Acetaminophen	20 mg/dl
Acetylsalicylic Acid	20 mg/dl
Ampicillin	20 mg/dl
Ascorbic Acid	20 mg/dl
Atropine	20 mg/dl
Caffeine	20 mg/dl

81

Gentisic Acid	20 mg/dl
Glucose	2,000 mg/dl
Hemoglobin	1 mg/dl
Human Serum Proteins	2,000 mg/dl
Tetracycline	20 mg/dl
Uric Acid	10 mg/dl

Homologous Hormones at the concentrations indicated below were found not to interfere with the *EZ[®] Sure OneStep Early Pregnancy Test* either:

Homologous Hormones	Concentration in Urine	Reference
hTSH	1,000 μ IU/mL	WHO 68/38
hLH	500 mIU/mL	WHO 2nd IRP HMG
hFSH	1,000 mIU/mL	WHO 2nd IRP HMG

Standardization :

The reference preparation and controls have been calibrated as follows :

$$1.0 \text{ mIU/mL Excel} = 1.0 \text{ mIU/mL 3rd I.S.}$$

recision :

Intra-Assay : Within run precision was determined using 11 replicates of four specimens containing 0, 25, 100 and 450,000 mIU/mL hCG. The negative and positive values were correctly identified 100% of the time.

Inter-Assay : Between run precision was determined using the same four specimens of 0, 25, 100 and 450,000 mIU/mL of hCG in 11 independent assays, and with three different lots of reaction devices over a two-month period. Again, the negative and positive values were correctly identified 100% of the time.