

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

A. 510(k) Number:

k053452

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative, lateral flow immunoassay, Over-the-Counter (OTC)

E. Applicant:

Bio Focus Co., Ltd.

F. Proprietary and Established Names:

Pure-Aid Pregnancy Test

G. Regulatory Information:

1. Regulation section:
21 CFR section 862.1155 Human chorionic gonadotropin test system
2. Classification:
Class II
3. Product code:
LCX
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indications for use below.
2. Indication(s) for use:
Pure-Aid Pregnancy Test is intended for the qualitative determination of human chorionic gonadotropin (hCG) in human urine. The test is for Over-the-Counter use. The test is for the early detection of pregnancy.

3. Special conditions for use statement(s):
For Over-the-Counter Use

4. Special instrument requirements:
None

I. Device Description:

The product is supplied as a single use test kit. The kit consists of the device, a rapid chromatographic immunoassay packaged in a sealed foil pouch, and the instructions for use.

J. Substantial Equivalence Information:

1. Predicate device name(s):
ACON Mid-stream Pregnancy Test

2. Predicate 510(k) number(s):
k983090

3. Comparison with predicate:

Similarities		
Item	k053452	Predicate
Analyte and test principle	Same	Qualitative detection of hCG using a chromatographic immunoassay
Sample type	Same	Urine

K. Standard/Guidance Document Referenced (if applicable):

None were referenced.

L. Test Principle:

The test utilizes a combination of mouse monoclonal antibody conjugated with a dye-binding system and a goat polyclonal antibody to qualitatively detect elevated levels of hCG in urine. The absorbent tip of the test stick is placed in the urine stream for about 5 seconds. Alternatively, the user may dip the absorbent tip into a the urine that was collected in a clean, dry container. After sample application, the urine specimen migrates via capillary action along the membrane to react with the monoclonal hCG antibody-dye conjugate to form a colored line in the test window if sufficient hCG is present in the sample. Absence of a colored line in the results window suggests a negative result. If the test has been performed properly a colored line will always appear in the control window, indicating that adequate sample volume has been absorbed and proper wicking has occurred.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

See detection limit below.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The assay was standardized using the hCG WHO 4th International Standard 75/589.

d. *Detection limit:*

Thirty-nine (39) normal, non-pregnant female urine samples were spiked with hCG (WHO 3rd IS) at concentrations of 0, 12.5, 18.75, 25, 50 and 100 mIU/mL and evaluated with three different lots of the Pure-Aid device. Samples containing 0, 12.5, and 18.75 mIU/mL were tested n=3 with each lot and the remaining levels were tested n=10 with each lot. The samples at 0, 12.5, and 18.75 mIU/mL were negative with all lots and the 25, 50, and 100 mIU/mL levels were positive with all lots. The claimed sensitivity for this device is 25 mIU/mL.

e. *Analytical specificity:*

Luteinizing hormone (500 mIU/mL, WHO 2nd IS), follicle stimulating hormone (1000 mIU/ml, WHO 1st IS) and thyroid stimulating hormone (1000 µIU/mL, WHO 3rd IS) were added to hCG negative and hCG positive samples. A normal, non-pregnant female urine pool was used to prepare the samples. The hCG positive samples were spiked with 25 mIU/mL hCG, WHO 4th IS. Each test sample was evaluated in triplicate (n=3) on three lots of devices. Each hormone spiked into hCG negative urine gave negative results in the assay. Each hormone spiked into the urine containing 25 mIU/mL hCG gave positive results.

Common prescription, over the counter, and drugs of abuse, as well as hemoglobin, protein, bilirubin and glucose were tested with three lots of the device at specified concentrations. The substances were spiked into normal, non-pregnant urine pools containing either 0 mIU/mL hCG or 25 mIU/mL hCG (WHO 4th IS). None of the substances caused interference.

The effect of varying pH on test results was examined. The pH of a normal, non-pregnant urine pool was adjusted to pH 6-9. Then, a portion of each urine pool was spiked with 25 mIU/mL hCG. The urine pools at each pH, with and without hCG were tested with the device in triplicate (n=3). The urines with

25 mIU/mL hCG were all positive while the urines without hCG were all negative.

- f. *Assay cut-off:*
See (d) Detection Limit above.

2. Comparison studies:

a. *Method comparison with predicate device:*

Urine specimens (n=120) were obtained at a clinic from women suspecting pregnancy. Specimens were randomly collected at different times of the day. Of the 120 study participants, 119 performed the testing using the mid-stream method and 2 used the dip method. The specimens were also collected in a clean container for testing by a laboratory professional using the predicate device. Additionally, each study participant underwent an ultrasound examination several weeks later for clinical confirmation of pregnancy. For the 98 positive and 22 negative specimens, there was 100% agreement between the predicate and the Pure-Aid device as well as 100% agreement between the Pure-Aid device and the results from the ultrasound.

- b. *Matrix comparison:*
Not applicable

3. Clinical studies:

- a. *Clinical Sensitivity:*
Not applicable

- b. *Clinical specificity:*
Not applicable

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

Consumer studies were performed to determine if the device could successfully be used by a lay person using only the provided written instructions. The 120 women described in section 2(a) were asked to perform the pregnancy test and the results were compared to the results obtained by a laboratory professional. The untrained users were demographically diverse, with respect to age and education. There was 100% agreement between the untrained user and the laboratory professional results.

A second consumer study was performed in order to evaluate the use of the dip method by lay users. Test samples were prepared from urine pool of normal, non-pregnant females spiked with six different concentrations of hCG (0, 12.5, 18.75, 25, 50, and 100 mIU/mL). The concentrations of each of the sample pools were confirmed using a quantitative method. Each spiked sample pool was then divided to create 10 samples at each hCG level. Sixty

(60) lay user participants were recruited to perform the test. Participants were randomly provided with a masked test sample and the test instructions. They were instructed to perform the test using the dip method and to record the results of the test. A laboratory professional was present to monitor and independently record the test results. There was 100% agreement between the lay user and professional test results.

Results from a questionnaire given to the lay user participants after completion of either study demonstrated that lay users could understand the test instructions and could successfully perform the test without assistance.

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
The expected values are based on literature.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports substantial equivalence decision.