510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K230741

B Applicant

Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.

C Proprietary and Established Names

Macro & Micro-Test HCG Pregnancy Test Midstream

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 21CFR862.1155 - Human Chorionic Gonadotropin (HCG) Test System	CH- Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device.

B Measurand:

Human Chorionic Gonadotropin (hCG).

C Type of Test:

Qualitative chromatographic immunoassay.

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
Macro & Micro-Test HCG Pregnancy Test Midstream is intended for over-the-counter use for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.

C Special Conditions for Use Statement(s):
OTC - Over The Counter

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

Macro & Micro-Test HCG Pregnancy Test Midstream is a qualitative lateral flow immunoassay for the detection of human chorionic gonadotropin (hCG). The midstream kits consist of one test device and a package insert. The result is displayed within the "result window" by two distinct colored lines, one control line and one test line.

B Principle of Operation:

The tests use a double antibody sandwich immunochromatography method to detect hCG in human urine. Goat anti-mouse polyclonal antibody is coated at the quality control line on the nitrocellulose membrane, and hCG monoclonal antibody is coated at the test line on the nitrocellulose membrane. hCG monoclonal antibody labeled with red tracers is coated on the glass cellulose membrane. After application of the urine specimen, the sample flows upward under the action of chromatography and hCG in the sample binds to the anti-hCG and is captured by the hCG monoclonal antibody at the test line, thus a red band appears at the test line. If hCG is not present or the concentration is too low, no red band appears at the test line. Regardless of the hCG concentration in the samples, a red band will form at the quality control line where goat anti-mouse polyclonal antibody will bind to hCG monoclonal antibody. The test result is shown in the result window and is read visually 5 to 10 minutes after urine application. Two distinct colored lines, one in the test zone and another in the control zone indicate a positive test result (pregnant). Absence of a colored line in the test zone and only a colored line in the control zone indicates a negative test result (not pregnant). Absence of a colored line in the control zone, even in the presence of a colored line in the test zone, indicates an invalid test result.

V Substantial Equivalence Information:

A Predicate Device Name(s):
ACCU NEWS One Step hCG Pregnancy Test Midstream

B Predicate 510(k) Number(s):
K150063

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230741	K150063
Device Trade Name	Macro & Micro-Test HCG Pregnancy Test Midstream	ACCU NEWS One Step hCG Pregnancy Test Midstream
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of human chorionic gonadotropin (hCG)to aid early detection of pregnancy.	Same
Sample Matrix	Urine	Same
Test Principle	chromatographic immunoassay	Same
hCG Sensitivity	25 mIU/mL	Same
Specificity	Beta and Alpha chain of hCG	Same
General Device Characteristic Differences		
Time to Result	5 - 10 min	5 min
Traceability	World Health Organization (WHO) 6th International Standard	WHO 3rd International Standard

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Urine samples from non-pregnant females (negative) were spiked with 0 mIU/mL, 12.5 mIU/mL, 18.75 mIU/mL, 25 mIU/mL, 50 mIU/mL and 100 mIU/mL of hCG. Three (3) lots of Macro & Micro-Test HCG Pregnancy Test Midstream were used to test each hCG concentration

in replicates of 10 per day, at 3 sites. A total of 150 replicates were tested for at each hCG concentration. Testing was repeated for 5 non-consecutive days. The device has 100% positive detection at the claimed sensitivity of 25 mIU/mL and above. There were no significant differences in performance between lots, between operators, between time of day and between days. Summary of results are presented in the following tables.

Macro & Micro-Test HCG Pregnancy Test Midstream				
hCG Concentration (mIU/mL)	**Positive**	**Negative**	**Samples (n)**	**% Positive**
0	0	150	150	0
12.5	0	150	150	0
18.75	80	70	150	53
25	150	0	150	100
50	150	0	150	100
100	150	0	150	100

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

Cross-reactivity:

The candidate device was tested for potential cross-reactivity from follicle-stimulating hormone (FSH), luteinizing hormone (LH), and thyroid-stimulating hormone (TSH). Each potential cross-reactant was spiked into a negative pooled human urine sample (control) and a positive pooled human urine sample containing 25mIU/mL hCG (test). Test and control samples were tested in replicates of 5 with 3 lots of the candidate device (Macro & Micro-Test HCG Pregnancy Test Midstream). The results demonstrated no cross-reactivity from potential cross-reactants up to 500 mIU/mL LH, 1000 mIU/mL FSH, and 1000 mIU/mL TSH in either negative or positive urine samples.

Interference from exogenous and endogenous substances:

Urine samples from non-pregnant women were collected (negative samples) and half were spiked with hCG to final concentration of 25 mIU/mL (positive samples). All samples were spiked with final concentrations of potential interferents listed in the below table. For each condition 15 replicates were tested on 3 device lots by a single operator. The results demonstrated no interference from substances at the concentrations shown in the table below.

Interfering Substances	**Final Concentration (mg/dL)**
Acetaminophen	20
Acetoacetic acid	2000

Acetone	20
Albumin	2000
Ampicillin	20
Aspirin	20
Atropine	20
Bilirubin	40
β-hydroxybutyrate	2000
Caffeine	20
Cannabinol	10
Estriol-17-β	1.4 mg/dl
Ethanol	1.00%
(1R,2S)-(-)-Ephedrine	20
(1S,2R)-(+)-Ephedrine	20
Gentisic Acid	20
Glucose	2000
Hemoglobin	500
Ibuprofen	40
Methanol	10%
Methadone	20
Morphine	10
Nicotine	20
Phenylpropanolamine	20
Phenothiazine	20
Pregnanediol	1.5
Salicylic acid	20
Tetracycline	20
Thiophene	20
Uric acid	20
Vitamin C	20

Effect of hCG Beta Core Fragment:

Urine samples from non-pregnant females (negative) were used to prepare samples at 0 mIU/mL (negative) and 25 mIU/mL (positive) hCG. The positive and negative samples were then spiked with the hCG β-core fragment concentrations of 500,000 pmol/L and 1,000,000 pmol/L. The results demonstrated that the candidate device is not affected by concentrations of hCG β-core fragment up to 1,000,000 pmol/L.

Effect of urine pH:

To evaluate potential interference from changes in urine pH, urine samples containing 0 mIU/mL and 25 mIU/mL of hCG were adjusted to pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0. The results demonstrated that changes in pH ranging from 4.0 to 9.0 do not interfere with either positive or negative results from the device.

Effect of urine specific gravity:

To evaluate potential interference from changes in specific gravity, urine samples containing 0 mIU/mL and 25 mIU/mL of hCG were adjusted to specific gravities of 1.00, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The results demonstrated that changes in specific gravity ranging from 1.000 to 1.035 do not interfere with either positive or negative results from the device.

High dose hook effect study:

Urine samples from non-pregnant women were used to prepare samples with hCG concentrations of 500 mIU/mL, 1000 mIU/mL, 10,000 mIU/mL, 100,000 mIU/mL, 500,000 mIU/mL and 1,000,000 mIU/mL. Each of the samples was tested using 3 lots of the device. No hook effect was observed at concentrations up to 1,000,000 mIU/mL hCG.

4. Assay Reportable Range:

   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The Macro & Micro-Test HCG Pregnancy Test Midstream device is calibrated against reference material traceable to the WHO International Standard (IS) 6th edition (NIBSC code 18/244).

6. Detection Limit:

   The detection limit was determined in the precision study (see section VII.A.1. above).

7. Assay Cut-Off:

   The device's cut-off is 25 mIU/mL. See Precision/Reproducibility (Section VII.A.1) section above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Urine samples were collected from a total of 250 women whose ages ranged from 18-55 years from 3 clinical sites, including subjects suspected of being pregnant (less than 5 weeks). The sampling times were randomly distributed throughout the day. Testing was carried out by three

different professionals at each of the three clinical sites. The data show 100% agreement with the predicate device.

		ACCU NEWS One Step hCG Pregnancy Test Midstream		
		Positive	Negative	Total
Macro & Micro-Test HCG Pregnancy Midstream	Positive	127	0	127
	Negative	0	123	123
	Total	127	123	250

2. Matrix Comparison:

Not applicable. This device is intended for urine samples only.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

A lay user study was performed with a total of 250 women whose ages ranged from 18-55 years from 3 clinical sites, including subjects whom were suspected of being pregnant (less than 5 weeks) with diverse educational and professional backgrounds. Each subject performed the testing following the package insert instructions without any assistance. Their results were compared to the results obtained from trained technicians testing the same urine sample. The results are summarized below.

Macro & Micro-Test HCG Pregnancy Test Midstream		Lay User		
		Positive	Negative	Total
Professional	Positive	127	0	127
	Negative	0	123	123
	Total	127	123	250

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.