

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

A. 510(k) Number:

K032987

B. Analyte:

Human Chorionic Gonadotropin (HCG)

C. Type of Test:

Immunoassay for the qualitative measurement of HCG in serum or urine

D. Applicant:

Unotech Diagnostics, Inc.

E. Proprietary and Established Names:

AccuTest™ hCG-Combo

AccuStrip™ hCG-Combo

F. Regulatory Information:

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

G. Intended Use:

1. Indication(s) for use:
The intended use of the Unotech Accutest and Accustrip hCG-Combo is for the qualitative determination of human chorionic gonadotropin (hCG) in human urine or serum for the early detection of pregnancy.
2. Special condition for use statement(s):
Prescription Use Only
3. Special instrument Requirements:
N/A

H. Device Description:

The AccuTest™ hCG-Combo device consists of a test strip enclosed in a plastic cassette, while the AccuStrip™ hCG-Combo device consists of a test strip only. The AccuTest has a sample well at one end, and both devices have a control region and a test region.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Quidel QuickVue hCG Combo Test
2. Predicate K number(s):

K 932042

3. Comparison with predicate:

Similarities		
Item	Devices	Predicate
Intended Use	Same	Simple, rapid immunoassay for the detection of hCG in serum or urine for the early detection of pregnancy
Matrix	Same	Serum, Urine
Methodology	Same	Immunochromatographic
Specificity	No cross-reactivity with: LH @ 300 mIU/mL FSH @ 1000 mIU/mL TSH @ 1000 mIU/mL	No cross-reactivity with: LH @ 500 mIU/mL FSH @ 1000 mIU/mL TSH @ 1000 mIU/mL
Accuracy	Same	>99% agreement
Antibodies	Same	Goat, mouse
Standardization	WHO 3 rd IS 75/537	WHO 4 th IS 75/589
Physical Characteristics	Test strip only (Accu-Strip) ----- Test strip housed in a plastic cartridge (Accu-Test)	Test strip housed in a plastic cartridge with a result window and a sample well
Test Read Times	Same	Urine: 3 minutes Serum: 5 minutes
Sensitivity/Detection Limit	Same	25 mIU/mL
Endpoint/Interpretation	Same	Test and control lines appear for a positive result. Control line only appears for a negative result. Absence of a control line indicates an invalid test.
Differences		
Item	Device	Predicate
Sample Volume/Application	Test strip is dipped into urine or serum (Accu-Strip) ----- Approximately 135 µL or 3 drops are added to the sample well with the supplied dropper (Accu-Test)	Approximately 125 µL or 3 drops are added to the sample well with the supplied dropper
Device Storage	2-30° C	15-30° C

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

None referenced

K. Test Principle:

Accu-Test: The test principle is immunochromatographic: using the supplied transfer pipette, 3 drops of urine or serum are applied to the strip through the sample well at one end. The urine mobilizes the mouse anti- β hCG monoclonal antibody-colloidal gold conjugate. HCG, if present in the sample, binds to the antibody-colloidal gold conjugate. The sample, antibody-gold conjugate and the hCG-antibody-gold complex migrate through the immobilized goat anti- α hCG capture antibody region and then to an immobilized goat anti-mouse IgG region. If hCG is present at 25 mIU/mL or greater, two colored bands will appear to indicate a positive result. If hCG is absent, only one band (in the control region) will appear to indicate a negative result.

AccuStrip: The test principle is immunochromatographic: in the procedure, the strip is dipped into the urine or serum. The urine or serum mobilizes the mouse anti- β hCG monoclonal antibody-colloidal gold conjugate. HCG, if present in the sample, binds to the antibody-colloidal gold conjugate. The sample, antibody-gold conjugate and the hCG-antibody-gold complex migrate through the immobilized goat anti- α hCG capture antibody region and then to an immobilized goat anti-mouse IgG region. If hCG is present at 25 mIU/mL or greater, two colored bands will appear to indicate a positive result. If hCG is absent, only one band (in the control region) will appear to indicate a negative result.

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 Third International Standard, 75/537

d. Detection limit:

25 mIU/mL

e. Analytical specificity:

The following compounds were added to urine and serum specimens at hCG concentrations of 0 and 25 mIU/mL. At the concentrations below there was no deviation from the expected results.

Substances added	in Urine	in Serum
Acetaminophen	20 mg/dL	20 mg/dL
Acetylsalicylic acid	20 mg/dL	20 mg/dL
Ampicillin	20 mg/dL	20 mg/dL
Ascorbic acid	20 mg/dL	20 mg/dL
Atropine	20 mg/dL	20 mg/dL
Bilirubin	2 mg/dL	2 mg/dL
Caffeine	20 mg/dL	20 mg/dL
Estradiol	25 ng/mL	25 ng/mL
Estriol	25 ng/mL	25 ng/mL

Ethanol	200 mg/dL	200 mg/dL
Gentisic acid	20 mg/dL	20 mg/dL
Glucose	2,000 mg/dL	2,000 mg/dL
Hemoglobin	25 mg/dL	250 mg/dL
Human serum albumin	2,000 mg/dL	2,000 mg/dL
Phenothiazine	2 mg/dL	2 mg/dL
Progesterone	40 ng/dL	40 ng/dL
Tetracycline	20 mg/dL	20 mg/dL
Triglycerides	—	1,000 mg/dL
Urine pH	5-9	

a. *Assay cut-off:*

See detection limit above

2. Comparison studies:

a. *Method comparison with predicate device:*

A total of 181 specimens (94 urine specimens and 87 serum specimens) from patients seeking confirmation of pregnancy were tested simultaneously with AccuTest™ hCG-Combo, AccuStrip™ hCG-Combo and the predicate. Test results show that both Unotech's AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo have 100% agreement with the predicate. Results were as follows.

	Unotech AccuTest™ hCG-Combo	Unotech AccuStrip™ hCG-Combo	Quidel QuickVue hCG Combo
Positive (Urine)	48	48	48
Negative (Urine)	46	46	46
Positive (Serum)	42	42	42
Negative (Serum)	45	45	45

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:

See detection limit above

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 Unotech AccuTest™ hCG-Combo or AccuStrip™ hCG-Combo

M. Conclusion:

Based upon the information provided for the file, I recommend that the Unotech AccuTest™ hCG-Combo and AccuStrip™ hCG-Combo are substantially equivalent to the predicate device.