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

A. 510(k) Number:

k061257

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin

D. Type of Test:

Semi-quantitative

E. Applicant:

Ameritek USA, Inc.

F. Proprietary and Established Names:

dBest hCG Panel Test Kit

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155

2. Classification:

   Class II

3. Product code:

   LCX, JHI

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   The dBest hCG Panel Test Kit is a simple one step immunochromatographic assay for rapid, semi-quantitative detection of hCG in urine with cutoff of 25, 100, 500, 2,000 and 10,000 mIU/mL. The dBest hCG Panel Test Kits are for professional, physician's offices laboratory and OTC use, for the early detection of pregnancy.

3. Special conditions for use statement(s):

   The device is for both over-the-counter and professional use.

4. Special instrument requirements:

   None required

I. Device Description:

The dBest hCG Panel Test Kit contains the following items: dBest test disk sealed in foil pouch, urine specimen collection container, and instructions for use. The test disk contains 5 embedded test strips (zones), each with a different cutoff. The 25, 100, and 500 mIU/mL zones contain mouse monoclonal antibodies and goat anti-mouse antibody (control line). The 2,000 and 10,000 mIU/mL zones contain mouse monoclonal antibodies and goat anti-rabbit antibody (control line).

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Biocheck HCG Enzyme Immunoassay Test Kit
   dBest hCG Pregnancy Test Kits, dBest hCG 2 IU/mL

2. Predicate 510(k) number(s):
   k991741
   k953606, k001215

3. Comparison with predicate:

Similarities		
Item	Device	Predicates
Indications for Use	Early detection of pregnancy	Same
Intended End Use Population	Professional and OTC use	Professional (k991741 & k001215); OTC (k953606)
Principle	Sandwich and competitive assay	Sandwich (k991741 & k953606); competitive (k001215)

Differences		
Item	Device	Predicate
Type of Test	Semi-quantitative	Qualitative (k953606 & k001215); quantitative (k991741)
Specimen Type	Urine	Serum (k991741)
Test Design/Format	Multiple test strips embedded in test disk	Single test strip(s) (k953606 & k001215)

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

None were referenced.

L. Test Principle:

The test principle is based on the sandwich technique (for three of the strips) and competitive binding (for two of the strips).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

One hundred twenty hCG free urine specimens collected in-house were divided into six groups of twenty each. Five groups of urine were spiked with hCG to 25, 100, 500, 2,000, and 10,000 mIU/mL, and one group remained unspiked. The specimens were then blind labeled and tested with the dBest hCG Panel Test Kit at three physician's office laboratories and a reference

laboratory. The results obtained from the three POL sites agreed 99% with the expected results. The results obtained from the reference laboratory agreed 100% with the expected results. The overall agreement was 99.5%.

Reproducibility was evaluated at three different sites. Urine samples containing hCG at 0, 25, 100, 500, 2,000 and 10,000 mIU/mL were tested twice a day in two different assays, each day for twenty days. This evaluated between day, between assay, and within-day. The results of the three sites yielded 100% agreement.

b. *Linearity/assay reportable range:*

Not applicable

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

The device was standardized to the World Health Organization (WHO) 3rd I.S.

d. *Detection limit:*

The dBest hCG Panel Test Kit will detect hCG in urine at concentrations of 25, 100, 500, 2,000, and 10,000 mIU/mL. For each detection concentration, three samples were prepared by spiking hCG to concentrations, at the cutoff, +25% above the cutoff and -25% below the cutoff and tested using the dBest hCH Panel Test Kit. The results are as follows:

-25 %	Results	Cutoff	Results	+25%	Results
18.75 mIU/mL	20/20 negative	25 mIU/mL	20/20 positive	31.25 mIU/mL	20/20 positive
75 mIU/mL	20/20 negative	100 mIU/mL	20./20 positive	125 mIU/mL	20./20 positive
375 mIU/mL	20/20 negative	500 mIU/mL	19/20 positsive	625 mIU/mL	20/20 positive
1500 mIU/mL	20/20 negative	2000 mIU/mL	19/20 positive	2500 mIU/mL	20/20 positive
7500 mIU/mL	20/20 negative	10000 mIU/mL	19/20 positive	12500 mIU/mL	20/20 positive

e. *Analytical specificity:*

Cross reactivity studies were performed on urine samples spiked with the following structurally and physiologically related hormones referenced to WHO: 500 mIU/mL luteinizing hormone, 1000 mIU/mL follicle stimulating hormone, and 1000 μIU/mL thyroid stimulating hormone. All zones of the

pregnancy test yielded the expected (negative) results.

Potentially interfering substances such as prescription and OTC drugs, protein and glucose were added to normal urine specimens devoid of hCG as well as specimens containing 25, 100, 500, 2,000, and 10,000 mIU/mL hCG. All samples without hCG consistently gave negative results. All samples with the various hCG concentrations consistently gave positive results.

f. Assay cut-off:

See Detection limit above.

2. Comparison studies:

a. Method comparison with predicate device:

An initial method comparison study using sixty (60) negative urine samples spiked with hCG at three different concentrations (0, 25, and 2000 mIU/mL) was conducted. The samples were blind labeled and tested with the subject device and two commercially available dBest hCG products. Testing was performed at three physician's office laboratories and a reference laboratory. The results showed greater than 99% agreement.

An additional study was performed to demonstrate method comparison across all dBest cutoffs. Five groups of urines were spiked with hCG to concentrations equal to the cutoff, 25% above the cutoff, and 25% below the cutoff. These were tested on the dBest hCG Panel Test Kit and commercially available pregnancy tests and challenged the precision of the device. The dBest hCG Panel Test Kit was in complete agreement with the commercially available pregnancy tests at -25% of the cutoff and at +25% of the cutoff for all five cutoff levels, and at the cutoff level of 25 and 100 mIU/mL. There was 98% agreement between the tests at the 500, 2,000, and 10,000 mIU/mL cutoff level.

To assess method comparison with natural, unspiked patient samples, a study was conducted using forty (40) non-pregnant and pregnant urine and serum samples. The patient's urine sample was assayed on the dBest test and their serum sample was run on an hCG ELISA. The results were as follows:

Patients (n)	**dBest test zone mIU/mL**	**ELISA mIU/mL**
20	< 25	Negative < 5
4	25	26 – 48
6	500	98 – 620
10	2,000 – 10,000	1,980 – 30,020

See other clinical supportive data below for additional comparisons.

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):

Clinical Study

A clinical study was conducted to evaluate the accuracy of the dBest hCG Panel Test Kit. The primary objectives were to observe hCG concentrations to determine the accuracy of the test by comparing urine and serum results from the same patient, assayed on the dBest hCG Panel Test Kit and an ELISA test, respectively. Samples from one hundred and twenty (120) women aged 18 years or older, forty (40) at three sites, were used. Nurses performed the urine tests and lab technicians performed the serum tests.

The results of the comparison of hCG concentrations are presented below:

Patients (n)	**dBest test zone mIU/mL**	**ELISA mIU/mL**
20	25	28 – 78
24	100	78 – 250
25	500	386 – 7,240
18	2,000	1,684 – 7,829
33	10,000	8,640 – 51,980

Most of the hCG concentrations fell in the appropriate dBest test zone. One patient had an hCG ELISA result of 7,240 mIU/mL, but the dBest HCG Panel Test Kit showed 500 mIU/mL. One other hCG ELISA result at 9829 was almost five times the cutoff of 2,000. However, the dBest test correctly produced a positive result for the 2000 mIU/mL cutoff level.

Consumer Studies

A consumer study of persons with various age, racial, educational, and professional backgrounds was conducted. hCG free urine specimens were divided into six groups of twenty each. Five groups of urines were spiked with hCG to 25, 100, 500, 2,000 and 10,000 mIU/mL, and one group remained unspiked. All the specimens (60 each for the consumers and technicians of the reference laboratory) were blind labeled and tested. At the 0, 100, and 500 mIU/mL levels, the results all agreed between the consumers and reference laboratory. At each of the 25, 2,000, and 10,000 mIU/mL levels, two results were read as negative by consumers, resulting in an overall agreement of 54/60 or 90%.

To supplement the study above, hCG free urine specimens collected in-house were divided into six groups of forty each. Five groups of samples were spiked with hCG to 25, 100, 500, 2,000, and 10,000 mIU/mL and one remained unspiked. Those (240) specimens were blind labeled and tested, with half (120) done by consumers and the other half (120) done by laboratory personnel. After the consumers completed their test, they were asked to complete a survey to assess their understanding of the revised package insert instructions. The results were as follows:

At 0, 100, and 500 mIU/mL, there was 100% agreement between the consumer and laboratory results. At 25, 2,000, and 10,000 mIU/mL, three consumers read a positive sample as negative. Therefore, the overall agreement between the consumers and professionals was 117/120 or 98.75%.

Out of 120 consumers, 64 thought the instructions were good, 16 thought they were very good, and 37 thought they were average. This demonstrated an acceptable readability of the new package insert.

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.