

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

A. 510(k) Number:

K033041

B. Analyte:

Human Chorionic Gonadotropin (HCG)

C. Type of Test:

Qualitative solid-phase sandwich-format immunochromatographic assay

D. Applicant:

ACON Laboratories, Inc.

E. Proprietary and Established Names:

ACON Quik-Check II Home Pregnancy Test Strip

F. Regulatory Information:

1. Regulation section:
CFR 862.1155
2. Classification:
Class II
3. Product Code:
LCX
4. Panel:
Clinical Chemistry

G. Intended Use:

1. Indication(s) for use:
The ACON Quik-Check II Home Pregnancy Test Strip is intended for non-professional, over-the-counter use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.
2. Special condition for use statement(s):
Non-professional, over-the-counter use
3. Special instrument Requirements:
N/A

H. Device Description:

The device consists of a single test strip with one end designated for dipping, and control and test regions in the middle. At one end of the strip are arrows indicating

which end of the strip is dipped into the urine and a MAX line indicating that the strip should not be dipped below this line.

I. Substantial Equivalence Information:

1. Predicate device name(s):
ACON Pregnancy Test
2. Predicate K number(s):
K993483
3. Comparison with predicate:

Similarities		
Item	Predicate	Device
Intended Use	OTC use for the qualitative identification of HCG to aid in detection of pregnancy	Same
Matrix	Urine	Same
Endpoint	Colored lines	Same
Storage	15-30° C	Same
Read Time	3-10 minutes	Same
Antibodies	Rabbit, goat	Same
Sensitivity	25 mIU/mL	Same
Specificity	No interference when tested with LH, FSH, or TSH	Same
Accuracy	>99% at cutoff	Same
Standardization	WHO 3 rd International Standard	Same

Differences		
Item	Predicate	Device
Methodology	Membrane EIA	Proprietary membrane ligand-binding EIA

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

None referenced

K. Test Principle:

Qualitative solid-phase sandwich-format immunochromatographic assay.

The user collects a urine sample in a clean, dry container and is instructed to dip the strip into the urine for a minimum of 5 seconds, to remove the strip from the urine and place it on a non-absorbent flat surface and begin timing. The urine will migrate via capillary action toward the result and control windows. If hCG is present in the urine it reacts with an anti-HCG-colored particle conjugate to form a colored line in the test region of the strip. A colored line in the control region of the device indicates adequate sample volume and capillary action. Absence of a colored line in the control region is an indication of an invalid result. Users are instructed to read the device between 3 and 10 minutes

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):*
This device has been standardized to the WHO 3rd Int'l Standard
- d. *Detection limit:*
The ACON Quik-Check II Home Pregnancy Test Strip detects urinary hCG concentrations equal to or greater than 25 mIU/mL.

HCG was spiked into known negative urines at concentrations of 10, 25, and 100 mIU/mL. The spiked samples were randomized and blinded, and tested by 35 consumers as part of a focus group study. Results were as follows:

Concentration (mIU/mL)	Positive results	Negative results
0	0	35
10	4	31
25	35	0
100	35	0

- e. *Analytical specificity:*
Cross-reactivity was tested at 0 and 25 mIU/mL with LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000mIU/mL) with no variation from expected results. Also tested were variations in pH (5-9), specific gravity (1.003 – 1.028) and the addition of 22 common compounds, none of which caused any variation from the expected results.

- f. *Assay cut-off:*
See detection limit above

2. Comparison studies:

- a. *Method comparison with predicate device:*
A consumer field study was done which included 113 participants. Urine samples were analyzed using the new device by both consumers and lab professionals and with the predicate device by lab professionals. The study evaluated the participants' ability to understand the package insert and to accurately perform the test. When tested by lab professionals, 75 samples tested positive by both methods and 38 samples tested negative by both methods. When tested by consumers, of the 38 negative samples, 36 were reported as negative with 2 invalid results. Of the 75 positive samples, 72 were

reported as positive with one discrepant result and two invalid results.

b. Matrix comparison:

N/A

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):

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 ACON Quik-Check II Home Pregnancy Test.

M. Conclusion:

Based upon the information provided for the file, I recommend that the ACON Quik-Check II Home Pregnancy Test Strip be found substantially equivalent to the predicate device.