

K964574  
Jan. 21, 1997

## **510 (k) SUMMARY**

### **AFFIRM ONE STEP PROFESSIONAL PREGNANCY TEST**

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**Submitted by:**

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**Product Name:**

**Proprietary Name:**  
Affirm One-Step Professional Pregnancy Test

**Classification Name:**  
human Chorionic Gonadotropin test systems

**Intended Use:**

Affirm One-Step Professional Pregnancy Test is a rapid one-step visual test for the qualitative detection of human Chorionic Gonadotropin in human urine to aid in the diagnosis of pregnancy. This test is intended for Professional use.

**Description of Device:**

Affirm detects the presence of hCG in urine by using a combination of polyclonal and monoclonal antibodies on the reagent pad and the test strip. The assay begins functioning with the addition of urine onto the absorbent wick. Through capillary action the urine is pulled to the reagent pad where the hCG reacts with the conjugate, and then through the membrane containing bound capture antibodies. Positive results are determined by one color line in the test window and one color line in the control window. The absence of hCG produces only one color line in the control window.

**Predicate device for substantial equivalence comparison:**

SAS™ Pregnancy Strip

**Date Prepared:**

November 1, 1996

**Substantial Equivalence:**

Comparison Product: SAS™ Pregnancy Strip  
 Manufactured by: SA Scientific™  
 4919 Golden Quail  
 San Antonio TX 78240

**Similarities to SAS™ Pregnancy Strip:**

Items to be compared	Affirm One-Step Professional Pregnancy Test	SAS™ Pregnancy Strip
• <u>Detection method:</u>	hCG in urine specimens reacts with the colored-conjugate on the pad producing a solid color (red) line in the test region. Mouse conjugate binds to goat anti-mouse antibody in the control region on the strip.	hCG in urine specimens reacts with the colored-conjugate on the pad producing a solid color (red) line in the test region. Mouse conjugate binds to goat anti-mouse antibody in the control region on the strip.
• <u>Method</u>	Mid-stream or dip.	Dip only.
• <u>Usage:</u>	Anytime of the day.	Anytime of the day.
• <u>Pregnancy determination:</u>	As early as the first day of a women's missed period.	As early as the first day of a women's missed period.
• <u>Antibodies:</u>	Polyclonal goat anti-alpha hCG antibody is on the test strip, monoclonal anti-beta hCG antibody is on the conjugate pad, and polyclonal goat anti-mouse IgG antibody is on the control line.	Polyclonal goat anti-alpha hCG antibody is on the test strip, monoclonal anti-beta hCG antibody is on the conjugate pad, and polyclonal goat anti-mouse IgG antibody is on the control line.
• <u>Results:</u>	Positive = color line in test window and control window. Negative = color line in control window only.	Positive = color line in specimen zone and control zone. Negative = color line in control zone only.
• <u>Format:</u>	Lateral Flow assay.	Lateral Flow assay.
• <u>Sensitivity:</u>	Detects level of hCG as low as 25 mIU/ml.	Detects level of hCG as low as 25 mIU/ml.
• <u>Device design:</u>	Slender, pen-like shape, removable cap, absorbent tip partially enclosed, two window result view.	Test strip utilizing an immersion zone, a specimen zone and control zone.
• <u>Visual detection:</u>	A solid color line appears in control and test window in the presence of hCG. A solid color line appears in the control window only in the absence of hCG.	A solid color band appears in specimen and control zones in the presence of hCG. A solid color band appears in the control zone only in the absence of hCG.

**Differences between Affirm and SAS™ Pregnancy Strip:**

<b>Items to be compared</b>	<b>Affirm One-Step Professional pregnancy test</b>	<b>SAS™ Pregnancy Strip</b>
• <b><u>Device engineering:</u></b>	Test device which contains an exposed absorbent wick, a conjugate pad, nitrocellulose membrane containing bound antibodies, and a wicking pad in a disposable plastic container. Result windows and two “tear drop” openings exposing the absorbent wick appear on the same side of the device. Area covering wick is a small cap. Result and control windows include a moisture resistant clear barrier.	Test strip only, which contains an exposed absorbent wick, a conjugate pad, nitrocellulose membrane containing bound antibodies, and a wicking pad. Test strips are stored in a desiccated canister until ready for use.
• <b><u>Developing time:</u></b>	Minimum of 4 minutes for negative results to appear; positive results as soon as 1 - 2 minutes (see Appendix A). Maximum of 20 minutes for any result.	Read results after 5 minutes. Do not interpret results after 30 minutes.
• <b><u>Absorbent wick:</u></b>	Partially enclosed with 2 tear drop openings in the plastic housing.	Wick is bottom 1/3 of test strip.
• <b><u>Results windows:</u></b>	Covered by a clear plastic shield which acts as splash guard to protect the results.	Colored bands are displayed in the specimen and/or control zones on the strip.
• <b><u>Test window/Control window:</u></b>	Test window shape is: “+”, control window shape is: “o”.	Test zones are bands in the middle to upper quadrant of the test strip.
• <b><u>Color of holder:</u></b>	Ivory	No holder

The differences between the Affirm One-Step Professional Pregnancy Test and SAS™ Pregnancy Strip are not significant and do not effect the safety and effectiveness of the device.

**Performance characteristics:**

*Specificity:*

Affirm One-Step Professional Pregnancy Test was evaluated for specificity against LH (300 mIU/ml), FSH (1000 mIU/ml), and TSH (1000  $\mu$ IU/ml). Affirm did not cross-react with these substances at these levels, nor were samples spiked with 25 mIU/ml concentration of hCG inhibited by these substances.

*Sensitivity:*

The sensitivity of the Affirm One-Step Professional Pregnancy Test was determined using 20 negative urine samples spiked with hCG at varying levels. The results are described in the table below.

**Sensitivity of Affirm One-Step Professional Pregnancy Test:**

Concentration Spiked at:	Results: Positive	Results: Negative	A 25 mIU/ml hCG urine reference control, SAS™ #087745P, Lot #5122101, Exp. 12/97 was ran during these studies.
10 mIU/ml	5	15	
25 mIU/ml	20	0	
50 mIU/ml	20	0	
100 mIU/ml	20	0	
0 mIU/ml	0	20	

Of the 20 samples that were tested at the 10 mIU/ml concentration, 5 of them generated a positive reading after about 15 minutes from the point of saturation. The 20 samples tested at the 25 mIU/ml concentration all generated a positive reading within 4 minutes. Therefore our claim is a 25 mIU/ml sensitivity with the Affirm One-Step Professional Pregnancy Test. Even though the test is sensitive enough to read concentrations lower than 25 mIU/ml this does not occur regularly for us to claim a lower sensitivity for the test.

***Interfering Substances:***

The following potentially interfering substances were added to hCG negative and 25 mIU/ml hCG spiked urine samples. Interfering test samples were compared directly to the control result. The following results are described in the table below:

**Interference of the Affirm One-Step Professional Pregnancy Test**

<b>Substance:</b>	<b>Concentration:</b>	<b>Interference:</b>
Acetaminophen	20 mg/dl	NONE
Acetylsalicylic Acid	20 mg/dl	NONE
Ascorbic Acid	20 mg/dl	NONE
Atropine	20 mg/dl	NONE
Caffeine	20 mg/dl	NONE
Gentisic Acid	20 mg/dl	NONE
Glucose	2 g/dl	NONE
Hemoglobin	200 mg/dl	NONE

***Predicate Device Accuracy Correlation:***

One hundred and four specimens were evaluated by the urine stream method and the dip method. The women participating in the study were solicited by a flyer appearing in clinics locally, and asked to participate at one of the following locations: Athena Medical Corporation, Planned Parenthood in either Southeast Portland or Beaverton, Oregon. Women who participated in the urine stream method answered a questionnaire about the product. The women participants identified 53 true positives and 46 true negatives, with 1 false negative, generating a 99% user accuracy rate for the Affirm One-Step Professional Pregnancy Test. The laboratory comparison of the same collected samples using the SAS™ Pregnancy Strip identified 54 true positives and 46 true negatives, generating a 100% laboratory accuracy rate. There were four invalid results due to insufficient urine placed on the device.