

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

A. 510(k) Number:

k062361

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Human Chorionic Gonadotropin (hCG)

D. Type of Test:

Qualitative

E. Applicant:

Innovacon, Inc.

F. Proprietary and Established Names:

hCG Ultra Test

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):
Innovacon hCG Ultra Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy.
2. Indication(s) for use:
Innovacon hCG Ultra Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy. It is for healthcare professionals only.
3. Special conditions for use statement(s):
For prescription and professional use only.

4. Special instrument requirements:
None.

I. Device Description:

Each Innovacon hCG Ultra test kit contains 40 sealed foil pouches. A disposable specimen dropper is also included. The test device contains a pad containing gold-conjugated mouse monoclonal anti-hCG antibody and a membrane with two stripes, each embedded with distinct goat polyclonal antibodies.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Fisher Sure-Vue Serum/Urine hCG-STAT
2. Predicate 510(k) number(s):
k965253
3. Comparison with predicate:
The proposed device is identical to the predicate in the following ways: intended use, matrices, and test principle.

The proposed device differs from the predicate device in the following ways:

| Differences | | |
|-------------|---|---|
| | Predicate device k965253 | Proposed device k062361 |
| Read time | 7 minutes for serum; 4 minutes for urine | 5 minutes for serum; 3 minutes for urine |
| Storage | Room temperature (15°-30°C) | 2°-30°C |

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

Chorionic Gonadotropin, WHO 4th International Standard 75/589
 Follicle Stimulating Hormone, WHO 1st International Standard 92/510
 Luteinizing Hormone, Pituitary, WHO 2nd International Standard 80/552
 Thyroid Stimulating Hormone, WHO 1st International Standard 90/672

L. Test Principle:

The Innovacon hCG Ultra Test device employs a combination of gold-conjugated monoclonal antibody and polyclonal solid phase antibody to selectively identify hCG in serum and urine. Users are instructed to transfer 3 drops of urine or serum to the specimen well. Mouse monoclonal antibodies (specific for the beta subunit of hCG and labeled with colloidal gold particle) found in the conjugated pad dissolve and migrate with the urine. If hCG is present in the urine, it binds to the mouse

monoclonal antibody. This complex is captured by the goat anti-hCG alpha subunit polyclonal antibody embedded at the test line. When a sufficient number of complexes have been captured at the test line, a pink to red-colored line becomes visible.

Any mouse monoclonal antibody not bound to hCG will continue past the test line and will be captured by goat anti-mouse polyclonal antibodies found at the control region of the device. 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 at 3 minutes (for urine) or 5 minutes (for serum).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
See “Detection limit” below.
 - b. *Linearity/assay reportable range:*
Male urine pools were spiked with hCG to concentrations ranging from 500 – 1,000,000 mIU/mL to determine if there was a decrease in signal with increasing analyte concentration. Urine results were read at 3 and 10 minutes; serum results were read at 5 and 10 minutes. All specimens obtained the expected result.
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The Innovacon hCG Ultra Test device is standardized against the World Health Organization (W.H.O.) 4th International Standard for chorionic gonadotropin 75/589.
 - d. *Detection limit:*
To assess the reproducibility and detection limit of the assay, the sponsor spiked hCG into serum and urine samples from known non-pregnant participants. Trained technicians at four Physician’s Office and Laboratory (POL) sites performed the testing over three days with devices from three different lots. The results are as follows:

Serum:

| | | hCG concentration (mIU/mL) | | | | | | | |
|-------------|---------|----------------------------|----|----|----|----|----|-----|---------|
| | | 0 | 5 | 8 | 10 | 12 | 20 | 100 | Invalid |
| Test result | - | 72 | 40 | 21 | 0 | 0 | 0 | 0 | 0 |
| | + | 0 | 32 | 51 | 72 | 72 | 72 | 72 | 0 |
| | Invalid | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 72 |

Urine:

| | | hCG concentration (mIU/mL) | | | | | | | |
|-------------|---------|----------------------------|----|----|----|----|----|-----|---------|
| | | 0 | 10 | 16 | 20 | 24 | 40 | 100 | Invalid |
| Test result | - | 72 | 45 | 15 | 0 | 0 | 0 | 0 | 0 |
| | + | 0 | 27 | 57 | 72 | 72 | 72 | 72 | 0 |
| | Invalid | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 72 |

In addition to establishing the cut-off value for the device, analysis of the study results showed there is no significant difference in the results obtained at the four different sites.

e. Analytical specificity:

The device was tested and found to be non-reactive to negative serum and urine specimens spiked with Luteinizing Hormone (hLH at 300mIU/mL), Follicle Stimulating Hormone (hFSH at 1000 mIU/mL) and Thyroid Stimulating Hormone (hTSH at 1000 mIU/mL). Similarly, none of the hCG positive urine and serum samples spiked with LH, FSH and TSH at the concentrations above yielded a negative result at read times.

Commonly found substances (prescription, OTC, chemical and biological analytes) were spiked into a male serum pool (containing 0 and 10 mIU/mL hCG) and a male urine pool (containing 0 and 20 mIU/mL hCG). Samples were tested in triplicate. Urine samples were read as positive or negative at 3 and 10 minutes. Serum samples were read at 5 and 10 minutes. The presence of these substances did not affect the test results.

In addition, the sponsor investigated the effect of urinary pH (ranging from pH 4.0 - 9.0) and urine specific gravity (ranging from 1.003 – 1.036) on the performance of this device. There was no variation from the expected results.

f. Assay cut-off:

The sponsor claims a cutoff of 10 mIU/mL hCG for serum and 20 mIU/mL hCG for urine.

2. Comparison studies:

a. Method comparison with predicate device:

The proposed device was compared to the predicate device and the results are shown in the chart below. The clinical urine and serum samples were collected from New York Biologics Inc. The assays were in agreement on 100 out of the 100 samples for both specimen types. There was no information regarding clinical follow-up of the donors. Summary results were as follows:

Serum:

| Results | Anticipated result | Proposed device | Predicate device k965253 |
|----------|--------------------|-----------------|--------------------------|
| Positive | 50 | 50 | 50 |
| Negative | 50 | 50 | 50 |
| Invalid | 0 | 0 | 0 |
| Totals | 100 | 100 | 100 |

Urine:

| Results | Anticipated result | Proposed device | Predicate device k965253 |
|----------|--------------------|-----------------|--------------------------|
| Positive | 50 | 50 | 50 |
| Negative | 50 | 50 | 50 |
| Invalid | 0 | 0 | 0 |
| Totals | 100 | 100 | 100 |

b. *Matrix comparison:*
Not applicable for this device.

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):

See "Detection limit" above.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Negative results are expected in healthy non-pregnant women and healthy men.

Healthy pregnant women have hCG present in their urine and serum specimens.

The amount of hCG will vary greatly with gestational age and between individuals.

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 a substantial equivalence decision.