

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

A. 510(k) Number:

k083716

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative

E. Applicant:

Church and Dwight

F. Proprietary and Established Names:

FIRST RESPONSE® Early Result Pregnancy Test

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1155

2. Classification:

Class II

3. Product code:

LCX

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The FIRST RESPONSE® Early Result Pregnancy Test is an *in vitro* diagnostic home use test device intended for the early detection of pregnancy. The test may detect the pregnancy hormone (hCG), in some cases, as early as 6 days before the missed period (5 days before the expected period).

This test is only intended for individual use at home. It is not intended for use in a healthcare setting.

Important note regarding negative results:

Some pregnant women will not be able to detect hCG in their urine 6 days before the missed period. If you test negative before your missed period, but think you may still be pregnant, you should re-test again a few days after your missed period.

Important note regarding positive results:

Because this test detects very low levels of hCG, there is a small chance that this test will give positive results even if you are not pregnant. Chances of this are greater for women nearing age 40 and older.

All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

3. Special conditions for use statement(s):

For over the counter use

This test is only intended for individual use at home. It is not intended for use in a healthcare setting.

4. Special instrument requirements:

None

I. Device Description:

The FIRST RESPONSE® Early Result Pregnancy Test kit consists of two chromatographic test strips enclosed in plastic housing and the package insert. The test strips contain avidin-biotin chemistry and mouse monoclonal and goat anti-mouse polyclonal antibodies.

The device is intended to detect pregnancy, in some cases, as early as 6 days before the missed period (5 days before the expected period). The ‘expected period’ is defined as Day 0 of a woman’s menstrual cycle while “missed period” is defined as Day 1 of the menstrual cycle.

J. Substantial Equivalence Information:

1. Predicate device name(s):

FIRST RESPONSE® Early Result Pregnancy Test

2. Predicate K number(s):

k030258, k992232

3. Comparison with predicate:

| Similarities | | |
|----------------|--------|------------------------------|
| Item | Device | Predicate |
| Intended Use | Same | Early detection of pregnancy |
| Sample matrix | Same | Urine (midstream or dip) |
| Time to result | Same | 3 minutes |

| Differences | | |
|--------------|---|---|
| Item | Device | Predicate |
| Intended Use | Maybe be used up to 5 days before the expected period | Maybe be used up to 4 days before the expected period |

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

None referenced

L. Test Principle:

The test principle is lateral flow chromatographic immunoassay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor performed two studies with lay user consumers where they were asked to interpret test results from masked samples containing varying

concentrations of hCG. In the first study the urine samples were prepared from a negative urine pool and also spiked with purified hCG at 8, 10, and 12 mIU/mL. In the second study urine samples were prepared from a negative urine pool and also spiked with purified hCG at lower hCG concentrations of 3.2 and 6.3 mIU/mL. Study participants were asked to interpret the result of the FIRST RESPONSE® Early Result Pregnancy test as either positive or negative using the instructions provided with the test. The results are summarized in the table below.

| Samples with hCG | Results |
|--------------------------|-------------------------|
| Study 1 (104 consumers) | |
| 0 mIU/mL (n=104) | 104/104 negative |
| 8 mIU/mL (n=104) | 101/104 positive (97%) |
| 10 mIU/mL (n=104) | 101/104 positive (97%) |
| 12 mIU/mL (n=104) | 104/104 positive (100%) |
| Study 2 (~300 consumers) | |
| 0 mIU/mL (n=104) | 104/104 negative |
| 3.2 mIU/mL (n=102) | 5/102 positive (5%) |
| 6.3 mIU/mL (n=104) | 40/104 positive (38%) |

b. Linearity/assay reportable range:

The effect of high dose hCG on the test was evaluated using hCG standards (WHO 4th IS) ranging from 1,000 mIU/mL to 500,000 mIU/mL. All samples yielded the expected positive results.

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

The test is calibrated against the WHO 4th I.S. for hCG.

The stability testing protocol used to support the shelf life was reviewed. The sponsor claims a 24-month shelf life for the test when stored below 86°F (30°C).

d. Detection limit:

Not applicable

e. Analytical specificity:

Various prescription and OTC drugs (acetaminophen, acetylsalicylic acid, ascorbic acid, caffeine, gentisic acid, atropine, phenothiazine, phenylpropanolamine, ampicillin tetracycline, all at 10 µg/mL), potential endogenous interferants (glucose and albumin at 20 mg/mL, hemoglobin,

bilirubin, estriol at 10 µg/mL) and homologous hormones (hLH and hFSH at 1000 mIU/mL and hTSH at 1 mIU/mL) were added to aliquots of non-pregnant urine pool at hCG levels of 0 and 25 mIU/mL. These samples were run on the FIRST RESPONSE® Early Results Pregnancy Test and in each case, no effect on the performance of the test was observed. All samples produced negative results at 0 mIU hCG/mL and positive results at 25 mIU hCG/mL.

f. Assay cut-off:

This device is intended to detect pregnancy 5 days before the expected menstrual period. See the precision section above for performance at different concentrations of hCG.

2. Comparison studies:

a. Method comparison with predicate device:

The performance of the subject device was compared to the predicate test of the same name, FIRST RESPONSE® Early Result Pregnancy Test. Urine samples from clinically determined pregnant and non-pregnant women were tested on both the predicate device and three lots of the device under review. All non-pregnant samples were negative and all pregnant samples were positive.

| Urine Sample | Number of Samples | Predicate Device | Subject Device Lot 1 | Subject Device Lot 2 | Subject Device Lot 3 |
|--------------|-------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Non-Pregnant | 103 | 103/103 (negative) | 103/103 (negative) | 100/100 (negative) | 100/100 (negative) |
| Pregnant | 50 | 50/50 (positive) | 50/50 (positive) | 50/50 (positive) | 50/50 (positive) |

Note: For lots 2 and 3, 100 non-pregnant samples were tested,

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 study was performed to determine the incidence of positive results in urine from non-pregnant females when tested with FIRST RESPONSE® Early Result Test. Urine specimens from non-pregnant women in pre-menopausal (ages 18-40) peri-menopausal (41-55 years) and post-menopausal (>55 years) age groups were evaluated. Testing was performed with three (3) lots of devices.

The results are summarized in the table below.

| Age Group | Urine specimens (n) | Positive results (%) |
|-------------|---------------------|----------------------|
| 18-40 years | 63 | 0/189 (0%) |
| 41-55 years | 104 | 13/312 (4.2%) |
| >55 years | 104 | 4/312 (1.3%) |

Detection of hCG in Early Pregnancy Clinical Samples

An early pregnancy study was performed to support the sponsor's claim that the device detects hCG in urine up to five (5) days before the expected period. Urine specimens were collected daily by women attempting to conceive. In all, 51 individual conceptive cycle sample panels were evaluated each having urine samples from 7 days prior to and 2 days after the first day of the expected menstrual period (day 0). A total of 102 women consumers participated in the study to evaluate and interpret the samples from the conceptive cycles. The samples were randomized and tested individually using three (3) lots of the First Response devices. Each sample was tested twice and each result recorded independently.

When performed and interpreted by the consumer participants, the FIRST RESPONSE® Early Result Pregnancy Test detected a positive result in 68% of the cycles 5 days before the expected menstrual period, 89% of the cycles 4 days before the expected menstrual period (EMP), 100% of the cycles 3 days before the EMP, 100% of the cycles 2 days before the EMP, and 100% of the cycles 1 days before the EMP.

Summary of Consumer Reading Results

| Day Relative to EMP | EMP-10 | EMP -9 | EMP - 8 | EMP-7 | EMP-6 | EMP-5 | EMP-4 | EMP-3 | EMP-2 | EMP-1 | EMP | EMP+1 |
|--------------------------------|--------|--------|---------|-------|--------|--------|--------|---------|---------|---------|---------|---------|
| Positive results / cycle day | 0/2 | 0/28 | 0/74 | 8/100 | 30/102 | 69/102 | 91/102 | 100/102 | 102/102 | 102/102 | 102/102 | 102/102 |
| % positive results / cycle day | 0% | 0% | 0% | 8% | 29% | 68% | 89% | 98% | 100% | 100% | 100% | 100% |

Note: EMP = Expected Menstrual Period

EMP+1 = Day of Missed Period

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.