

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

K032159

**B. Analyte:**

Human Chorionic Gonadotropin (HCG)

**C. Type of Test:**

Qualitative solid-phase sandwich-format immunochromatographic assay

**D. Applicant:**

Access Bio, Inc.

**E. Proprietary and Established Names:**

*Care Start*<sup>TM</sup> Pregnancy Test and *Care Start*<sup>TM</sup> Plus Pregnancy Test

**F. Regulatory Information:**

1. Regulation section:  
21CFR862.1155, Human Chorionic Gonadotropin (HCG) Test System
2. Classification:  
Class II
3. Product Code:  
LCX
4. Panel:  
Clinical Chemistry (75)

**G. Intended Use:**

1. Indication(s) for use:  
The *Care Start*<sup>TM</sup> Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy. The test is intended for over-the-counter sale to laypersons.
2. Special condition for use statement(s):  
Over-the-counter use only
3. Special instrument Requirements:  
None

**H. Device Description:**

The *Care Start*<sup>TM</sup> Pregnancy Test consists of a test stick with an absorbent tip at one end, a results window in the middle, and a thumb grip at the other end. The absorbent strip is placed directly in the urine stream or dipped into a urine collection cup immediately after the urine is collected. The test is read at 3-10 minutes. The results window consists of a test area and a control area. The control area must always contain a visible pink line or the test is invalid. A line in the test area indicates pregnancy.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):  
Applied Biotech Sure Step hCG One-Step Pregnancy Test (prescription)

2. Predicate K number(s):  
K953988
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Methodology	Lateral flow immunoassay	Lateral flow immunoassay
Result format	Visible pink lines	Visible pink lines
Sensitivity	20 mIU/mL	20 mIU/mL
Antibodies	Mouse anti-hCG, Goat anti-mouse	Mouse anti-hCG, Goat anti-mouse
Differences		
Item	Device	Predicate
Read time	3-10 minutes	4-10 minutes
Intended Use	Over the counter	Professional use

**J. Standard/Guidance Document Referenced (if applicable):**

Guidance for Industry and FDA Reviewers/Staff: **Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s**

**K. Test Principle:**

If HCG is present in the urine sample it will react with an anti-HCG – dye conjugate and immobilized anti-HCG to produce a colored pink line. A control line is provided further up the strip where the excess conjugate is captured by a second immobilized anti-HCG antibody. Absence of a control line indicates a failure of the device.

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:
  - a. *Precision/Reproducibility:*  
N/A
  - b. *Linearity/assay reportable range:*  
N/A
  - c. *Traceability (controls, calibrators, or method):*  
WHO Standard (4<sup>th</sup> IS 75/589) was used to calibrate this kit.
  - d. *Detection limit:*  
20 mIU/mL
  - e. *Analytical specificity:*  
Results of samples at concentrations of 0 (negative) and 20 mIU/mL (positive) were found to be unchanged by the addition of the following analytes:

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
Gentisic Acid	20 mg/dL
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic Acid	20 mg/dL
Tetracycline	20 mg/dL
Bilirubin	2 mg/dL
Glucose	2000 mg/dL
Hemoglobin	1 mg/dL
Ketones	20 mg/dL
Protein	2000 mg/dL
Triglyceride	800 mg/dL

Additionally, adjustment of the urine pH from 3 to 10 did not change the results of any of the samples.

*f. Assay cut-off:*  
N/A

2. Comparison studies:

*a. Method comparison with predicate device:*

115 samples were parallel tested in a consumer study with the *Care Start*<sup>TM</sup> Pregnancy Test (both midstream and dip methods) and the Applied Biotech Sure Step hCG One-Step Pregnancy Test. 46 samples tested positive with both kits and 69 samples tested negative with both kits.

*b. Matrix comparison:*

Both the predicate and the device are used with a urine matrix

3. Clinical studies:

*a. Clinical sensitivity:*

N/A

*b. Clinical specificity:*

N/A

*c. Other clinical supportive data (when a and b are not applicable):*

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Human Chorionic Gonadotropin is not found in healthy males or healthy non-pregnant females in concentrations that can be detected by the *Care Start*<sup>TM</sup> Pregnancy Test

**M. Conclusion:**

I recommend that the *Care Start*<sup>TM</sup> Pregnancy Test is substantially equivalent to the predicate device.