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

A. 510(k) Number:

k181551

B. Purpose for Submission:

New Device

C. Measurand:

Human chorionic gonadotropin

D. Type of Test:

Qualitative Lateral flow immunoassay.

E. Applicant:

Runbio BioTech Co., Ltd.

F. Proprietary and Established Names:

DAVID One Step Home Use Pregnancy Test Strip
DAVID One Step Home Use Pregnancy Test Cassette
DAVID One Step Home Use Pregnancy Test Midstream
DAVID One Step Prescription Pregnancy Test Strip
DAVID One Step Prescription Pregnancy Test Cassette

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155 Human Chorionic Gonadotropin (HCG) test system

2. Classification:

   Class II

3. Product code:

   LCX: Kit, test, pregnancy, hCG, over the counter

   JHI: Visual, pregnancy hCG, prescription use

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

   DAVID One Step Home Use Pregnancy Test Strip is an in-Vitro diagnostic test device for the qualitative detection of human chorionic gonadotropin (HCG) in the urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

   This product is intended for over-the-counter use.

   DAVID One Step Home Use Pregnancy Test Cassette is an in-Vitro diagnostic test device for the qualitative detection of human chorionic gonadotropin (HCG) in the urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

   This product is intended for over-the-counter use.

   DAVID One Step Home Use Pregnancy Test Midstream is an in-Vitro diagnostic test device for the qualitative detection of human chorionic gonadotropin (HCG) in the urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

   This product is intended for over-the-counter use only.

   DAVID One Step Prescription Pregnancy Test Strip is an in-Vitro diagnostic test device for the qualitative detection of human chorionic gonadotropin (HCG) in the urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

   This product is intended for prescription use.

   DAVID One Step Prescription Pregnancy Test Cassette is an in-Vitro diagnostic test device for the qualitative detection of human chorionic gonadotropin (HCG) in the urine.

The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

This product is intended for prescription use.

3. Special conditions for use statement(s):
   DAVID One Step Home Use Pregnancy Test Strip is intended for over-the-counter use.
   DAVID One Step Home Use Pregnancy Test Cassette is intended for over-the-counter use.
   DAVID One Step Home Use Pregnancy Test Midstream is intended for over-the-counter use.
   DAVID One Step Prescription Pregnancy Test Strip is intended for prescription use.
   DAVID One Step Prescription Pregnancy Test Cassette is intended for prescription use.

4. Special instrument requirements:

   None

I. Device Description:

DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Prescription Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette, DAVID One Step Prescription Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream each contain a pouch with the device and instructions in addition the cassette and strip formats are packaged with one pipette dropper and one desiccant.

DAVID One Step Home Use Pregnancy Test Midstream consist of a single test strip encased in plastic device housing. The devices utilize a combination of antibodies to detect hCG in urine as well as to serve as a run control. Each 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FIRST RESPONSE Early Result Pregnancy Test

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

   k123436

3. Comparison with predicate:

Similarities		
Item	DAVID One Step Pregnancy Test Candidate Device (k181551)	FIRST RESPONSE Early Result Pregnancy Test Predicate Device (k123436)
Intended Use	Aid in early detection of pregnancy	Same
Early Detection claim	Detects pregnancy as early as 5 days before the expected period or as early as 6 days before the day of the missed period	Same
Results	Qualitative	Same
Test Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Analytical Sensitivity	10mIU/mL	Same

Differences		
Item	DAVID One Step Pregnancy Test Candidate Device (k181551)	FIRST RESPONSE Early Result Pregnancy Test Predicate Device (k123436)
Device format	Strip, Cassette, Midstream	Midstream
Intended Use	Prescription use (strip and cassette) and OTC use (strip, cassette and midstream)	OTC Use
Time to Result	5 minutes	3 minutes
Traceability	World Health Organization (WHO) 5th International Standard (IS) for hCG	WHO 4th International Standard for hCG

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

None referenced.

L. Test Principle:

DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Prescription Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette, DAVID One Step Prescription Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream utilize a double antibody sandwich method. During the test procedure, 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. This complex migrates by capillary action along the test strip to the α-hCG antibody test line; If hCG is present in the sample, the complex is captured onto the test line, where if hCG is present at concentrations above the cutoff, a red line becomes visible indicating a positive result. If hCG is not present in the sample above the cutoff, no line is visible on the test line, indicating a negative result. The control line should develop regardless of the test line result, if the test was correctly used and/or performed correctly, since mouse anti-β-hCG antibody-colloidal gold conjugate is present in excess to bind to the antibodies at the control line, resulting in a visible red line.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision study were performed for the DAVID One Step Prescription Pregnancy Test Strip, DAVID One Step Prescription Pregnancy Test Cassette, and DAVID One Step Home Use Pregnancy Test Midstream devices using 50 urine samples spiked with hCG traceable to the WHO 5th IS. The DAVID One Step Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for the intended user, therefore the DAVID One Step Prescription Pregnancy Test Strip was used in this study. The DAVID One Step Prescription Pregnancy Test Cassette and the DAVID One Step Home Use Pregnancy Test Cassette are identical, therefore the DAVID One Step Prescription Pregnancy Test Cassette was used in this study. Samples created had concentrations of 0, 3, 6, 7.5, 9, 10, 15, 25 mIU/mL. Samples were masked and randomized prior to testing. The study was conducted in replicates of 10 for 5 days using 3 different lots of each format in 3 sites with one format per site. A total of 150 test results per lot of device for each concentration were obtained. The results for each format are summarized in the following tables

DAVID One Step Prescription Pregnancy Test Strip results

hCG Concentration	LOT1	LOT2	LOT3	% positive
HCG 0mIU/mL	-/-(50/50)	-/-(50/50)	-/-(50/50)	0%
HCG 3mIU/mL	-/-(50/50)	-/-(50/50)	-/-(50/50)	0%
HCG 6mIU/mL	-/-(49/50)	-/-(49/50)	-/-(50/50)	1%
HCG 7.5mIU/mL	+/+(26/50)	+/+(24/50)	+/+(24/50)	49%
HCG 9mIU/mL	+/+(49/50)	+/+(49/50)	+/+(48/50)	97%
HCG 10mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%
HCG 15mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%
HCG 25mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%

DAVID One Step Prescription Pregnancy Test Cassette results

hCG Concentration	LOT1	LOT2	LOT3	% positive
HCG 0mIU/mL	-/-(50/50)	-/-(50/50)	-/-(50/50)	0%
HCG 3mIU/mL	-/-(50/50)	-/-(50/50)	-/-(50/50)	0%
HCG 6mIU/mL	-/-(49/50)	-/-(49/50)	-/-(49/50)	2%
HCG 7.5mIU/mL	+/+(25/50)	+/+(26/50)	+/+(24/50)	50%
HCG 9mIU/mL	+/+(49/50)	+/+(50/50)	+/+(49/50)	98%
HCG 10mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%
HCG 15mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%
HCG 25mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%

DAVID One Step Home Use Pregnancy Test Midstream results

hCG Concentration	LOT1	LOT2	LOT3	% positive
HCG 0mIU/mL	-/-(50/50)	-/-(50/50)	-/-(50/50)	0%
HCG 3mIU/mL	-/-(50/50)	-/-(50/50)	-/-(50/50)	0%
HCG 6mIU/mL	-/-(50/50)	-/-(50/50)	-/-(50/50)	0%
HCG 7.5mIU/mL	+/+(24/50)	+/+(24/50)	+/+(24/50)	48%
HCG 9mIU/mL	+/+(47/50)	+/+(48/50)	+/+(47/50)	95%
HCG 10mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%
HCG 15mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%
HCG 25mIU/mL	+/+(50/50)	+/+(50/50)	+/+(50/50)	100%

b. Linearity/assay reportable range:

Not applicable. The device provides qualitative results only.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Prescription Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette, DAVID One Step Prescription Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream devices are traceable to the WHO 5th reference material.

d. Detection limit:
An analytical sensitivity/cutoff study was performed using DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream. The DAVID One Step

Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for intended user , therefore DAVID One Step Home Use Pregnancy Test Strip was used in this study. The DAVID One Step Home Use Pregnancy Test Cassette and the DAVID One Step Prescription Pregnancy Test Cassette are identical except for the intended user, therefore DAVID One Step Home Use Pregnancy Test Cassette was used in this study. Testing was performed using negative native human urine samples with hCG traceable to the WHO 5th IS for hCG to obtain concentrations of 0, 3, 5, 6, 7.5, 9, 10, 13, 15, 25 mIU/mL of hCG. The samples were measured using 3 formats strip, cassette and midstream. The samples were tested in 10 replicates, using 3 lots of reagents of each format. The tests were performed by 12 different operators for 3 days. A different set of operators tested each format of the device. The obtained results are summarized in the following tables.

DAVID One Step Home Use Pregnancy Test Strip results

HCG concentration	LOT1	LOT2	LOT2	% positive
HCG0mIU/mL	+/+(0/30)	+/+(0/30)	+/+(0/30)	0%
HCG3mIU/mL	+/+(0/30)	+/+(0/30)	+/+(1/30)	1%
HCG5mIU/mL	+/+(1/30)	+/+(0/30)	+/+(0/30)	1%
HCG 6mIU/mL	+/+1/30)	+/+(2/30)	+/+(1/30)	3%
HCG 7.5mIU/mL	+/+(15/30)	+/+(15/30)	+/+(14/30)	48%
HCG 9mIU/mL	+/+(30/30)	+/+(29/30)	+/+(29/30)	98%
HCG 10mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 13mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 15mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 25mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%

DAVID One Step Home Use Pregnancy Test Cassette results

HCG concentration	LOT1	LOT2	LOT2	% positive
HCG0mIU/mL	+/+(0/30)	+/+(0/30)	+/+(0/30)	0%
HCG3mIU/mL	+/+(0/30)	+/+(1/30)	+/+(0/30)	1%
HCG5mIU/mL	+/+(1/30)	+/+(0/30)	+/+(0/30)	2%
HCG 6mIU/mL	+/+(2/30)	+/+(1/30)	+/+(1/30)	4%
HCG 7.5mIU/mL	+/+(15/30)	+/+(14/30)	+/+(16/30)	50%
HCG 9mIU/mL	+/+(29/30)	+/+(30/30)	+/+(30/30)	99%
HCG 10mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 13mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%

HCG concentration	LOT1	LOT2	LOT2	% positive
HCG 15mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 25mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%

DAVID One Step Home Use Pregnancy Test Midstream dip method results

HCG concentration	LOT1	LOT2	LOT2	% positive
HCG0mIU/mL	+/+(0/30)	+/+(0/30)	+/+(0/30)	0%
HCG3mIU/mL	+/+(0/30)	+/+(0/30)	+/+(0/30)	0%
HCG5mIU/mL	+/+(0/30)	+/+(1/30)	+/+(1/30)	2%
HCG 6mIU/mL	+/+(2/30)	+/+(1/30)	+/+(1/30)	4%
HCG 7.5mIU/mL	+/+(14/30)	+/+(15/30)	+/+(14/30)	48%
HCG 9mIU/mL	+/+(30/30)	+/+(29/30)	+/+(30/30)	99%
HCG 10mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 13mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 15mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 25mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%

DAVID One Step Home Use Pregnancy Test Midstream simulated stream method results

HCG concentration	LOT1	LOT2	LOT2	% positive
HCG0mIU/mL	+/+(0/30)	+/+(0/30)	+/+(0/30)	0%
HCG3mIU/mL	+/+(0/30)	+/+(0/30)	+/+(130)	1%
HCG5mIU/mL	+/+(1/30)	+/+(1/30)	+/+(1/30)	3%
HCG 6mIU/mL	+/+(2/30)	+/+(1/30)	+/+(2/30)	6%
HCG 7.5mIU/mL	+/+(14/30)	+/+(14/30)	+/+(14/30)	46%
HCG 9mIU/mL	+/+(30/30)	+/+(29/30)	+/+(30/30)	99%
HCG 10mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 13mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 15mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%
HCG 25mIU/mL	+/+(30/30)	+/+(30/30)	+/+(30/30)	100%

e. *Analytical specificity:*

For all analytical specificity testing, the DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Prescription Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream devices were evaluated. 3 lots of each device

format were used in all studies. The DAVID One Step Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for the intended user, therefore the DAVID One Step Home Use Pregnancy Test Strip was used in this study. The DAVID One Step Prescription Pregnancy Test Cassette and the DAVID One Step Home Use Pregnancy Test Cassette are identical, therefore the DAVID One Step Prescription Pregnancy Test Cassette was used in this study. Results from the three formats were the same for all analytical specificity studies, therefore results presented below apply to all formats.

Interference study:

To evaluate potential interference from certain exogenous and endogenous compounds, and potential interfering clinical conditions, were tested using

Testing was performed using two urine samples with concentrations of 0 and 10 mIU/mL. These two samples were spiked with each of the known interferents to obtain the desired test concentration. Three different lots of each device format were tested. The results demonstrated that no interferences were observed from substances at the following concentrations for both negative and positive hCG urine samples.

Substance Tested	**Highest Concentration tested that demonstrated no interference**
Acetaminophen	200 µg/mL
Atropine	200 µg/mL
Aspirin	200 µg/mL
Ascorbic Acid	200 µg/mL
Ampicillin	200 µg/mL
Vitamins C	200 µg/mL
Caffeine	200 µg/mL
Gentisic Acid	200 µg/mL
Ethanol	1%
Glucose	20mg/mL
Albumin	20mg/mL
Ephedrine	200 µg/mL
Thiophene	200 µg/mL
Phenylpropanolamine	200 µg/mL
Ephidrine	200 µg/mL
Acetylsalicylic Acid	200 µg/mL
Salicyclic Acid	200 µg/mL

Substance Tested	Highest Concentration tested that demonstrated no interference
Phenothiazine	200 µg/mL
Tetracycline	200 µg/mL
estriol	10 µg/ /mL
Bilirubin	20µg/mL
Hemoglobin	10 µg/mL

Effects of hCG β-core Fragment:
To evaluate potential interference by hCG β-core fragment, a negative urine sample and a urine sample with 10 mIU/mL were spiked with hCG beta core fragment (traceable to WHO reference reagent 99/708) to yield samples with concentrations of (62,500, 125,000, 250,000, 500,000, and 1,000,000 pmol/L. These samples were tested with 3 lots of each device. The data obtained demonstrated that there is no interference by hCG β-core fragment at the concentrations tested.

Cross reactivity of similar compounds:
To evaluate cross-reactivity, hCG negative urine and hCG positive urine containing 10 mIU/mL hCG were spiked with various concentrations of glycoprotein hormones: Luteinizing Hormone (LH), Follicle stimulating Hormone (FSH), and thyroid stimulating hormone (TSH). These samples were tested using 3 lots of each device. The results demonstrated there is no interference from the tested glycoprotein hormones up to 500 mIU/mL LH, 1000 mIU/mL FSH, and 1000 µIU/mL TSH in either negative or positive urine samples

pH Interference Study：
To evaluate potential interference from changes in urine pH, urine samples containing 0 mIU/mL 10 mIU/mL were tested with 3 lots of each device using samples at pH 4, 5, 6, 7, 8, and 9. The results demonstrated that samples within the pH range of 4-9 do not interfere with either positive or negative results from the device.

Specific Gravity Interference study:
To evaluate potential interference from changes in specific gravity, testing was performed with urine samples containing 0 mIU/mL and 10 mIU/mL hCG were adjusted to specific gravities spanning the physiological range and tested with 3 lots of each device. The results indicate that changes in specific gravity do not interfere with either positive or negative results from the device

High dose hook effect study:
To evaluate the high dose hook effect, testing was performed with hCG free urine sample was spiked with varying hCG concentration of ranging from 50 mIU/mL to 2,000,000 mIU/mL. These samples were tested using 3 lots of each device. The result show that there is no hook effect observed at the concentrations tested.

f. Assay cut-off:

See Section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed with the DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette, and DAVID One Step Home Use Pregnancy Test Midstream devices. The DAVID One Step Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for the intended user, therefore the DAVID One Step Home Use Pregnancy Test Strip was used in this study. The DAVID One Step Prescription Pregnancy Test Cassette and the DAVID One Step Home Use Pregnancy Test Cassette are identical, therefore the DAVID One Step Home Use Pregnancy Test Cassette was used in this study.

Testing was performed at 3 hospital sites with 120 urine samples in each of the sites for a total of 360 samples from women of child bearing age (age range 18-45), who were suspecting pregnancy. Samples were randomly collected at various times throughout the day and were masked and randomized prior to testing. Results of the professional using the candidate device were compared to results obtained from the predicate device. Summary of results is presented in the table below:

DAVID One Step Home Use Pregnancy Test Strip results

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	52	0
	Negative	0	68

DAVID One Step Home Use Pregnancy Test Cassette results

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	64	0
	Negative	0	56

DAVID One Step Home Use Pregnancy Test Midstream dip method results

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	73	0
	Negative	0	47

DAVID One Step Home Use Pregnancy Test Midstream results (simulated method)

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	73	0
	Negative	0	47

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 total of 1287 urine samples were collected from 99 different women (21-40 years old) who planned to become pregnant. These women were followed throughout their conception cycles with urine collected from approximately day -10 to day 2, based on their estimated expected period date. Testing was performed using DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream devices. The DAVID One Step Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for the intended user, therefore the DAVID One Step Home Use Pregnancy Test Strip was used in this study. The DAVID One Step Prescription Pregnancy Test Cassette and the DAVID One Step Home Use Pregnancy Test Cassette are identical, therefore the DAVID One Step Home Use Pregnancy Test Cassette was used in this study

All samples were masked and randomized then tested by laboratory technicians in all 3 formats with one lot of (strip format, cassette format, midstream format both dip and stream methods). The results are summarized in the following table for women who successfully conceived.

DAVID One Step Home Use Pregnancy Test Strip results

Day relative to EMP	EMP +2	EMP +1	EMP - 0	EMP -1	EMP -2	EMP -3	EMP -4	EMP -5	EMP -6	EMP -7	EMP -8	EMP -9	EMP -10
# of cycles positive for hCG	99	99	99	99	98	98	95	77	38	17	7	3	0
# of cycles negative for hCG	0	0	0	0	1	1	4	22	61	82	92	96	99
% cycles positive for hCG	100%	100%	100%	100%	99%	99%	96%	77%	38%	17%	7%	3%	0%

DAVID One Step Home Use Pregnancy Test Cassette results

Day relative to EMP	EMP +2	EMP +1	EMP - 0	EMP -1	EMP -2	EMP -3	EMP 4	EMP -5	EMP -6	EMP -7	EMP -8	EMP -9	EMP -10
# of cycles positive for hCG	99	99	99	99	99	97	95	76	37	17	8	3	0
# of cycles negative for hCG	0	0	0	0	0	2	4	23	62	82	91	96	99
% cycles positive for hCG	100%	100%	100%	100%	100%	98%	97%	77%	37%	17%	9%	3%	0%

DAVID One Step Home Use Pregnancy Test Midstream dip method results

Day relative to EMP	EMP +2	EMP +1	EMP - 0	EMP -1	EMP -2	EMP -3	EMP -4	EMP -5	EMP -6	EMP -7	EMP -8	EMP -9	EMP -10
# of cycles positive for hCG	99	99	99	99	98	98	96	76	38	18	7	3	0
# of cycles negative for hCG	0	0	0	0	1	1	3	23	61	81	92	96	99
% cycles positive for hCG	100%	100%	100%	100%	99%	99%	97%	77%	38%	18%	7%	3%	0%

DAVID One Step Home Use Pregnancy Test Midstream results (simulated stream method)

Day relative to EMP	EMP +2	EMP +1	EMP - 0	EMP -1	EMP -2	EMP -3	EMP -4	EMP -5	EMP -6	EMP -7	EMP -8	EMP -9	EMP -10
# of cycles positive for hCG	99	99	99	99	90	99	96	80	39	18	9	4	1
# of cycles negative for hCG	0	0	0	0	0	0	3	19	60	80	91	95	98
% cycles positive for hCG	100%	100%	100%	100%	100%	100%	97%	80%	39%	19%	9%	4%	1%

Lay-user study:

The sponsor performed two studies with lay users.

The first study was conducted in 3 sites with 360 volunteers, 120 study subjects per site using DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream devices were used in the study. The DAVID One Step Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for the intended user, therefore the DAVID One Step Home Use Pregnancy Test Strip was used in this study. The DAVID One Step Prescription Pregnancy Test Cassette and the DAVID One Step Home Use Pregnancy Test Cassette are identical, therefore the DAVID One Step Home Use Pregnancy Test Cassette was used in this study

Study subjects were aged 20-40 years. Each subject tested their own urine on the candidate device following instructions on the package insert. The same sample was tested by a healthcare professional using the candidate devices. All samples were masked and randomized prior to professional testing. This included 120 lay users using test strip, 120 using test cassette, 120 using actual midstream method and the dip method respectively.

Summary of results for the comparison between the lay user testing with the candidate device versus the professional testing using the candidate device are presented the table below. Lay user results with the candidate device versus professional results using the predicate device are not shown, but were identical to those shown below

DAVID One Step Home Use Pregnancy Test Strip results

		Professionals	
		Positive	Negative
Lay user	Positive	50	0
	Negative	0	70

DAVID One Step Home Use Pregnancy Test Cassette results

		Professional	
		Positive	Negative
Lay user	Positive	50	0
	Negative	0	70

DAVID One Step Home Use Pregnancy Test Midstream results

		Professionals	
		Positive	Negative
Lay user	Positive	50	0
	Negative	0	70

DAVID One Step Home Use Pregnancy Test Midstream results
(lay user using the actual midstream method and professional using the simulated midstream method)

		Professional	
		Positive	Negative
Lay user	Positive	50	0
	Negative	0	70

Lay users also completed a user survey, and the results supported that lay users believed that the device was easy to use.

A second lay-user study with an additional 120 volunteers at each site tested 4 samples using DAVID One Step Home Use Pregnancy Test Strip, DAVID One Step Home Use Pregnancy Test Cassette and DAVID One Step Home Use Pregnancy Test Midstream devices were used in this study. The DAVID One Step Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for the intended user, therefore the DAVID One Step Home Use Pregnancy Test Strip was used in this study. The DAVID One Step Prescription Pregnancy Test Cassette and the DAVID One Step Home Use Pregnancy Test

Cassette are identical, therefore the DAVID One Step Home Use Pregnancy Test Cassette was used in this study.

Testing was performed using samples with concentrations of hCG around the device cutoff (5.0, 8, 10, 11.5 mIU/mL). The testing was performed at 3 sites with one lot of each of the three test formats in each site. The midstream format was used for detection in the dip method and the simulated stream method. The results are summarized in the tables below:

DAVID One Step Home Use Pregnancy Test Strip results

Concentration	Lay user Results		%positive
	Number of positives	Number of Negatives	
HCG 5mIU/mL	2	118	2%
HCG 8mIU/mL	52	68	43%
HCG 10mIU/mL	120	0	100%
HCG 11.5mIU/mL	120	0	100%

DAVID One Step Home Use Pregnancy Test Cassette results

Concentration	Lay user Results		%positive
	Number of positives	Number of Negatives	
HCG 5mIU/mL	1	119	1%
HCG 8mIU/mL	55	65	46%
HCG 10mIU/mL	120	0	100%
HCG 11.5mIU/mL	120	0	100%

DAVID One Step Home Use Pregnancy Test Midstream results

Concentration	Lay user Results		%positive
	Number of positives	Number of Negatives	
HCG 5mIU/mL	1	119	1%
HCG 8mIU/mL	55	65	46%
HCG 10mIU/mL	120	0	100%
HCG 11.5mIU/mL	120	0	100%

A Flesch-Kincaid reading analysis was performed on each package inserts and the score demonstrates a reading Grade Level of 8. The results of the questionnaire reflect that the consumers found the device easy to use and follow and that they did not have trouble understanding the labeling or interpreting results.

Study to Determine false-positive result rate:

A study was conducted at three sites using DAVID One Step Prescription Pregnancy Test Strip, DAVID One Step Prescription Pregnancy Test Cassette and DAVID One

Step Home Use Pregnancy Test Midstream devices were used in the study. The DAVID One Step Home Use Pregnancy Test Strip and the DAVID One Step Prescription Pregnancy Test Strip are identical except for the intended user, therefore the DAVID One Step Prescription Pregnancy Test Strip was used in this study. The DAVID One Step Prescription Pregnancy Test Cassette and the DAVID One Step Home Use Pregnancy Test Cassette are identical, therefore the DAVID One Step Prescription Pregnancy Test Cassette was used in this study

Testing was performed to determine the false positive rate of the device in 300 women: 100 pre-menopausal women (18-40 years), 100 peri-menopausal group (41-55 years) and 100 post-menopausal group (>55 years old. All samples were tested by a professional with 3 lot of devices in only one format for each site. Women with positive results were confirmed not pregnant. The results are summarized in the tables below:

DAVID One Step Prescription Pregnancy Test Strip results

Age Group	Lot I	Lot II	Lot III
Pre-menopausal (18-40 years)	0+/100-	0+/100-	0+/100-
Peri-menopausal (41-51 years)	0+/100-	0+/100-	0+/100-
Post-menopausal (>55 years)	0+/100-	0+/100-	0+/100-

DAVID One Step Prescription Pregnancy Test Cassette results

Age Group	Lot I	Lot II*	Lot III
Pre-menopausal (18-40 years)	0+/100-	0+/100-	0+/100-
Peri-menopausal (41-51 years)	0+/100-	0+/100-	0+/100-
Post-menopausal (>55 years)	0+/100-	1+/100-	0+/100-

*The positive sample was confirmed to be positive by the predicate but negative with the ultrasound.

DAVID One Step Home Use Pregnancy Test Midstream dip method results

Age Group	Lot I	Lot II	Lot III
Pre-menopausal (18-40 years)	0+/100-	0+/100-	0+/100-
Peri-menopausal (41-51 years)	0+/100-	0+/100-	0+/100-
Post-menopausal (>55 years)	0+/100-	0+/100-	0+/100-

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 Parts 801 and 809, as applicable

O. Conclusion:

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