

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k103487

B. Purpose for Submission:

New assay

C. Measurand:

Human chorionic gonadotropin

D. Type of Test:

Lateral flow immunoassay

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

Fora PNC100 Digital Pregnancy Test; TD-5301 Pregnancy Test Strip

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1155
2. Classification: Class II
3. Product code: LCX
4. Panel: 75 – Clinical Chemistry

H. Intended Use:

1. Intended use(s):
See Indications for use, below.

2. Indication(s) for use:

Device Name: FORA PNC100 Digital Pregnancy Test

The FORA PNC100 Digital Pregnancy Test is an in vitro diagnostic test device for the qualitative determination of human chorionic gonadotropin (hCG) in urine. It is intended for use as an aid in the early detection of pregnancy by lay users. Additional clinical examination should be performed to confirm the pregnancy. The device uses visually read lateral flow technology for the detection of hCG and provides a digitally read result. The device is intended for home use.

The TD-5301 Pregnancy Test (Strip) is an in vitro diagnostic test device for the qualitative determination of human chorionic gonadotropin (hCG) in urine. It is intended for use as an aid in the early detection of pregnancy by lay users. Additional clinical examination should be performed to confirm the pregnancy. This device uses visually read lateral flow technology for the detection of hCG. The device is intended for home use.

3. Special conditions for use statement(s):

The assays are for OTC use.

4. Special instrument requirements:

No additional instruments are needed.

The digital reader can only be used with the test strips that come with the kit and should be discarded with the last test strip, as stated in the Owner's Booklet. No test strip designed for use with FORA PNC 100 Digital Pregnancy Test meter is sold separately. One test meter (digital reader) is sold with each FOR A PNC100 test strip box kit.

I. Device Description:

The TD-5301 Pregnancy Test consists of a test strip coated with reagents and enclosed in a plastic cassette.

The FORA PNC100 Digital Pregnancy Test consists of a meter and a plastic test stick containing a test strip. The meter has a slot where the test stick is attached to activate the procedure. This device uses the same test strip, as TD-5301 Pregnancy Test. The meter is to be discarded after use with the test strips packaged in the same box. It is not for use with additional test strips. Three to five strips are included per box.

J. Substantial Equivalence Information:

1. Predicate device name(s): Blue Cross BioMedical One Step hCG Pregnancy Test
2. Predicate 510(k) number(s): k071930
3. Comparison with predicate: The intended use is the same for both predicate and the two new assays. In addition all three assays use lateral flow immunoassay technology. Differences are tabulated below.

Similarities			
Device:	k071930	PNC 100	TD-5301
Indications for Use			
Coated antibody on the test strip	Mouse monoclonal anti-beta-hCG antibodies, mouse monoclonal anti-alpha-hCG antibodies (on test region) and goat anti-mouse IgG polyclonal antibodies.	Same as predicate	Same as predicate
Sensitivity	25 mIU/mL	Same as predicate	Same as predicate
Sample type	Urine	Same as predicate	Same as predicate

Differences			
Formats	Strip, cassette and midstream formats	Meter and test stick	Test stick
Visual display	Test line; control line	Digital test result, (non-digital)	Test line, control line

		control line.	
Power source	None	Battery is contained in the meter.	None

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

ISO 14971:2007, Medical devices - Application of risk management to medical devices

EN 61326-1, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirement

EN 13640: 2002, Stability Testing of In Vitro Diagnostic Reagents

L. Test Principle:

The assay is based on a two-site sandwich immunoassay technology. Each test device contains monoclonal anti-β hCG antibody colloidal gold conjugate pre-dried on a pad. Monoclonal anti-α hCG antibodies (on the test region) and goat anti mouse IgG (on the control region) are coated and immobilized on a membrane.

As the urine specimen contacts the membrane, it dissolves the conjugate and migrates by capillary action along the membrane to the test region. In specimens containing hCG, the hCG antigen will attach to the anti-βhCG monoclonal antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-α hCG monoclonal antibody affixed on the test region (“T”) will bind the hCG-gold conjugate complex, forming a red line. Absence of this line at the test region is interpreted as a negative result. In addition, all samples will cause a red colored line to appear in the control region (“C”). This line is formed by the binding of the polyclonal antibodies goat anti-mouse IgG) affixed onto the control region to the sample-colloidal gold conjugate. As a procedural control, a red line should always appear in the control region.

The FORA PNC100 Digital Pregnancy Test is supplied with a meter to interpret the result by determining the reflected color lightness produced by the test and control lines. This meter contains electronic and optical components along with a microprocessor and specific algorithms powered by a CR2032 lithium battery to digitally display test results. The result appears on the display window. The procedural control line is visually-read.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

See detection limit and user performance sections below.

b. *Linearity/assay reportable range:*

Not applicable this is a qualitative test. (See hook effect studies in the interference section below.)

c. *Detection limit:*

Urine samples were spiked with hCG (commercially available purified α - β dimer traceable to the Third WHO International Standard) at the following concentrations: 0, 3.12, 6.25, 12.5, 18.75, 22.5, 25, 50 and 100 mIU/mL. Both (simulated) stream (7 seconds) and dipping method were tested.

FOR A PNC100:

The testing included three FORA PNC100 Digital Pregnancy Test meters, and test strips from 3 lots. A total of 30 replicates at each concentration were tested. Results for all concentrations tested are shown for lot 1. Results were similar for the other two lots. Only the near-cutoff concentrations are summarized for the additional two lots. (All concentration levels were included in the 510(k)).

Stream		Dip	
Lot 1 all results			
hCG Concentration (mIU/mL)	Number of Positive / Total Sample	hCG Concentration (mIU/mL)	Number of Positive / Total Sample
0	0/50	0	0/50
3.12	0/50	3.12	0/50
6.25	0/50	6.25	0/50
12.5	0/50	12.5	0/50
18.75	24/50	18.75	23/50
22.5	38/50	22.5	35/50
25	50/50	25	50/50
50	50/50	50	50/50
100	50/50	100	50/50
Lot 2 – near – cutff results			
12.5	0/50	12.5	0/50
18.75	21/50	18.75	21/50
22.5	36/50	22.5	37/50
25	50/50	25	50/50

Near cutoff results – lot 3			
hCG Concentration (mIU/mL)	Number of Positive / Total Sample	hCG Concentration (mIU/mL)	Number of Positive / Total Sample
12.5	0/50	12.5	0/50
18.75	20/50	18.75	23/50
22.5	38/50	22.5	35/50
25	50/50	25	50/50

TD 5301:

The results of the test with TD-5301 Pregnancy Test with 3 lots of test strips are summarized below.

Stream		Dip	
hCG Concentration (mIU/mL)	Number of Positive / Total Sample	Test hCG Concentration (mIU/mL)	Number of Positive / Total Sample
0	0/50	0	0/50
3.12	0/50	3.12	0/50
6.25	0/50	6.25	0/50
12.5	10/50	12.5	9/50
18.75	18/50	18.75	13/50
22.5	36/50	22.5	37/50
25	50/50	25	50/50
50	50/50	50	50/50
100	50/50	100	50/50
Lot 2 – near – cutoff results		0	0/50
6.25	0/50	6.25	0/50
12.5	14/50	12.5	10/50
18.75	23/50	18.75	20/50
22.5	40/50	22.5	36/50
25	50/50	25	50/50

Near cutoff results – lot 3			
hCG Concentration (mIU/mL)	Number of Positive / Total Sample	hCG Concentration (mIU/mL)	Number of Positive / Total Sample
6.25	0/50	6.25	0/50
12.5	12/50	12.5	13/50
18.75	25/50	18.75	23/50
22.5	38/50	22.5	42/50
25	50/50	25	50/50

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

Traceability:

The FORA PNC100 Digital Pregnancy Test and TD-5301 Pregnancy Test are calibrated against commercially available purified hCG α - β dimer with activity traceable to the WHO 3rd International Standard.

Stability:

Stability testing is performed for digital readers and strip lots to support the shelf life of 24 months under the temperature conditions specified for the finished products: (2°C - 30°C, or 35.6°F - 86°F), and 50% to 85% relative humidity. Test samples include spiked urine at hCG concentrations of 0, 5, and 25 mIU/mL. Acceptance criteria are positive results for hCG concentrations of 0 and 5 mIU/mL and negative results for concentrations of 25 mIU/mL. Testing is in accordance with EN 13640, 2002.) Testing up to 3 months was included in the 510(k). Expiration testing for lots up to 25 months is ongoing.

e. Analytical specificity:

FSH, TSH and LH were tested for cross reactivity. Other analytes including endogenous compounds and conditions, various prescriptions, over-the-counter drugs and contraceptive ingredients were tested for interference. In addition, specific gravity, and pH of urine, as well as hook effect of high dose hCG and hCG isoforms were evaluated for interference. Four different concentrations of hCG were spiked into urine samples. Concentrations of the samples tested included: 5 (negative sample) and 25 (positive sample) mIU/mL hCG. Replicates were run for each sample on multiple lots and digital readers. No interference was observed. Compounds tested are shown below.

Substances	Test Concentration
FSH	600 mIU/ml and 1000 mIU/ml
LH	3000 mIU/ml and 5000 mIU/ml
TSH	1.0 mIU/ml
Bilirubin	20 mg/dL
Creatinine	30 mg/dL
Uric Acid	10 mg/dL
Hemoglobin	1 mg/dL
Albumin	1000 mg/dL

Estriol	300 mg/dL
Estadiol	1.2 mg/dL
Progesterone	300 mg/dL
Acetaminophen	25 mg/dL
Ascorbic Acid	4 mg/dL
Dopamine	0.1 mg/dL
Gentisic Acid	2 mg/dL
Ibuprofen	55 mg/dL
Salicylic Acid	60 mg/dL
Tetracycline	1.5 mg/dL
Caffeine	308 µmol/L
pH 5.0 – pH 8.5	pH 5.0, pH 5.5, pH 6.5, pH 7.5 and pH 8.5

In addition, no interference was observed for specific gravity ranging from 1.00 to 1.035.

Five isoforms of hCG, including beta core fragment were tested for negative interference with samples containing high concentrations of hCG (α/β dimer). Isoform levels ranging from 60,000 to 500,000 pmol/L were tested. All test results were positive.

The assays were tested for hook effect by spiking pooled urine specimens with hCG concentrations ranging from 125,000 to 1,000,000 mIU/mL. No hook effect was observed at these concentrations.

f. Assay cut-off

See Detection Limit Section, above.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed comparing results of a predicate device to the FORA PNC100 Digital Pregnancy Test, and the TD 5301 Pregnancy Test developed by TaiDoc Technology Corporation.

Urine samples were obtained from 209 women presenting at a clinic and tested for pregnancy. Samples were randomly collected at various times throughout the day. Ages of subjects ranged from 20 to 49 years. Women taking medications containing hCG were excluded from this study. In this study the tests were run by healthcare professionals at three point of care sites. Samples were tested using the new devices and predicate device at

the manufacturer's site by the dip and the (simulated) stream application methods. (Also see below for the lay user method comparison and reproducibility studies.) Ten percent of samples tested were from women at first day of (missed) period, and 50 percent were within the first week after the missed period.

Results are tabulated below. Results were similar for both devices and all application methods:

	Cleared device:	+	-
New device	+	97	0
	-	0	112

Lay user study:

Another comparison study was performed to evaluate the use of FORA PNC100 Digital Pregnancy Test and TD-5301 by lay users following the instructions in the owner's booklet. Two hundred female subjects (suspecting pregnancy) from three clinical sites were included in the study. The FOR A PNC100 and TD5301 were each evaluated by one hundred females. Both stream and dip methods were tested for each device (50 subjects each). Each subject tested (i) her own urine sample and (ii) one masked spiked sample with concentrations near (above and below) the cutoff concentration. All participants were instructed to read the proposed package insert (in English) and operate the device. Each subject was also given a questionnaire to rate the how well they understood the instructions. Ages ranged from 20 to > 41 years. A range of education levels (including non-high school graduates) were included. Subjects were women suspecting pregnancy and early in pregnancy. All were first-time users of a digital pregnancy test.

For comparison healthcare professionals then tested subject's urine sample using a cleared device. Results of the comparison study are shown below:

	Blue Cross Positive (+) (Pregnant)	Blue Cross Negative (-) (Not Pregnant)	Total
FORA PNC100 Positive (+) (Pregnant)	81	0	81
FORA PNC100 Negative (-) (Not Pregnant)	0	19	19
Total	81	19	100

	Blue	Blue	Total
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	Cross Positive (+)	Cross Negative (-) (Not Pregnant)	
TD-5301 Positive (+) (Pregnant)	84	0	84
TD-5301 Negative (-) (Not Pregnant)	0	16	16
Total	84	16	100

In addition, all spiked samples were read correctly by the lay users.

b. *Matrix comparison:* Not applicable. The test is only for urine specimens.

3. Clinical studies:

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

5. Expected values/Reference range:

N. Instrument Name:

FORA PNC100 Digital Pregnancy Test Meter

O. System Descriptions:

1. Modes of Operation:

FORA PNC100 Digital Pregnancy Test consists of a meter and a plastic test stick containing a test strip. The meter has a slot where the test stick is inserted to activate the procedure. This device uses the same test strip, as TD-5301 Pregnancy Test. The meter has an LCD display. The test line is converted to a digital read by the user. The control line is not converted, but is read after the test is performed and the test stick is removed from the meter.

2. Software:

Software (including firmware) documentation for all instrument components was included in the 510(k).

3. Specimen Identification:

The device is indicated for OTC use, so there is no issue of specimen identification.

4. Specimen Sampling and Handling:

The OTC user applies connects the strip to the “meter” and then applies the sample by dipping or holding in the urine stream. Calibration:

The device is pre-calibrated. The user does not calibrate the device.

6. Quality Control:

The procedural control line is visually read after the test result is read.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the “Performance Characteristics” Section above:

All recommended software elements were included in the submission.

A search of the postmarket database did not identify new issues related to this device.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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