DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
BUSINESS DIRECTOR
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20878

August 7, 2015

Re: K150022
Trade/Device Name: Wondfo One Step HCG Urine Pregnancy Test Strip,
Wondfo One Step HCG Urine Pregnancy Test Cassette,
Wondfo One Step HCG Urine Pregnancy Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: LCX, JHI
Dated: March 31, 2015
Received: April 3, 2015

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Yung W. Chan -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150022

Device Name
Wondfo One Step HCG Urine Pregnancy Test Strip
Wondfo One Step HCG Urine Pregnancy Test Cassette

Indications for Use *(Describe)*
Wondfo One Step HCG Urine Pregnancy Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, 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.
Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.
This product is intended for both prescription use and over-the-counter use.

Wondfo One Step HCG Urine Pregnancy Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, 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.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.
This product is intended for both prescription use and over-the-counter use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150022

Device Name
Wondfo One Step HCG Urine Pregnancy Test Midstream

Indications for Use *(Describe)*
Wondfo One Step HCG Urine Pregnancy Test Midstream is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, 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.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.
This product is intended for over-the-counter use.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

k150022

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Date: August 4, 2015

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
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Luogang District, Guangzhou, Guangdong, P.R.
China 510663

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: Wondfo One Step HCG Urine Pregnancy Test Strip
Wondfo One Step HCG Urine Pregnancy Test Cassette
Wondfo One Step HCG Urine Pregnancy Test Midstream

Classification: Class II

Product Code	**CFR #**
LCX, JHI	21 CFR, 862.1155 Human Chorionic Gonadotropin (hCG) Test System

5. Predicate Device:

Church & Dwight Co., Inc.
FIRST RESPONSE™ Early Result Pregnancy Test (K123436)

6. Intended Use

Wondfo One Step HCG Urine Pregnancy Test Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, 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.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.
This product is intended for both prescription use and over-the-counter use.

Wondfo One Step HCG Urine Pregnancy Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, 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.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.
This product is intended for both prescription use and over-the-counter use.

Wondfo One Step HCG Urine Pregnancy Test Midstream is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, 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.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.
This product is intended for over-the-counter use.

7. Device Description

Each of the devices (strip, cassette, and midstream) contains a pouch with the test and instructions. The cassette and midstream nitrocellulose test strips are contained in plastic housing. The cassette test also contains a dropper. The strips of each device contain mouse monoclonal anti-β-hCG antibody colloidal gold conjugate pre-dried on the pad, mouse monoclonal anti-α-hCG antibody (on the Test Line) and goat anti mouse IgG polyclonal antibody (on the Control Line).

8. Substantial Equivalence Information

Similarities and Differences		
Item	Candidate device	Predicate device
Intended use	A rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, 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. Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period. Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.	An over-the-counter chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The 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. Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period. Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.
Specimen	Urine	Same
Assay technical	Immunochromatographic assay	Same

Sensitivity	10mIU/ml	Same
Results	Qualitative	Same
Target user	Prescription use（strip and cassette） & over the counter use(strip, cassette and midstream)	Over the counter use
Device format	Strip, cassette, midstream	Midstream
Time to result	5 minutes	3 minutes

9. Standard/Guidance Document Reference (if applicable)

None

10. Test Principle

It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a sample, the sample is absorbed into the device by capillary action and mixes with the antibody-dye conjugate (mouse anti-beta HCG monoclonal antibody), flowing across the pre-coated (Goat anti HCG polyclonal antibody) membrane. During the test procedures, hCG in the urine specimen reacts with the dye conjugate and forms a complex. 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.

11. Performance Characteristics

A. Analytical performance

a. Sensitivity/ Cut-Off Value

Urine standards containing intact hCG at concentrations of 0, 5, 7.5,8, 9, 10, 15, 20 mIU /ml were prepared in negative urine pool and calibrated against the WHO 4th IS for hCG. Each standard was tested by twelve operators. Each operator tests only one lot one format of the devices of the Wondfo One Step HCG Urine Pregnancy Test. The obtained results are summarized in the following table.

Strip format:

HCG concentration	Lot I	Lot II	Lot III	%Positive
0mIU/ml	20-/0+	20-/0+	20-/0+	0%
5mIU/ml	20-/0+	20-/0+	20-/0+	0%
7.5mIU/ml	14-/6+	14-/6+	14-/6+	30%
8mIU/ml	10-/10+	10-/10+	10-/10+	50%
9mIU/ml	2-/18+	2-/18+	3-/17+	88.3%
10mIU/ml	0-/20+	0-/20+	0-/20+	100%
15mIU/ml	0-/20+	0-/20+	0-/20+	100%
20mIU/ml	0-/20+	0-/20+	0-/20+	100%

Cassette format:

HCG concentration	Lot I	Lot II	Lot III	%Positive
0mIU/ml	20-/0+	20-/0+	20-/0+	0%
5mIU/ml	20-/0+	20-/0+	20-/0+	0%
7.5mIU/ml	14-/6+	14-/6+	15-/5+	28%
8mIU/ml	9-/11+	10-/10+	10-/10+	51.7%
9mIU/ml	2-/18+	2-/18+	3-/17+	88.3%
10mIU/ml	0-/20+	0-/20+	0-/20+	100%
15mIU/ml	0-/20+	0-/20+	0-/20+	100%
20mIU/ml	0-/20+	0-/20+	0-/20+	100%

Midstream format (dip method):

HCG concentration	Lot I	Lot II	Lot III	%Positive
0mIU/ml	20-/0+	20-/0+	20-/0+	0%
5mIU/ml	20-/0+	20-/0+	20-/0+	0%
7.5mIU/ml	14-/6+	14-/6+	14-/6+	30%
8mIU/ml	9-/11+	10-/10+	10-/10+	51.7%
9mIU/ml	2-/18+	2-/18+	2-/18+	90%
10mIU/ml	0-/20+	0-/20+	0-/20+	100%
15mIU/ml	0-/20+	0-/20+	0-/20+	100%
20mIU/ml	0-/20+	0-/20+	0-/20+	100%

Midstream format (stream method):

HCG concentration	Lot I	Lot II	Lot III	%Positive
0mIU/ml	20-/0+	20-/0+	20-/0+	0%
5mIU/ml	20-/0+	20-/0+	20-/0+	0%
7.5mIU/ml	15-/5+	14-/6+	14-/6+	28%
8 mIU/ml	9-/11+	10-/10+	10-/10+	51.7%
9 mIU/ml	2-/18+	2-/18+	2-/18+	90%
10mIU/ml	0-/20+	0-/20+	0-/20+	100%
15mIU/ml	0-/20+	0-/20+	0-/20+	100%
20mIU/ml	0-/20+	0-/20+	0-/20+	100%

Cut-off value of 8 mIU/mL and analytical sensitivity of 10 mIU/mL are established.

b. Stability

Stable at 4-30℃ for 24 months based on the accelerated stability study at 50^{o}C and real time stability determination at both 4^{o}C and 30^{o}C.

c. Specificity and cross reactivity

High Dose Effect

Negative urine samples were spiked with varying high hCG concentrations ranging from 6,250 to 200,000 mIU/mL. The spiked samples were tested by 3 different lots and 3 different operators. No hook effect was observed at these concentrations.

Effects of hCG β-core fragment

Negative and positive samples (0 and 10 mIU/mL hCG in urine) were spiked with various concentrations of β -core fragment hCG (63,000, 125,000, 250,000 and 500,000 pmol/L). These samples were tested by 3 different lots and 3 different operators. No difference was observed for different lots and different operators. No interference was observed for urine samples with 0mIU/mL hCG and 10mIU/mL hCG for the device except that false negative was observed at the 500000 pmol/L of β -core fragment hCG.

Effects of glycoprotein LH, FSH and TSH

Negative and positive samples (0 and 10 mIU/mL hCG in urine) were spiked with various concentrations of other glycoprotein hormones such as LH, FSH, and TSH. Samples were tested using three different lots by three operators. No interference was observed for urine samples with 0mIU/mL hCG and 10mIU/mL hCG for the device at LH concentrations up to 500 IU/mL, FSH concentrations up to 1000 mIU/mL, and TSH concentrations up to 1000 μIU/mL

d. Interfering substance

To evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked in both hCG free and hCG positive (10 and 100mIU/mL) samples. Each spiked urine sample was mixed for 5 minutes to ensure a homogeneous solution before testing. Each sample was tested using 3 different lots of the testing kit. Results are shown in the following table.

Substances tested	**Results**								
	0mIU/ml hCG			**10mIU/ml hCG**			**100mIU/ml hCG**		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Acetaminophen 20 mg/dl	-	-	-	+	+	+	+	+	+
Acetylsalicylic acid 20mg/dl	-	-	-	+	+	+	+	+	+
Ascorbic acid 20mg/dl	-	-	-	+	+	+	+	+	+
Atropine 20mg/dl	-	-	-	+	+	+	+	+	+
Caffeine 20mg/dl	-	-	-	+	+	+	+	+	+
Gentisic acid 20mg/dl	-	-	-	+	+	+	+	+	+
Glucose 2g/dl	-	-	-	+	+	+	+	+	+
Hemoglobin 20mg/dl	-	-	-	+	+	+	+	+	+
Tetracycline 20mg/dl	-	-	-	+	+	+	+	+	+
Ampicillin 20mg/dl	-	-	-	+	+	+	+	+	+
Albumin 20mg/dl	-	-	-	+	+	+	+	+	+
B-hydroxybutyrate	-	-	-	+	+	+	+	+	+

(2000mg/dL)									
Ephedrine (20mg/dL)	-	-	-	+	+	+	+	+	+
Phenylpropanolamine(20mg/dL)	-	-	-	+	+	+	+	+	+
Phenothiazine (20mg/dL)	-	-	-	+	+	+	+	+	+
EDTA (80mg/dL)	-	-	-	+	+	+	+	+	+
Salicyclic Acid (20mg/dL)	-	-	-	+	+	+	+	+	+
Benzoylecgonine (10mg/dL)	-	-	-	+	+	+	+	+	+
Cannabinol (10mg/dL)	-	-	-	+	+	+	+	+	+
Codeine (6ug/dL)	-	-	-	+	+	+	+	+	+
Ethanol (1.0%)	-	-	-	+	+	+	+	+	+
Bilirubin (2mg/dL)	-	-	-	+	+	+	+	+	+
Atropine (20mg/dL)	-	-	-	+	+	+	+	+	+
Pregnanediol (1500ug/dL)	-	-	-	+	+	+	+	+	+
Thiophene (20mg/dl)	-	-	-	+	+	+	+	+	+
Ketone(20mg/dl)	-	-	-	+	+	+	+	+	+

All data show that there is no interference for the listed compounds at the stated concentrations.

e. Effect of Urine Specified Gravity and Urine pH

Negative and positive urine samples containing 0, 10 and 100 mIU/mL hCG were tested at pH values from 4 to 9 or at density values ranging from 1.000 to1.035 using 3 different lots by 3 different operators. Data show that there is no interference from pH ranging from 4 to 9 and specific gravity ranging from 1.000 to 1.035 of tested urine samples

f. Precision

A precision study was performed using negative human urine samples spiked with varying hCG (commercially available and traceable to the 4thWHO international standard) concentrations. The spiked urine samples were measured in 10 replicates per day using 3 different lots for each format. Tests were performed for 5 consecutive days by three different operators at each of 3 point-of-care (POC) sites for a total of 9 POC operators. Different set of operators tested each format. Results are shown in the following tables.

Strip format:

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3
0	50-/0+	50-/0+	50-/0+
2.5	50-/0+	50-/0+	50-/0+
5	50-/0+	50-/0+	50-/0+
7.5	36-/14+	35-/15+	36-/14+
8	24-/26+	25-/25+	24-/26+
10	0-/50+	0-/50+	0-/50+

15	0-/50+	0-/50+	0-/50+
20	0-/50+	0-/50+	0-/50+
25	0-/50+	0-/50+	0-/50+
50	0-/50+	0-/50+	0-/50+

Cassette format:

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3
0	50-/0+	50-/0+	50-/0+
2.5	50-/0+	50-/0+	50-/0+
5	50-/0+	50-/0+	50-/0+
7.5	35-/15+	35-/15+	36-/14+
8	25-/25+	24-/26+	24-/26+
10	0-/50+	0-/50+	0-/50+
15	0-/50+	0-/50+	0-/50+
20	0-/50+	0-/50+	0-/50+
25	0-/50+	0-/50+	0-/50+
50	0-/50+	0-/50+	0-/50+

Midstream format:

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3
0	50-/0+	50-/0+	50-/0+
2.5	50-/0+	50-/0+	50-/0+
5	50-/0+	50-/0+	50-/0+
7.5	35-/15+	36-/14+	36-/14+
8	24-/26+	24-/26+	24-/26+
10	0-/50+	0-/50+	0-/50+
15	0-/50+	0-/50+	0-/50+
20	0-/50+	0-/50+	0-/50+
25	0-/50+	0-/50+	0-/50+
50	0-/50+	0-/50+	0-/50+

B. Comparison study

Method comparison with predicate device

A method comparison study was performed, comparing the results obtained from the Wondfo One Step HCG Urine Pregnancy Test to the results from predicate devices. 100 urine samples were collected for each format from 100 women (about half of them were pregnant, early stage at less than 5 weeks) for a total of 300 samples. Samples were randomly collected at various times throughout the day. Ages ranged from 20 to 45 years. The samples were blind labeled. Samples were tested by three different health professionals at each of the 3 POC sites for a total of 9 POC operatorswith the proposed and the predicate devices. Each person could only perform tests for one device format. For example, a person who tested the strips could not test the cassettes or the midstream. Each person tested three different lots of the device and one predicate device at the same time, but not sequentially. Summary results are shown in the following tables.

For Strip Format

Wondfo Device	Predicate device	+	-
Viewer A, B, C	+	49	0
Lot 1, 2, 3	-	0	51

For Cassette Format

Wondfo Device	Predicate device	+	-
Viewer D, E, F	+	48	0
Lot 1, 2, 3	-	0	52

For Midstream Format

Wondfo Device	Predicate device	+	-
Viewer G, H, I	+	49	0
Lot 1, 2, 3	-	0	51

Results show that 100% agreements for both positive and negative samples.

Lay person study

A lay user study was performed at three intended use sites with 100 lay persons testing the strip devices, 100 lay persons testing the cassette devices and another set of 100 persons testing the midstream devices (60 by stream method and 40 by dip method). A total of 300 females with diverse educational and professional backgrounds and ranged in age from 21 to > 50 years performed the study. Urine samples were prepared at 5mIU/ml, 7.5mIU/ml, 8.0mIU/ml and 10mIU/ml hCG concentrations by spiking hCG into negative pooled urine specimens. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 2 blind labeled samples (5mIU/ml and 10mIU/ml) and Wondfo's test kits. Each lay person also tested her own urine sample using the Wondfo device and provided a sample for professional testing. Additional lay-person tests were performed for the spiked hCG 7.5mIU/ml and 8.0mIU/ml samples by 100 lay persons for each device formats.

The results are summarized below.

Strip format

Lay person	Professional	+	-
	+	49	0
	-	0	51

Number of samples	hCG Concentration (mIU/ml)	Lay person results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
100	5	1	99	99%
100	10	100	0	100%

Number of samples	hCG Concentration (mIU/mL)	Lay person results		Professionals results		Consistence rate (%)
		No. of Positive	No. of Negative	No. of Positive	No. of Negative	
100	7.5	26	74	30	70	96%
100	8	49	51	52	48	97%

Cassette format

Lay person	Professional	+	-
	+	48	1
	-	0	51

Number of samples	hCG Concentration (mIU/ml)	Lay person results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
100	5	0	100	100%
100	10	100	0	100%

Number of samples	hCG Concentration (mIU/mL)	Lay person results		Professionals results		Consistence rate (%)
		No. of Positive	No. of Negative	No. of Positive	No. of Negative	
100	7.5	25	75	29	71	96%
100	8	47	53	51	49	96%

Midstream format

Lay person	Professional	+	-
	+	49	0
	-	0	51

Number of samples	hCG Concentration (mIU/ml)	Lay person results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
100	5	0	100	100%
100	10	99	1	99%

Number of samples	hCG Concentration (mIU/mL)	Lay person results		Professionals results		Consistence rate (%)
		No. of Positive	No. of Negative	No. of Positive	No. of Negative	
100	7.5	25	75	29	71	96%
100	8	49	51	52	48	97%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

False Positive Rate Study

In this study, 300 non-pregnant females tested their own urine samples using the strip devices. The obtained results show that the test strip yields 0.3% false positive results.

Lot / Group	I	II	III
Pre-menopasual	0+/34-	0+33-	0+/33-
Peri-menopasual	1+*/32-	0+/34-	0+/33-
Post-menopasual	0+/33-	0+/33-	0+/34-

*This result was from a 49 year old woman. The ultrasound scan showed non- pregnancy.

Another 300 non-pregnant females tested their own urine samples using the cassette devices. The obtained results show that the test cassette yields 0.3% false positive results.

Lot / Group	I	II	III
Pre-menopasual	0+/34-	0+/33-	0+/33-
Peri-menopasual	0+/33-	0+/34-	1+*/32-
Post-menopasual	0+/33-	0+/33-	0+/34-

*This result was from a 51 years old woman. The ultrasound scan showed non- pregnancy.

The last 300 non-pregnant females tested their own urine samples using the midstream devices. The obtained results show none false positive results.

Lot / Group	I	II	III
Pre-menopasual	0+/34-	0+/33-	0+/33-
Peri-menopasual	0+/33-	0+/34-	0+/33-
Post-menopasual	0+/33-	0+/33-	0+/34-

Early Pregnancy Test Study

In this study, total 585 urine samples from 65 characterized cycle segments of conceptive cycles were collected from 65 pregnant women. All samples were masked and randomized. Each sample was tested by all three formats of the device. The new device detected 68% positive hCG five days before the Expected Menstrual Period (EMP), and 100% positive hCG on the day of EMP. No differences were observed between different device formats. The following table is the summary of the data.

Day relative to EMP	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP
# of cycles positive for hCG	4/65	9/65	25/65	44/65	58/65	63/65	64/65	65/65	65/65
% cycles positive for hCG	6%	14%	38%	68%	89%	97%	98%	100%	100%

12. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that Wondfo One Step HCG Urine Pregnancy Test is substantially equivalent to the predicate.