

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

A. 510(k) Number:

k142754

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Sugentech, Inc.

F. Proprietary and Established Names:

Surearly Pregnancy Test Strip
Surearly Digital Pregnancy Test

G. Regulatory Information:

Product code	Classification	Regulation section	Panel
LCX	Class II	21 CFR 862.1155 Human chorionic gonadotropin test system	Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Surearly Pregnancy Test Strip is an in vitro diagnostic medical device for the rapid

determination of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the determination of pregnancy. It is intended for over-the-counter (OTC) use only.

Surearly Digital Pregnancy Test is an in vitro diagnostic medical device for the rapid determination of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the determination of pregnancy. It is intended for over-the-counter (OTC) use only.

3. Special conditions for use statement(s):

For over the counter use

4. Special instrument requirements:

None

I. Device Description:

Both Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test are in vitro diagnostic medical devices, which use the qualitative assay for the detection of human chorionic gonadotropin (hCG) in urine, as an aid in the early determination of pregnancy. The assays are based on a lateral-flow immunochromatographic assay.

For Surearly Pregnancy Test Strips, users immerse the sample pad of the strip into the collected urine, see their test results with colored lines on the strip and interpret the test result according to the instructions for use. Users are able to read test results in 5 minutes.

For Surearly Digital Pregnancy Test, the colored lines are not visible to users as the strip is located inside a plastic housing of the test reader. The pregnancy test result is displayed as a “YES” or “NO” on the device. The device displays the test result after 3 minutes. The digital device could be used in either dip mode or mid-stream mode.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Clearblue Easy Digital Urine Pregnancy Test

2. Predicate K number(s):

k060128

3. Comparison with predicate:

Similarities			
Feature	Clearblue Easy Digital Urine Pregnancy Test (Predicate Device, k060128)	Surearly Pregnancy Test Strip (Candidate Device 1)	Surearly Digital Pregnancy Test (Candidate Device 2)
Intended Use	Qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy	Same	Same
Sample Matrix	Urine	Same	Same
Test Principle	Lateral flow immunochromatographic assay	Same	Same
Sensitivity	25 mIU/mL	Same	Same
Differences			
Feature	Clearblue Easy Digital Urine Pregnancy Test (Predicate Device, k060128)	Surearly Pregnancy Test Strip (Candidate Device 1)	Surearly Digital Pregnancy Test (Candidate Device 2)
Intended User	Over the Counter (OTC)	OTC use	OTC use
Sample application (Sampling time)	Dip (3 seconds)	Dip (5 seconds)	Dip (10 seconds) Stream (5 second)
Time to Result	3 minutes	5 minutes	3 minutes
Format	Automatic reading with a digital display	Visual reading	Automatic reading with a digital display
Traceability	WHO 4th International Standard	WHO 5th International Standard	WHO 5th International Standard

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

- CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition
- CLSI EP12-P, User Protocol for Evaluation of Qualitative Test Performance

L. Test Principle:

Both devices (Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test) use a double antibody sandwich method. Each test device contains mouse monoclonal anti- β -hCG antibody colloidal gold conjugate pre-dried on a pad. Mouse monoclonal anti- α -hCG antibody (on the Test Line) and goat anti-mouse IgG polyclonal antibody (on the Control Line) are coated and immobilized on a nitrocellulose membrane. During the test procedures, hCG in the urine specimen reacts with the dye conjugate (mouse anti- β -hCG antibody- colloidal gold conjugate specific to the beta subunit of hCG) and forms a complex. Because of capillary and chromatographic effects of the nitrocellulose membrane, the complex migrates along the membrane to the α -hCG antibody line (T), and remains captured in the T line. As a result a red colored band develops in the T line, indicating a positive result. If there is no hCG in the urine, there is no red band in the test zone, indicating a negative result. The Control line should develop in the control zone regardless of the test result if sufficient sample volume has been applied to the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Both devices (Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test) were tested using the protocol described below. For the digital device, both the dip method and the stream method were tested.

Eight samples containing intact hCG at concentrations of 0, 6.25, 8.5, 22.25, 25, 50, 250, 500 mIU/mL were prepared in negative urine. The hCG used for spiking contained purified intact hCG traceable to the WHO 5th International Standard (IS) for hCG. The stream method in this study was a simulated midstream testing. For within-run precision, each sample was tested in replicates of 30 using one lot of each device. For lot-to-lot and day-to-day precision, each sample was tested 3 times/day for 5 days, using 3 lots of each device. For between-run & between-operator precision, each sample was tested by three laboratory professionals 2 times/day for 5 days using one lot of each device.

The results obtained with Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test are summarized in the tables below:

Within-run precision- Surearly Pregnancy Test Strip format

hCG concentration (mIU/mL)	Positive/Total	% positive
0	0/30	0%
6.25	0/30	0%
8.5	1/30	3.3%
22.5	28/30	93.3%
25	30/30	100%
50	30/30	100%
250	30/30	100%
500	30/30	100%

Within-run precision- Surearly Digital Pregnancy Test-Dip Method

hCG concentration (mIU/mL)	Positive/Total	% positive
0	0/30	0%
6.25	0/30	0%
8.5	2/30	6.6%
22.5	28/30	93.3%
25	30/30	100%
50	30/30	100%
250	30/30	100%
500	30/30	100%

Within-run precision- Surearly Digital Pregnancy Test-Simulated Midstream Method

hCG concentration (mIU/mL)	Positive/Total	% positive
0	0/30	0%
6.25	0/30	0%
8.5	2/30	6.6%
22.5	28/30	93.3%
25	30/30	100%
50	30/30	100%
250	30/30	100%
500	30/30	100%

Lot-to-lot and day-to-day precision (5 days)- Surearly Pregnancy Test Strip

hCG concentration (mIU/mL)	Positive/Total			% positive
	Lot# 1	Lot# 2	Lot# 3	
0	0/15	0/15	0/15	0%
6.25	0/15	0/15	0/15	0%
8.5	0/15	0/15	0/15	0%
22.5	15/15	15/15	15/15	100%
25	15/15	15/15	15/15	100%
50	15/15	15/15	15/15	100%
250	15/15	15/15	15/15	100%
500	15/15	15/15	15/15	100%

Lot-to-lot and day-to-day precision (5 days)- Surearly Digital Pregnancy Test-
Dip Method

hCG concentration (mIU/mL)	Positive/Total			% positive
	Lot# 1	Lot# 2	Lot# 3	
0	0/15	0/15	0/15	0%
6.25	0/15	0/15	0/15	0%
8.5	0/15	0/15	0/15	0%
22.5	15/15	15/15	15/15	100%
25	15/15	15/15	15/15	100%
50	15/15	15/15	15/15	100%
250	15/15	15/15	15/15	100%
500	15/15	15/15	15/15	100%

Lot-to-lot and day-to-day precision (5 days)- Surearly Digital Pregnancy Test-
Simulated Midstream Method

hCG concentration (mIU/mL)	Positive/Total			% positive
	Lot# 1	Lot# 2	Lot# 3	
0	0/15	0/15	0/15	0%
6.25	0/15	0/15	0/15	0%
8.5	0/15	0/15	0/15	0%
22.5	15/15	15/15	15/15	100%
25	15/15	15/15	15/15	100%
50	15/15	15/15	15/15	100%
250	15/15	15/15	15/15	100%
500	15/15	15/15	15/15	100%

b. *Linearity/assay reportable range:*

Linearity is not applicable since this is a qualitative test.

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

The test is calibrated against the WHO 5th International Standard for hCG.

The stability testing protocol and acceptance criteria used to support the shelf life were reviewed and found to be acceptable. The sponsor claims a 24-month shelf life for the test when stored at 36-86°F (2-30°C).

d. *Detection limit:*

Urine was collected from thirty (30) confirmed non-pregnant women and divided into aliquots spiked with the indicated amounts of hCG standard (0, 6.25, 8. 8.5, 9, 9.4, 12.5, 18.75, 22.5, 25, 50, 100 mIU/mL). The samples were masked and randomized prior to testing.

The test was performed by laboratory professionals using the Surearly Pregnancy Test Strip and the Surearly Digital Pregnancy Test, and by 120 lay users (aged 19-45 years) using the Surearly Pregnancy Test Strip. The results are summarized in the tables below:

Professional Study:
Sensitivity of Surearly Pregnancy Test Strip

hCG concentration (mIU/mL)	Number of positive/Total			% positive rate
	Lot #1	Lot #2	Lot #3	
0	0/30	0/30	0/30	0%
6.25	0/30	0/30	0/30	0%
8.0	0/30	0/30	0/30	0%
8.5	1/30	2/30	2/30	5.6%
9.0	6/30	5/30	5/30	17.8
9.4	7/30	9/30	9/30	27.8%
12.5	14/30	14/30	13/30	45.6%
18.75	23/30	23/30	21/30	74.4%
22.5	29/30	29/30	28/30	95.6
25	30/30	30/30	30/30	100%
50	30/30	30/30	30/30	100%
100	30/30	30/30	30/30	100%

Professional Study:
Sensitivity of Surearly Digital Pregnancy Test

hCG concentration (mIU/mL)	Number of positive/Total			% positive rate
	Lot #1	Lot #2	Lot #3	
0	0/30	0/30	0/30	0%
6.25	0/30	0/30	0/30	0%
8	0/30	0/30	0/30	0%
8.5	1/30	2/30	1/30	4.4%
9	4/30	4/30	4/30	13.3%
9.4	7/30	5/30	7/30	21.1%
12.5	12/30	12/30	13/30	41.1%
18.75	20/30	23/30	21/30	71.1%
22.5	29/30	28/30	28/30	94.4%
25	30/30	30/30	30/30	100%
50	30/30	30/30	30/30	100%
100	30/30	30/30	30/30	100%

Lay-user study:

Sensitivity of Surearly Pregnancy Test Strip

hCG concentration (mIU/mL)	Number of positive/Total			% positive rate
	Lot #1	Lot #2	Lot #3	
0	0/30	0/30	0/30	0%
6.25	0/30	0/30	0/30	0%
8.0	0/30	0/30	0/30	0%
8.5	1/30	1/30	1/30	3.3%
9.0	4/30	5/30	4/30	14.4%
9.4	8/30	8/30	7/30	25.6%
12.5	12/30	13/30	12/30	41.1%
18.75	22/30	22/30	21/30	72.2%
22.5	29/30	28/30	28/30	94.4%
25	30/30	30/30	30/30	100%
50	30/30	30/30	30/30	100%
100	30/30	30/30	30/30	100%

The results demonstrated that the sensitivity of the Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test (the lowest concentration that yields 100% positive results) is 25mIU/mL. The concentration at which approximately half of the devices yield positive results is 12.5 mIU/ml.

e. Analytical specificity:

Cross-reactivity:

Follicle-Stimulating Hormone (FSH), Luteinizing Hormone (LH), and Thyroid Stimulating Hormone (TSH) were tested for cross-reactivity by spiking high concentrations of each substance into negative urine samples and negative urine samples spiked with 6.25 mIU/mL, 25 mIU/mL and 50 mIU/mL hCG. Each sample was tested in triplicate using both the Surearly Pregnancy Test Strip and the Surearly Digital Pregnancy Test. No cross-reactivity was observed for FSH at concentrations up to 1000 mIU/mL, LH at up to 500 mIU/mL and TSH at up to 1000 μ IU/mL.

Interference:

Fourteen endogenous and exogenous substances were tested for interference by spiking high concentrations of each substance into negative urine samples and negative urine samples spiked with 6.25 mIU/mL, 25 mIU/mL, and 50 mIU/mL hCG. Each sample was tested in replicates of 3 using both the Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test. The highest concentration tested that demonstrate no interference are summarized in the below table.

Surearly Pregnancy Test Strip/ Surearly Digital Pregnancy Test

Interfering Substances		
Substance Category	Substance	Highest Concentration tested with no interference
Prescription/ OTC drugs	Acetaminophen	0.2 mg/mL
	Acetylsalicylic acid	0.7 mg/mL
	Atropine	0.2 mg/mL
	Gentisic acid	0.2 mg/mL
	Ampicillin	0.2 mg/mL
	Tetracycline	0.2 mg/mL
	Phenothiazine	0.01 mg/mL
	Estriol	0.01 mg/mL
Chemical Analytes	Ascorbic acid	0.2 mg/mL
	Caffeine	0.2 mg/mL
	Ethanol	1% v/v
Biological Analytes	Albumin	60 mg/mL
	Glucose	20 mg/mL
	Hemoglobin	2 mg/mL
	Bilirubin	1 mg/mL

PH effect:

The pH of negative urine pools were adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with hCG to 6.25 mIU/mL, 25 mIU/mL and 50 mIU/mL. The unspiked aliquots (hCG at 0 mIU/mL) were used as controls. Each test was performed in triplicate with Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test according to the instructions for use. The results demonstrate that pH ranging from 4 to 9 in urine samples does not interfere with the performance of the test.

Specific gravity:

To evaluate potential interference from changes in specific gravity, urine samples with specific gravity from 1.000 to 1.030 in 0.010 unit increments were tested with the urine samples spiked with hCG to 6.25 mIU/mL, 25 mIU/mL

and 50 mIU/mL. Each test was performed in triplicate with Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test according to the instructions for use. The results demonstrate that specific gravity ranging from 1.000 to 1.030 in urine samples does not interfere with the performance of the test.

High dose hook effect:

The high dose hook effect was evaluated using intact hCG standards (WHO 5th IS) ranging from 0.1 to 500 IU/mL hCG concentrations, and hCG β cf at 500,000 and 1,000,000 pmol/L levels. All samples yielded the expected positive results. The results demonstrate that no hooks effect was observed at the concentrations tested.

f. Assay cut-off:

See detection limit section above.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 456 urine specimens were tested by laboratory technicians, including 150 samples from non-pregnant women and 306 samples from women who were clinically confirmed to be pregnant, among them 156 were in their first trimester based on their last menstrual period. Ages of subjects ranged from 18 to 48 years. The samples were blind coded and randomized prior to testing. The results are summarized below.

		Pregnancy (Clinically Confirmed)		
		Positive	Negative	Total
Surearly Pregnancy Test Strip	Positive	306	0	306
	Negative	0	150	150
	Total	306	150	456

		Pregnancy (Clinically Confirmed)		
		Positive	Negative	Total
Surearly Digital Pregnancy Test	Positive	306	0	306
	Negative	0	150	150
	Total	306	150	456

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):*

Lay user study

A total of 198 lay users aged 18 to 45 years participated in this study. Among the 198 users, 100 were non-pregnant and 98 were recruited who might be pregnant or were clinically confirmed to be pregnant. Each user tested their own urine using the Surearly Pregnancy Test Strip and Surearly Digital Pregnancy Test. For the digital test, 100 users (randomly assigned) tested with urine midstream procedure and the other 98 users tested with urine dip procedure. The same urine samples collected from the lay users were also tested by professionals using the dip procedure and the results are presented in the table below.

Surearly Pregnancy Test Strip		Professionals		
		Positive	Negative	Total
Lay users	Positive	98	0	98
	Negative	0	100	100
	Total	98	100	198

Surearly Digital Pregnancy Test (98 dip+100 mid-stream)		Professionals		
		Positive	Negative	Total
Lay users	Positive	98	0	98
	Negative	0	100	100
	Total	98	100	198

All lay users were instructed to read the proposed package insert in order to operate the device for the studies above. Each lay user was also given a questionnaire to rate how well they understood the instructions and how easy to use the device. The devices were demonstrated to be easy to use, and the results easy to interpret.

The readability of the labeling (strip format and the digital format) was found to be at the 7th grade level using a Flesch-Kincaid analysis.

Pre-, Peri- and Post-Menopausal study

A study of Pre-, Peri- and Post-Menopausal women was performed by 510 non-pregnant lay users (170 women in pre-menopausal age of 18-40 years old, 170 women in peri-menopausal age of 41-55 years old, and 170 women in post-menopausal age over 55 years old) to demonstrate whether the test devices might have false positive results from women who are not pregnant. Each

participant tested 2 or 3 test methods (Strip, Digital-Dip, or Digital-Stream), and the number of samples tested for each test format and the test results are summarized in the below tables. All test results were negative and no false positive results were observed.

Surearly Pregnancy Test Strip		Total test results		
		No. of samples	Positive results	Positive rate
Age group	18-40	170	0	0%
	41-55	103	0	0%
	> 55	103	0	0%

Surearly Digital Pregnancy Test (Dip Method)		Total test results		
		No. of samples	Positive results	Positive rate
Age group	18-40	117	0	0%
	41-55	103	0	0%
	> 55	103	0	0%

Surearly Digital Pregnancy Test (Stream Method)		Total test results		
		No. of samples	Positive results	Positive rate
Age group	18-40	123	0	0%
	41-55	104	0	0%
	> 55	103	0	0%

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

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.