



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

**I Background Information:**

**A 510(k) Number**

K242135

**B Applicant**

Nanjing Synthgene Medical Technology Co., Ltd.

**C Proprietary and Established Names**

Synthgene Home Test HCG Test Strip; Synthgene Home Test HCG Test Cassette; Synthgene Home Test HCG Test Midstream

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 862.1155 - 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 lateral flow immunoassay

**III Intended Use/Indications for Use:**

**A Intended Use(s):**

See Indications for Use below.

**B Indication(s) for Use:**

Synthgene Home Test HCG Test Midstream is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

Synthgene Home Test HCG Test Cassette is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

Synthgene Home Test HCG Test Strip is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

**C Special Conditions for Use Statement(s):**

OTC - Over The Counter

**D Special Instrument Requirements:**

Not applicable.

**IV Device/System Characteristics:**

**A Device Description:**

The test comes in three formats (strip, cassette, and midstream) named Synthgene Home Test HCG Test Strip, Synthgene Home Test HCG Test Cassette and Synthgene Home Test HCG Test Midstream, respectively. Each test kit contains the individually packaged test, medical waste bag, urine cup, and instructions for use. The strip format is a single test strip. The cassette format consists of a single test strip assembled in a plastic housing. A pipette dropper is included in the packaging. The strip is designed to be used in dip sampling mode only while the cassette format is designed to be used in drop sampling mode only. The midstream format consists of a single test strip assembled in a plastic housing with an absorbent tip and is designed to be tested in dip or in-stream sampling mode.

**B Principle of Operation:**

Synthgene Home Test HCG Test Strip, Synthgene Home Test HCG Test Cassette and Synthgene Home Test HCG Test Midstream use lateral flow immunoassay technology for in vitro qualitative detection of human chorionic gonadotropin (hCG) in human urine. When hCG is present in the sample, the hCG antigen in the sample reacts with the colloidal gold-labeled antibody (hCG mAb1) on the conjugate pad to form the labeled antibody-antigen complex. The complex moves upward by capillary action and is captured by the test line (T line) antibody (hCG mAb2) coated on the nitrocellulose membrane, appearing as a red band. The complex continues to migrate and is captured by the control line (C line) antibody (goat anti-mouse IgG polyclonal antibody) coated on the nitrocellulose membrane, and a red band appears. When the test is performed properly, a colored line will always appear on the C line. The test result appears within 5-20 minutes of urine addition. Two distinct colored lines, one at the T line

and another at the C line indicate a positive test result (pregnant). Absence of a colored line at the T line and only a colored line at the C line indicates a negative test result (not pregnant). Absence of a colored line at the C line even in the presence of a colored line at the T line indicates an invalid test result.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):

HIGHTOP Pregnancy Rapid Test Cassette, HIGHTOP Pregnancy Rapid Test Strip, HIGHTOP Pregnancy Rapid Test Midstream

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

K192123

### C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K242135</u>	<u>K192123</u>
Device Trade Name	Synthgene Home Test HCG Test Strip; Synthgene Home Test HCG Test Cassette; Synthgene Home Test HCG Test Midstream	HIGHTOP Pregnancy Rapid Test Cassette, HIGHTOP Pregnancy Rapid Test Strip, HIGHTOP Pregnancy Rapid Test Midstream
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	Qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy	Same
Specimen Type	Urine	Same
Assay Methodology	Immunochromatographic assay	Same
Formats	Strip, cassette, and midstream	Same
Intended Use environment	Over the counter use	Same
Cutoff	25 mIU/mL	Same
<b>General Device Characteristic Differences</b>		
Read Time	5 – 20 minutes	5 minutes

## VI Standards/Guidance Documents Referenced:

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

CLSI EP07 3rd Edition: Interference Testing in Clinical Chemistry

CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition

EP25-A (Replaces EP25-P): Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

ISO 14971 Third Edition 2019-12: Medical devices - Application of risk management to medical devices

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

#### 1. Precision/Reproducibility:

A precision study was performed on the Synthgene Home Test HCG Test Strip, Synthgene Home Test HCG Test Cassette and Synthgene Home Test HCG Test Midstream using negative female urine samples spiked with hCG to obtain samples with hCG concentrations of 0, 12.5, 18.75, 22.5, 25, 50, 100, and 200 mIU/mL. Each sample was tested using three lots of the candidate device for all three formats. For the midstream format, samples were tested using the dip sampling mode and simulated midstream sampling mode. Tests were performed over the course of five days, at three sites, by three different operators, and in replicates of ten per sample. A total of 450 replicates were performed per sampling mode per hCG concentration. The samples were blinded and randomized before being given to the operators. The results are summarized in the tables below:

Summary of Synthgene Home Test HCG Test Midstream testing in dip sampling mode

Sample No.	hCG conc (mIU/mL)	Lot 1		Lot 2		Lot 3		Total		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	20	130	20	130	17	133	57	393	87.3%	12.7%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

Summary of Synthgene Home Test HCG Test Midstream testing in midstream sampling mode

Sample No.	hCG conc (mIU/mL)	Lot 1		Lot 2		Lot 3		Total		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	23	127	24	126	21	129	68	382	84.9%	15.1%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

Summary of Synthgene Home Test HCG Test Cassette in drop sampling mode

Sample No.	hCG conc (mIU/mL)	Lot 1		Lot 2		Lot 3		Total		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	19	131	24	126	19	131	62	388	86.2%	13.8%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

Summary of Synthgene Home Test HCG Test Strip testing in dip sampling mode

Sample No.	HCG con (mIU/mL)	Lot 1		Lot 2		Lot 3		Total		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	23	127	23	127	21	129	67	383	85.1%	14.9%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

The claimed analytical sensitivity is 25 mIU/mL hCG.

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

*Interference from exogenous and endogenous substances:*

To evaluate potential interference from certain exogenous and endogenous substances, negative urine samples from normal healthy females containing 0 mIU/mL and 25 mIU/mL hCG were spiked with the potentially interfering substances at the concentrations listed in the table below. For each test format, samples were tested in triplicate, using three lots of the test. No interference was observed at the concentrations shown in the table below:

Substance	Concentration
2,5-Dihydroxybenzoic acid	0.2 mg/mL
Acetaminophen	0.2 mg/mL
Acetoacetic Acid	20 mg/mL
Acetylsalicylic Acid	0.2 mg/mL
Ampicillin	0.2 mg/mL
Ascorbic Acid	0.2 mg/mL
Atropine	0.2 mg/mL
Benzoylcegonine	0.1 mg/mL
B-hydroxybutyrate	20 mg/mL
Bilirubin	0.02 mg/mL
Caffeine	0.2 mg/mL
Cannabinol	0.1 mg/mL
Codeine	0.06 µg/mL
EDTA	0.8 mg/mL
Ephedrine	0.2 mg/mL
Estriol-17-beta	14 mg/mL
Ethanol	1%
Gentisic Acid	0.2 mg/mL
Glucose	20 mg/mL
Hemoglobin	5 mg/mL
Human Albumin	20 mg/mL
Ketone	0.2 mg/mL
Methanol	10%

Phenothiazine	0.2 mg/mL
Phenylpropanolamine	0.2 mg/mL
Pregnanediol	15 µg/mL
Salicylic Acid	0.2 mg/mL
Tetracycline	0.2 mg/mL
Thiophene	0.2 mg/mL
Triglyceride	8 mg/mL
Vitamin C	0.2 mg/mL

#### *Cross-reactivity of Similar Compounds:*

To evaluate cross-reactivity, negative and positive urine samples were spiked to contain 0 mIU/mL hCG (negative matrix) and 25 mIU/mL hCG and then spiked with potential cross-reactants. Samples were spiked with 500 mIU/mL luteinizing hormone (hLH), 1000 mIU/mL follicle-stimulating hormone (hFSH), and 1 mIU/mL thyroid-stimulating hormone (hTSH). Samples were tested in replicates of three using three lots of the test. No cross-reactivity was observed at tested concentrations.

#### *Effect of Urine pH:*

A study was performed to evaluate the effects of urine pH on the candidate devices. Negative, female, human urine samples were used to make samples containing 0 mIU/mL and 25 mIU/mL hCG, which were then adjusted to pH values at 4, 5, 6, 7, 8, and 9 and tested using the candidate devices. Samples were tested in replicates of three, using three lots of the candidate devices. The results demonstrated that urine pH ranges between 4 and 9 do not affect test performance.

#### *Effect of Urine Specific Gravity:*

A study was performed to evaluate the effects of specific gravity on the candidate devices. Negative, female, human urine sample were used to make samples containing 0 mIU/mL and 25mIU/mL hCG, which were then adjusted to specific gravity values of 1.000, 1.002, 1.009, 1.012, 1.018, 1.028, 1.032, and 1.035 and tested using the candidate devices. Samples were tested in replicates of three, using three lots of the candidate device. The results demonstrated that urine with a specific gravity ranging from 1.000 to 1.035 does not affect test performance.

#### *High dose hook effect study*

A study was performed to evaluate whether there is a high dose hook effect using the candidate devices. Negative, female, human urine samples were spiked with hCG concentrations up to 1,860,000 mIU/mL and tested in replicates of ten using three lots of the candidate device. No hook effect was observed at concentrations of up to 1,860,000 mIU/mL hCG.

*Effects of hCG  $\beta$ -core fragment:*

Urine samples with hCG concentrations of 0 and 25 mIU/mL were spiked with hCG  $\beta$ -core fragment (hCG $\beta$ cf) at a concentration of 2,000,000 pmol/L. The samples were tested in replicates of three using three lots of the device. All samples using all three test formats yielded correct results with hCG  $\beta$ -core fragment at a concentration of 2,000,000 pmol/L.

4. Assay Reportable Range:

Not applicable.

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

The candidate devices are calibrated against reference material traceable to WHO International Standard 6th edition (NIBSC code:18/244).

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

The device claimed cutoff is 25 mIU/mL. See Precision/Reproducibility section above (Section VII.A.1).

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Urine samples were collected from 333 women aged 18 – 49 who presented for pregnancy testing at 3 sites. Samples were randomly collected at various times throughout the day and blinded before being tested by professionals using the candidate devices and the predicate device. A total of 121 samples tested with the Synthgene Home Test HCG Test Midstream, 103 samples tested with the Synthgene Home Test HCG Test Strip, and 109 samples tested with the Synthgene Home Test HCG Test Cassette. Of the 121 samples tested using the midstream format, 61 were tested in dip sampling mode and 60 were tested in midstream sampling mode. The results of the study are summarized in the tables below:

Summary of Synthgene Home Test HCG Test Midstream testing in dip sampling mode:

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	38	0	38
Negative	0	23	23
Total	38	23	61



Summary of Synthgene Home Test HCG Test Midstream testing in simulated midstream sampling mode

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	40	0	40
Negative	0	20	20
Total	40	20	60

Summary of Synthgene Home Test HCG Test Cassette testing in drop sampling mode

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	60	0	60
Negative	0	49	49
Total	60	49	109

Summary of Synthgene Home Test HCG Test Strip testing in dip sampling mode

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	54	0	54
Negative	0	49	49
Total	54	49	103

The test performance of Synthgene Home Test HCG Test Midstream, Synthgene Home Test HCG Test Cassette, and Synthgene Home Test HCG Test Strip are 100% concordant when compared to the predicate.

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 total of 333 women with varying educational and occupational backgrounds with an age range of 18 – 49 years old from three test sites tested their own urine specimens. A total of 121 lay users tested the midstream format (61 in dip sampling mode and 60 in midstream sampling mode), 109 lay users tested the cassette format, and 103 tested the strip format.

Each lay user also provided a sample for professional testing. The data, summarized below, demonstrated 100% agreement between lay user results and professional results.

Summary of Synthgene Home Test HCG Test Midstream testing in dip sampling mode:

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	38	0	38
Negative	0	23	23
Total	38	23	61

Summary of Synthgene Home Test HCG Test Midstream testing in simulated midstream sampling mode

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	40	0	40
Negative	0	20	20
Total	40	20	60

Summary of Synthgene Home Test HCG Test Cassette testing in drop sampling mode

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	60	0	60
Negative	0	49	49
Total	60	49	109

Summary of Synthgene Home Test HCG Test Strip testing in dip sampling mode

Candidate Device	Predicate Device		Total
	Positive	Negative	
Positive	54	0	54
Negative	0	49	49
Total	54	49	103

Participants also completed a questionnaire in which they reported that testing was easy to perform, and the instructions were easy to follow.

#### **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.