

K963341

DEC -2 1996

Summary of Safety and Effectiveness

- 1. Company: **Syntron Bioresearch, Inc.**
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- 2. Date Prepared: **August 18, 1996**

Midstream OneStep pregnancy test is Syntron Bioresearch, Inc. name for OTC use of solid phase immunoassay in vitro diagnostic test kit for the qualitative determination of human Chorionic Gonadotropin (hCG) in urine. *Midstream OneStep* pregnancy test is based on comparative data with *Besure Plus OneStep* immunoassay, an assay for human Chorionic Gonadotropin currently being marketed.

The Principle of *Midstream* and *Besure Plus* Pregnancy Test is as follows:

The *Midstream* and *Besure Plus* pregnancy test 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 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 purple-pink color band when hCG concentration is equal or greater than 25 mIU/ml. In the absence of hCG, there is no purple-pink line 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, demonstrating that the reagents and device are functioning correctly.

The Two Protocols Are

	<i>Besure Plus OneStep</i> Pregnancy Test	<i>Midstream OneStep</i> Pregnancy Test
Incubation	5minutes	5minutes
Reagent	No	No
Step	1 Step	1 Step
Cutoff	25 mIU/ml	25 mIU/ml
Urine Cup	No	No

The *Midstream* OneStep Pregnancy Home Test was performed by 102 consumers: females selected between the ages of 18 and 49 years old, pregnant and non-pregnant, were told to use midstream test and BeSure Plus pregnancy test and compare both results obtained. Confirmation of clinical status was also based on the clinical diagnosis submitted by physician.

Of the 102 samples tested, 93 had a confirmed clinical diagnosis of non-pregnancy and 9 had a diagnosis of pregnancy. Test results obtained by the consumers showed a 100% correlation between midstream pregnancy test with Syntron's *Besure Plus* OneStep hCG test. Physician report also indicated a 100% correlation between midstream test and clinical diagnosis.

A survey was conducted on the consumers' educational background who had participated in our pregnancy studies. Of the 102 consumers, approximately 8% of the people have bachelor degrees. 75% of the consumers have high school education and various training in vocational schools. The remaining 17% of the consumers have only junior high school education.

The results form also indicated consumer remarks on the performance of the midstream test. Their remarks are:

- A. Two test are virtually the same.
- B. Quick & easy.
- C. Simple test.
- D. Easy to use.
- E. Clear signal.
- F. Good test.

Patient I.D.	<i>Midstream OneStep</i> hCG Pregnancy Test	<i>Besure Plus</i> Pregnancy Test	Clinical Diagnosis
1.	-	-	Non-Pregnant
2.	-	-	Non-Pregnant
3.	-	-	Non-Pregnant
4.	-	-	Non-Pregnant
5.	-	-	Non-Pregnant
6.	-	-	Non-Pregnant
7.	-	-	Non-Pregnant
8.	-	-	Non-Pregnant
9.	+	+	Pregnant
10.	-	-	Non-Pregnant
11.	-	-	Non-Pregnant
12.	-	-	Non-Pregnant
13.	-	-	Non-Pregnant
14.	-	-	Non-Pregnant
15.	+	+	Pregnant
16.	-	-	Non-Pregnant
17.	-	-	Non-Pregnant
18.	-	-	Non-Pregnant
19.	-	-	Non-Pregnant
20.	-	-	Non-Pregnant
21.	-	-	Non-Pregnant
22.	-	-	Non-Pregnant
23.	+	+	Pregnant
24.	-	-	Non-Pregnant
25.	-	-	Non-Pregnant
26.	-	-	Non-Pregnant
27.	-	-	Non-Pregnant
28.	-	-	Non-Pregnant

29.	-	-	Non-Pregnant
Patient I.D.	Midstream OneStep hCG Pregnancy Test	Besure-Plus Pregnancy Test	Clinical Diagnosis
30.	-	-	Non-Pregnant
31.	-	-	Non-Pregnant
32.	-	-	Non-Pregnant
33.	-	-	Non-Pregnant
34.	-	-	Non-Pregnant
35.	-	-	Non-Pregnant
36.	-	-	Non-Pregnant
37.	-	-	Non-Pregnant
38.	-	-	Non-Pregnant
39.	-	-	Non-Pregnant
40.	-	-	Non-Pregnant
41.	-	-	Non-Pregnant
42.	-	-	Non-Pregnant
43.	-	-	Non-Pregnant
44.	-	-	Non-Pregnant
45.	-	-	Non-Pregnant
46.	-	-	Non-Pregnant
47.	-	-	Non-Pregnant
48.	-	-	Non-Pregnant
49.	-	-	Non-Pregnant
50.	-	-	Non-Pregnant
51.	-	-	Non-Pregnant
52.	-	-	Non-Pregnant
53.	-	-	Non-Pregnant
54.	-	-	Non-Pregnant
55.	-	-	Non-Pregnant
56.	-	-	Non-Pregnant
57.	-	-	Non-Pregnant
58.	-	-	Non-Pregnant

Patient I.D.	Midstream OneStep hCG Pregnancy Test	Besure Plus Pregnancy Test	Clinical Diagnosis
59.	+	+	Pregnant
60.	-	-	Non-Pregnant
61.	-	-	Non-Pregnant
62.	-	-	Non-Pregnant
63.	-	-	Non-Pregnant
64.	+	+	Pregnant
65.	-	-	Non-Pregnant
66.	-	-	Non-Pregnant
67.	-	-	Non-Pregnant
68.	-	-	Non-Pregnant
69.	-	-	Non-Pregnant
70.	-	-	Non-Pregnant
71.	-	-	Non-Pregnant
72.	-	-	Non-Pregnant
73.	-	-	Non-Pregnant
74.	-	-	Non-Pregnant
75.	-	-	Non-Pregnant
76.	-	-	Non-Pregnant
77.	-	-	Non-Pregnant
78.	-	-	Non-Pregnant
79.	-	-	Non-Pregnant
80.	-	-	Non-Pregnant
81.	-	-	Non-Pregnant
82.	-	-	Non-Pregnant
83.	-	-	Non-Pregnant
84.	-	-	Non-Pregnant
85.	-	-	Non-Pregnant
86.	-	-	Non-Pregnant
87.	-	-	Non-Pregnant

Patient I.D.	<i>Midstream OneStep</i> hCG Pregnancy Test	<i>Besure Plus</i> Pregnancy Test	Clinical Diagnosis
88.	-	-	Non-Pregnant
89.	-	-	Non-Pregnant
90.	-	-	Non-Pregnant
91.	-	-	Non-Pregnant
92.	-	-	Non-Pregnant
93.	-	-	Non-Pregnant
94.	+	+	Pregnant
95.	-	-	Non-Pregnant
96.	+	+	Pregnant
97.	-	-	Non-Pregnant
98.	-	-	Non-Pregnant
99.	-	-	Non-Pregnant
100.	-	-	Non-Pregnant
101.	-	-	Non-Pregnant
102.	-	-	Non-Pregnant