

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

A. 510(k) Number:

k062096

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative

E. Applicant:

KoreaMedico Co. LTD

F. Proprietary and Established Names:

KoreaMedico Chextic

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1155

2. Classification:

Class II

3. Product code:

LCX

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for use.

2. Indication(s) for use:

The Chextic is a rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

3. Special conditions for use statement(s):

The device is intended for over-the-counter use.

4. Special instrument requirements:

None required

I. Device Description:

The Chextic consists of a chromatographic test strip enclosed in plastic housing and a package insert. The test device contains monoclonal anti-hCG and rabbit anti-mouse IgG antibodies.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON hCG Urine/Serum Pregnancy Test Strip

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

k980736

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use / Indications for Use	Qualitative detection of hCG for the early detection of pregnancy	Same
Methodology	Membrane particle assay	Same

Similarities		
Item	Device	Predicate
Standardization	WHO 3 rd I.S.	Same

Differences		
Item	Device	Predicate
Specimen	Urine	Urine and serum

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

None referenced

L. Test Principle:

The test is a chromatographic immunoassay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

To determine the amount of variation of the KoreaMedico Chextic within and between assay days, assays were performed with urine hCG standard specimens (0, 15, 25, 100, and 100,000 mIU/mL). For inter-assay precision (repeatability), each standard was tested with three different batches on three separate days. All standards at 25 mIU/mL and above yielded positive results. All standards at 15 mIU/mL were negative with two lots and yielded very faint lines on the other lot. All 0 mIU/mL standards yielded negative results. For intra-assay precision (reproducibility), each standard (0, 15, 25, 100, 1000, and 100,000 mIU/mL) was tested with three different batches. All standards at 25 mIU/mL and above yielded positive results. The 15 mIU/mL standard yielded negative results on two lots and very faint lines on the other lot. All 0 mIU/mL standards yielded negative results. For the negative comparisons, hLH, hFSH, and hTSH were also used and all yielded negative results.

b. Linearity/assay reportable range:

Not applicable

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

The test is calibrated against the World Health Organization 3rd International Standard.

d. Detection limit:

Performance of the test strip at various hCG concentrations was determined by spiking 20 clinical samples from normal, non-pregnant females with five different concentrations of hCG (0, 15, 20, 50, and 100 mIU/mL). All samples tested with concentrations of hCG as low as 15 mIU/mL produced positive results.

In a second study, standard controls (0, 25, 100, 1000, and 100,000 mIU/mL) were tested in 50 replicates. All specimens at 0 mIU/mL were negative, and all specimens at 25 mIU/mL and above were positive.

In a third study, urine specimens from normal, non-pregnant females were spiked with intact hCG standard at 0, 10, 15, 25, 50, 100, 1000, and 100,000 mIU/mL and confirmed by RIA. All hCG standards were randomized and coded. Each coded standard was run in a random order for a total of 100 for each level. All specimens at 0 mIU/mL were negative, and all specimens at 25 mIU/mL and above were positive. Sixty-three percent (63%) of the results at 10 mIU/mL were negative and 37% were positive. Forty-six percent (46%) of the results at 15 mIU/mL were negative and 54% were positive. The minimum concentration of hCG standard giving 100% positive results by visual inspection was found to be ≥ 25 mIU/mL.

e. Analytical specificity:

Specificity was determined by first spiking urine specimens from normal, non-pregnant females with hCG to 0, 25, 100, and 1000 mIU/mL. These hCG solutions were then spiked with 300 mIU/mL luteinizing hormone (LH), 1000 mIU/mL follicle stimulating hormone (FSH), and 1000 mIU/mL thyroid stimulating hormone (TSH) and tested in 20 replicates. Negative results were obtained for all specimens containing 0 mIU/mL hCG. Positive results were obtained for all specimens containing 25 mIU/mL hCG and above. Therefore, no cross-reactivity was observed with structurally related glycoprotein hormones.

To test for potentially interfering substances, various prescription and OTC drugs and urinary analytes were added to urine specimens containing 0, 25, 100, and 1000 mIU/mL of hCG. Twenty (20) replicates per hCG level were tested. Negative results were obtained for all specimens containing 0 mIU/mL hCG. Positive results were obtained for all specimens containing 25 mIU/mL hCG and above. No interference was observed with the substances at the concentrations tested.

Urinary pH was also assessed for potential interference. The pH of negative urine samples was adjusted within the range of 5 to 9 in 1 pH unit increments. Each pH-adjusted urine was split into aliquots: hCG was added to one aliquot to obtain a 25 mIU/mL sample, and the other aliquot remained unspiked. Each pH-adjusted urine was tested in duplicate and read three and ten minutes after sample application. The pH (5 to 9) of the samples did not interfere with the performance of the strips. Correct positive and negative results were obtained at each time point.

f. Assay cut-off:

See Detection limit above for performance of the test strip at various hCG concentrations.

2. Comparison studies:

a. Method comparison with predicate device:

A multi-center evaluation was conducted in which the results obtained on the KoreaMedico Chextic were compared to those obtained on the Acon hCG Urine/Serum Pregnancy Test. One hundred (100) urine specimens obtained from an Ob/Gyn Department were used. The results of the study showed that both tests identified the same 17 negative and 83 positive results, demonstrating 100% agreement.

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):

A consumer study was conducted to check the ease of use of the device and the readability of the package insert. One hundred (100) females ranging from 19 to 63 years old and with various backgrounds participated in the study. The participants were divided into two groups of 50 (half for the urine stream method and half for the dip procedure) and asked to perform the test and

interpret the test result using the package insert only and to complete a consumer survey. In order to assess if the participant interpreted her result properly, the study conductor re-read the participant's result and independently recorded it on a separate sheet.

Out of 100 participants, two clearly knew they were pregnant and their results were positive. Two participants suspected pregnancy, however their results were negative. The other 96 participants knew they were not pregnant, and all their results were negative. The consumer survey results showed that $\geq 85\%$ strongly agreed that the instructions were clear and the results were easy to interpret.

Because of the potential bias in result interpretation given that the majority knew their pregnancy status, a second consumer study was conducted using 105 participants. Participants were from various backgrounds and ranged in age from 21 to 54. Fifteen (15) participants used their own urine and ninety (90) participants used standard hCG solutions. The hCG solutions were normal urine from non-pregnant females spiked to nine different concentrations of hCG (10, 20, 25, 30, 50, 90, 100, 1000, and 300,000 mIU/mL). As in the first study, the consumers performed testing using the package insert only and completed a consumer survey. The study conductor re-read the participants' results and independently recorded their interpretation on a separate sheet.

The study results were as follows: With the natural urine samples, both the consumers and professional recorded 15 negative results. With the hCG solutions at 10 mIU/mL, the consumers recorded 10 negative results and the professional recorded 9 negative results. For all other hCG solutions, the consumers recorded 80 positives and the professional recorded 81 positives. The consumer survey results showed that almost 90% strongly agreed that the instructions were clear and the results were easy to interpret. Ninety-one percent (91%) strongly agreed that the device was easy to use.

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 a substantial equivalence decision.