



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

I Background Information:

A 510(k) Number

K240242

B Applicant

Anhui DEEPBLUE Medical Technology Co. LTD.

C Proprietary and Established Names

HCG Home Use Pregnancy Test Strip (Colloidal Gold), HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 862.1155 - Human Chorionic Gonadotropin	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:

The HCG Home Use Pregnancy Test Strip (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test strip is designed for over-the-counter use.

Important note regarding positive results: this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.

This device is intended for home use only.

The HCG Home Use Pregnancy Test Cassette (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test cassette is designed for over-the-counter use.

Important note regarding positive results: this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.

This device is intended for home use only.

The HCG Home Use Pregnancy Test Midstream (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test midstream is designed for the over-the-counter use.

Important note regarding positive results: this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.

This device is intended for home use only.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

The device is intended for home-use only and not intended for clinical-care settings.

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

The test comes in three test formats (strip, cassette, and midstream) named HCG Home Use Pregnancy Test Strip (Colloidal Gold), HCG Home Use Pregnancy Test Cassette (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold), respectively. The test strip format is packaged as a single test strip sealed in a desiccated aluminum pouch with instructions for use. The midstream format is a test strip assembled in a plastic housing with an absorbent tip and is packaged as a single test sealed in a desiccated aluminum pouch with instructions for use. The cassette format is the test strip assembled in a plastic cassette and is packaged as a single test with a dropper, a collection container, and instructions for use.

B Principle of Operation:

HCG Home Use Pregnancy Test Strip (Colloidal Gold), HCG Home Use Pregnancy Test Cassette (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) are qualitative, lateral flow sandwich immunochromatographic assays for the in vitro detection of human chorionic gonadotropin (hCG) in urine. Each test reagent strip consists of an anti-rat- α -hCG monoclonal antibody coated test line on the nitrocellulose membrane and a dried glass fiber membrane pad containing an anti-rat- β -hCG monoclonal antibody labeled with gold nanoparticle conjugate. The control antibodies are goat anti-mouse polyclonal antibody coated at the quality control region on the nitrocellulose membrane.

To use the strip format of the test, the user dips the sample pad into urine collected in a collection cup for at least 10 seconds. To use the cassette format, the user applies 3 full drops of urine specimen to the specimen well on the cassette. To use the midstream format, the user applies a specimen by keeping the absorbent tip in a urine midstream for at least five (5) seconds.

After application of the urine specimen, the test result is shown in the result window and read visually after 5 minutes of 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):

hCG Urine Test Strip, hCG Urine Test Cassette, hCG Urine Test Midstream

B Predicate 510(k) Number(s):

K200133

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K240242</u>	<u>K200133</u>
Device Trade Name	HCG Home Use Pregnancy Test Strip (Colloidal Gold) HCG Home Use Pregnancy Test Cassette (Colloidal Gold) HCG Home Use Pregnancy Test Midstream (Colloidal Gold)	hCG Urine Test Strip hCG Urine Test Cassette hCG Urine Test Midstream
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.	Same
Specimen	Urine	Same
Methodology	Chromatographic immunoassay	Same
Analytical Sensitivity	25 mIU/mL	Same
General Device Characteristic Differences		
Specific Gravity Interference	No interference in urine with specific gravity 1.000 -1.035	No interference in urine with specific gravity 1.000 -1.039
High Dosage Hook Effect	No high dosage hook effect for hCG up to 1,000,000 mIU/mL	No high dosage hook effect for hCG up to 850,000 mIU/mL

VI Standards/Guidance Documents Referenced:

Clinical Laboratory Standard Institute (CLSI) EP07: Interference Testing in Clinical Chemistry, 3rd edition.

CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents.

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; 3rd edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Single-Site/Single-Day Precision Study

A precision study was performed using a pooled negative female urine sample spiked with hCG (traceable to the 5th WHO IS) to obtain samples with hCG concentration of 0, 12.5, 18.75, 25, 50, and 100 mIU/mL. Each sample was tested using 3 lots of HCG Home Use Pregnancy Test Cassette (Colloidal Gold), 3 lots of HCG Home Use Pregnancy Test Strip (Colloidal Gold) and 3 lots of HCG Home Use Pregnancy Test Midstream (Colloidal Gold). Each sample was tested in replicates of 20 per lot of device format at 1 site on 1 day by 3 different operators. A total of 60 replicates were performed per test format per hCG concentration. Summary of results are presented in the following tables.

HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

hCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	20	0	20	0	20	0	60	0	100	0
12.5	20	0	20	0	20	0	60	0	100	0
18.75	12	8	11	9	12	8	35	25	58.33	41.67
25	0	20	0	20	0	20	0	60	0	100
50	0	20	0	20	0	20	0	60	0	100
100	0	20	0	20	0	20	0	60	0	100

HCG Home Use Pregnancy Test Strip (Colloidal Gold)

hCG concentration (mIU/mL)	Lot 4		Lot 5		Lot 6		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	20	0	20	0	20	0	60	0	100	0
12.5	20	0	20	0	20	0	60	0	100	0
18.75	11	9	12	8	12	8	35	25	58.33	41.67
25	0	20	0	20	0	20	0	60	0	100
50	0	20	0	20	0	20	0	60	0	100
100	0	20	0	20	0	20	0	60	0	100

HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

hCG concentration (mIU/mL)	Lot 7		Lot 8		Lot 9		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	20	0	20	0	20	0	60	0	100	0
12.5	20	0	20	0	20	0	60	0	100	0
18.75	11	9	12	8	12	8	35	25	58.33	41.67
25	0	20	0	20	0	20	0	60	0	100
50	0	20	0	20	0	20	0	60	0	100
100	0	20	0	20	0	20	0	60	0	100

Single-Site/Multi-Day Precision Study

A multi-day precision study was performed using a pooled negative female urine sample spiked with hCG (traceable to the 5th WHO IS) to obtain samples with hCG concentration of 0, 12.5, 18.75, 25, 50, and 100 mIU/mL. Each sample was tested using 3 lots of HCG Home Use Pregnancy Test Cassette (Colloidal Gold), 3 lots of HCG Home Use Pregnancy Test Strip (Colloidal Gold) and 3 lots of HCG Home Use Pregnancy Test Midstream (Colloidal Gold). Each sample was tested in 20 replicates per run, 2 runs per day over the course of 5 days per lot per device test format. A total of 600 replicates per sampling method per hCG concentration. The table below summarized the precision data for each test format.

HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

hCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	200	0	200	0	200	0	600	0	100	0
12.5	200	0	200	0	200	0	600	0	100	0
18.75	115	85	111	89	114	86	340	260	56.67	43.33
25	0	200	0	200	0	200	0	600	0	100
50	0	200	0	200	0	200	0	600	0	100
100	0	200	0	200	0	200	0	600	0	100

HCG Home Use Pregnancy Test Strip (Colloidal Gold)

hCG concentration (mIU/mL)	Lot 4		Lot 5		Lot 6		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	200	0	200	0	200	0	600	0	100	0
12.5	200	0	200	0	200	0	600	0	100	0
18.75	113	87	113	87	112	88	338	262	56.33	43.67
25	0	200	0	200	0	200	0	600	0	100
50	0	200	0	200	0	200	0	600	0	100
100	0	200	0	200	0	200	0	600	0	100

HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

hCG concentration (mIU/mL)	Lot 4		Lot 5		Lot 6		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	200	0	200	0	200	0	600	0	100	0
12.5	200	0	200	0	200	0	600	0	100	0
18.75	118	82	113	87	114	86	345	255	57.5	42.5
25	0	200	0	200	0	200	0	600	0	100
50	0	200	0	200	0	200	0	600	0	100
100	0	200	0	200	0	200	0	600	0	100

Multi-Site Precision Study

A multi-site precision study was performed using pooled negative female urine sample spiked with hCG (traceable to the 5th WHO IS) to obtain samples with hCG concentration of 0, 12.5, 18.75, 25, 50, and 100 mIU/mL. Each sample was tested using 3 lots of HCG Home Use Pregnancy Test Cassette (Colloidal Gold), 3 lots of HCG Home Use Pregnancy Test Strip (Colloidal Gold) and 3 lots of HCG Home Use Pregnancy Test Midstream (Colloidal Gold) at 3 sites. At each site, each sample was tested in 10 replicates per run, 2 runs per day over the course of 5 days per lot per device test format. All lots were tested at each site for each test format and a total of 900 replicates per test format per hCG concentration were obtained at 3 sites together. The table below summarized the precision data for each test format.

HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

hCG concentration (mIU/mL)	Site 1 (Lot 1, Lot 2, Lot 3)		Site 2 (Lot 1, Lot2, Lot 3)		Site 3 (Lot 1, Lot 2, Lot 3)		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	300	0	300	0	300	0	900	0	100	0
12.5	300	0	300	0	300	0	900	0	100	0
18.75	150	150	150	150	150	150	450	450	50	50
25	0	300	0	300	0	300	0	900	0	100
50	0	300	0	300	0	300	0	900	0	100
100	0	300	0	300	0	300	0	900	0	100

HCG Home Use Pregnancy Test Strip (Colloidal Gold)

hCG concentration (mIU/mL)	Site 1 (Lot4, Lot5, Lot6)		Site 2 (Lot4, Lot5, Lot6)		Site 3 (Lot4, Lot5, Lot6)		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	300	0	300	0	300	0	900	0	100	0
12.5	300	0	300	0	300	0	900	0	100	0
18.75	150	150	150	150	140	160	440	460	51.11	48.89
25	0	300	0	300	0	300	0	900	0	100
50	0	300	0	300	0	300	0	900	0	100
100	0	300	0	300	0	300	0	900	0	100

HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

hCG concentration (mIU/mL)	Site 1 (Lot7, Lot8, Lot9)		Site 2 (Lot7, Lot8, Lot9)		Site 3 (Lot7, Lot8, Lot9)		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	300	0	300	0	300	0	900	0	100	0
12.5	300	0	300	0	300	0	900	0	100	0
18.75	170	130	150	150	140	160	480	420	53.53	46.67
25	0	300	0	300	0	300	0	900	0	100
50	0	300	0	300	0	300	0	900	0	100
100	0	300	0	300	0	300	0	900	0	100

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

Interference from exogenous and endogenous substances:

A study was performed to evaluate potential interference from certain exogenous and endogenous substances for the HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Strip (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold). A urine pool from non-pregnant females was used to prepare samples with hCG levels of 0 mIU/mL, 10 mIU/mL and 25 mIU/mL, which were then spiked with potentially interfering substances at the concentrations listed below. Samples were tested in replicates of 5 per lot using 3 lots of each device format. The results demonstrated no interferences at the concentrations shown in the table below.

Potential Interferent	Highest Concentration Tested that demonstrated no interference
Endogenous Interferents	
Albumin	2000 mg/dL
Bilirubin	2mg/dL
Ethanol	1%
Glucose	2000 mg/dL
Hemoglobin	1000 mg/dL
Ketone	>80 mg/dL
Protein	5.65 mmol/L
Erythrocytes	>250/ μ L
Leukocyte	>500/ μ L
Uric acid	450 mmol/L
Exogenous Interferents	
Ascorbic acid	20 mg/dL
Acetaminophen	20 mg/dL
Aspirin	20 mg/dL
Tetracycline	20 mg/dL
Ampicillin	20 mg/dL
β hydroxybutyrate	2000 mg/dL
Benzoylecgonine	10 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Folic acid	800 μ g/mL
Phenylpropanolamine	20 mg/dL
Pheothiazine	20 mg/dL
Thiophene	20 mg/dL
Vitamin B1	800 μ g/mL

Cross-Reactivity of Structurally Related Compounds:

A study was performed to evaluate the potential cross-reactivity from luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH) on the HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Strip (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) devices. Urine specimens from non-pregnant females were pooled and used to prepare samples with hCG levels of 0 mIU/mL, 12.5 mIU/mL and 25 mIU/mL. Then hCG samples were spiked with each cross-reactants at the following concentrations: 500 mIU/mL LH, 1000 mIU/mL FSH and 1 mIU/mL TSH. The samples were tested in replicates of 5 per lot using 3 lots of each device format. The results demonstrated no cross reactivity with LH at 500 mIU/mL, FSH at 1000 mIU/mL and TSH at 1 mIU/mL in either negative or positive urine samples.

Effects of hCG β -core fragment:

A study was performed to evaluate the effect of hCG β -core fragment on the HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Strip (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) devices. Negative female urine samples (0 mIU/mL) and negative samples spiked with hCG to levels of 10 mIU/mL and 25 mIU/mL were spiked with hCG β -core fragment at concentrations of 125,000, 250,000, 500,000 and 1,000,000 pmol/mL. The samples were tested in replicates of 10 per lot using three lots of each device format. The results demonstrated that the candidate devices are not affected by concentrations of hCG β -core fragment up to 1,000,000 pmol/mL.

Effects of Urine pH:

A study was performed to evaluate the effects of pH on the HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Strip (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) devices. Negative female urine samples (0 mIU/mL) and negative samples spiked with hCG to levels of 10 mIU/mL and 25 mIU/mL were adjusted to have pH values of 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 and 9.0. The negative and positive hCG samples with the different pH levels were tested in replicates of 10 per lot using 3 lots of each device. The results demonstrated that changes in pH ranging from 3.0 to 9.0 do not interfere with either negative or positive results from the devices.

Effects of Urine Specific Gravity:

A study was performed to evaluate the effects of urine specific gravity HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Strip (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) devices. Negative female urine samples (0 mIU/mL) and negative samples spiked with hCG to levels of 10 mIU/mL and 25 mIU/mL were adjusted to have urine specific gravities of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The negative and positive hCG samples with the different urine gravity levels were tested in replicates of 10 per lot using 3 lots of each device format. The results demonstrated that changes in urine specific gravity from 1.000 to 1.035 do not interfere with either negative or positive results from the devices.

Hook Effect:

A study was performed to evaluate the high dose hook effect on HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Strip (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) devices. Negative female urine samples were spiked with hCG at concentrations of 5000, 10,000, 100,000, 500,000, 650,000, 850,000, 950,000 and 1,000,000 mIU/mL. The samples were tested in replicates of 30 using three device lots per test format. The results demonstrated that no hook effect was observed at hCG concentration up to 1,000,000 mIU/mL.

4. Assay Reportable Range:

Not applicable

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

HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Strip (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) devices are calibrated against reference material traceable to WHO International Standard 5th edition (NIBSC code 07/364)

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:

A total of 300 urine samples were collected from women whose ages ranged from 18 to 48 years, who presented to the clinics for pregnancy testing. Approximately half of the 300 women were suspected to be pregnant and most of them were in the early stage of pregnancy (less than 5 weeks). The samples were masked and randomized prior to testing by professionals using 1 lot of the candidate devices and a single lot of the predicate device. One hundred (100) samples were tested using the HCG Home Use Pregnancy Test Cassette (Colloidal Gold), 100 samples were tested using the HCG Home Use Pregnancy Test Strip (Colloidal Gold), and 100 samples were tested using HCG Home Use Pregnancy Test Midstream (Colloidal Gold). Summary results are presented in the tables below.

HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

Candidate Device		Predicate Device		Total
		Positive	Negative	
Cassette	Positive	50	0	50
	Negative	0	50	50
	Total	50	50	100

HCG Home Use Pregnancy Test Strip (Colloidal Gold)

Candidate Device		Predicate Device		Total
		Positive	Negative	
Test Strip	Positive	50	0	50
	Negative	0	50	50
	Total	50	50	100

HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

Candidate Device		Predicate Device		Total
		Positive	Negative	
Midstream	Positive	50	0	50
	Negative	0	50	50
	Total	50	50	100

An additional method comparison study was performed in which 100 people tested their own sample for each test format. One false positive result was observed using the cassette format of the device when results were compared to the predicate. Limiting statements have been added to the labeling to indicate that false positives are possible when using this device.

2. Matrix Comparison:

Not Applicable. The 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 conducted at 3 sites with 300 volunteers with diverse educational and occupational backgrounds who were between the age of 18 and 48. This included 100 lay users using the HCG Home Use Pregnancy Test Cassette (Colloidal Gold) at site 1, 100 lay-users using the HCG Home Use Pregnancy Test Strip (Colloidal Gold) at site 2, and 100 lay-users using the HCG Home Use Pregnancy Test Midstream (Colloidal Gold) at site 3. Lay users collected their own sample, and these samples were split into two groups, one group was for the lay-user testing, and the other was for the professional testing. All samples were masked and randomized prior to professional testing. Each lay user tested her own urine sample with only one test method on the candidate device following the instructions on the package insert. The same sample was tested by the professional using the predicate device. Then the results of lay-user tests were compared to results reported by a laboratory professional. The data shows that the agreement between lay-user results and professional results was 100% (below):

HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

Cassette		Professional User Predicate Device		Total
		Positive	Negative	
Lay-User	Positive	50	0	50
	Negative	0	50	50
	Total	50	50	100

HCG Home Use Pregnancy Test Strip (Colloidal Gold)

Test Strip		Professional User Predicate Device		Total
		Positive	Negative	
Lay-User	Positive	50	0	50
	Negative	0	50	50
	Total	50	50	100

HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

Midstream		Professional User Predicate Device		Total
		Positive	Negative	
Lay-User	Positive	50	0	50
	Negative	0	50	50
	Total	50	50	100

Each lay person was given a questionnaire that was completed at the end of the study. The questionnaire results indicated that lay-users found the tests easy to use, the results clear and easy to read, and the instructions for use easy to understand.

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.